

UNITED STATES OF AMERICA

+ + + + +

FOOD AND DRUG ADMINISTRATION

+ + + + +

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

+ + + + +

PUBLIC MEETING ON UNIQUE DEVICE IDENTIFICATION

+ + + + +

WEDNESDAY,

OCTOBER 25, 2006

+ + + + +

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.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

I-N-D-E-X

AGENDA ITEM	PAGE
Welcome	4
Dr. Janet Woodcock Deputy Commissioner for Operations, FDA	
Introduction and Format for the Meeting	11
Dr. Larry Kessler Director, Office of Science and Engineering Laboratories Center or Devices and Radiological Health Food and Drug Administration	
The Benefits and Costs of a UDI System	16
Panel Discussion:	16
John Eyraud (Presenter), Eastern Research Group	16
Jon White, M.D., AHRQ	31
Dr. Marcel Salive, CMS	34
Michelle Allender, Bon Secours Health System	41
Joe Pleasant, Premier, Inc.	43
Paul Pandiscio, Johnson and Johnson	49
Audience discussion	66
Design and Implementation of a System of UDI	99
Panel discussion:	99
Chuck Franz (Presenter), Cook Group, Inc.	99
Michael Dempsey, Partners Health Care	110
Lu Figarella, HIBCC	114
Leighton Hansel, Abbott Laboratories	117
John Terwilliger, UCC	120
Audience discussion	143

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

AGENDA ITEM (Continued)	PAGE
The Development, Maintenance, and Use of a Repository	178
Panel discussion:	178
Kathleen Garvin (Presenter), DOD	178
Steve Stenkowski, Premier, Inc.	195
Jonathan Sherman, DOD	201
Jon White, AHRQ	205
Dr. Randy Levin, FDA	210
Audience discussion	222
The Use of Automatic Identification Technologies	230
Panel discussion:	230
Jim Keller (Presenter), ECRI	230
Dr. Julian Goldman, Partners Health Care	241
Ilisa Bernstein, FDA	253
Ann Ferriter, FDA	258
John Terwilliger, UCC	259
Lu Figarella, HIBCC	264
Audience discussion	273
Other presentations from Public	276
Cathy Denning, Novation	276
Michael Dempsey, Partners Health Care	281
Richard Eaton, National Electrical Manufacturers Association	286
Fred Freedman, Dental Trade Association	292
Dr. In Mun, Hospital Corporation of America	296
Mark Piper, DOD	304
Jeff Schaengold, Siemens	311
Elliot Sloane, Villanova School of Business	319
Brad Sokol, Fast Track Technologies	327
Jori Frahler, Medical Device Manufacturers Association	334
Next steps, wrap up and housekeeping	340
Dr. Daniel Schultz Director, Center for Devices and Radiological Health, FDA	

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

(9:04 a.m.)

1
2
3 MODERATOR KESSLER: Good morning. My name
4 is Larry Kessler. I am from the Food and Drug
5 Administration. And I am pleased to present to you
6 our first presenter, Deputy Commissioner of the FDA,
7 Dr. Janet Woodcock.

8 DR. WOODCOCK: Thank you, Larry.

9 WELCOME

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

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

25 As you know, we started this effort with

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 extremely important.

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

16 Thank you very much. And good luck today.

17 MODERATOR KESSLER: Thank you, Janet,
18 appreciate it.

19 INTRODUCTION AND FORMAT FOR THE MEETING

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

25 So simple logistics. Restrooms are down

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 with us as best as possible.

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

11 MR. CROWLEY: Lunch is on your own.

12 MODERATOR KESSLER: It's on your own.

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

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

20 Anything else logistically on this?

21 MR. CROWLEY: No.

22 MODERATOR KESSLER: Thank you.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 THE BENEFITS AND COSTS OF A UDI SYSTEM

2 PANEL DISCUSSION

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

21 But we have looked at -- let's see. Where
22 am I here? We have looked at a couple of things here.

23 The goals for patient safety benefits, first of all,
24 three main areas: better identification of the
25 devices implicated in adverse events. This would be

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 comparisons of effectiveness of medical devices.

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 medications.

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 required.

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

10 Thanks very much.

11 (Applause.)

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

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

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

23 DR. WHITE: Good morning.

24 MODERATOR KESSLER: Good morning.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

15 And God says, "Noah."

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

9 So thank you.

10 MODERATOR KESSLER: Thank you, Jon.

11 Marcel?

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

9 (Laughter.)

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

25 Other devices are approved based on

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 effectiveness. So we have some differences there.

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

19 Thanks.

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

25 (Laughter.)

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

4 Michelle?

5 MS. ALLENDER: Good morning, everyone.

6 MODERATOR KESSLER: Good morning.

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

6 MODERATOR KESSLER: Thank you.

7 MR. PLEASANT: Good morning. In terms of
8 recall improvement, unlike just about every other
9 product sold in the United States, medical devices
10 really can't be electronically tracked or inventoried.

11 So finding those recalled products is certainly
12 unreliable.

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

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

25 Another Premier Hospital executive said a

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 significant risk to patient care and safety is the
2 possibility of implanting an outdated device or using
3 an outdated device because we cannot track outdated
4 information and bar code technology or lack of a UDI.

5 It's not available from the manufacturers.

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

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

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

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

25 Premier currently has a very large

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

23 There are many hospitals spending over
24 \$100,000 just to synchronize their master item files
25 with others in the supply chain. And that's a small

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

11 MR. PLEASANT: Yes.

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

15 MODERATOR KESSLER: Thanks.

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

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

25 That does not mean that we don't see

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

25 From the standpoint of auto

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

15 Thank you.

16 MODERATOR KESSLER: Thank you, Paul.

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

14 Marcel, your comments, please?

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

19 (Laughter.)

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

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

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

25 (Laughter.)

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

15 You know, we have had discussions with the
16 Orthopods, actually, about could we somehow facilitate
17 device identifiers being placed on the billing forms.

18 And I think we said to them, "The ball is in your
19 court. You need to push back." That's not a small
20 task, actually, because Medicare does not control the
21 billing form.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

6 MODERATOR KESSLER: Jon?

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

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

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

19 (Whereupon, there was a show of hands.)

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

22 (Whereupon, there was a show of hands.)

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 helps me think about the discussion report.

2 Okay. Electronic health records and
3 health IT generally speaking, there has been a lot of
4 activity in the federal space over the past two years.

5 It's kind of felt like being in a washing machine,
6 frankly.

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

14 MODERATOR KESSLER: Thank you, Jon.

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 MODERATOR KESSLER: You can. I see no one
2 going up to the microphone. So I'm trying to figure
3 out. Maybe I should offer incentives, like a free
4 510(k) or something, --

5 (Laughter.)

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

10 Paul?

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

17 I think the case that we're trying to put
18 forward is if, in fact, there's a patient safety
19 benefit, let's get this right. Let's find out where.

20 Let's document it in peer review type of analyses,
21 not do it in a blanket type of way, and truly get to
22 root cause to really derive a benefit versus move too
23 quickly in a non-systemic way that potentially could
24 cause future work and in the end potentially delay the
25 benefits in total. So just to clarify that as well.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

3 (Laughter.)

4 MODERATOR KESSLER: I have that on the
5 record.

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

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

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

17 MODERATOR KESSLER: Thank you.

18 Sir?

19 AUDIENCE DISCUSSION

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

17 MODERATOR KESSLER: Thank you.

18 Jon?

19 DR. WHITE: That is an excellent point.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

17 MODERATOR KESSLER: Thanks.

18 Jim?

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

12 (Laughter.)

13 PARTICIPANT: Different American.

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

14 Does that address your question?

15 MR. KELLER: That's helpful.

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

18 MODERATOR KESSLER: On my right.

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

7 MODERATOR KESSLER: Thank you.

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

25 I've coordinated work with projects that

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

6 Thank you.

7 MODERATOR KESSLER: Thank you.

8 Comment from the panel? Okay. Jon?

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

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

23 MODERATOR KESSLER: Marcel?

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

25 MODERATOR KESSLER: I think one of the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

5 Over here?

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

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

20 We also by vote last Friday created a
21 priority list to go to the Secretary of Health and to
22 Dr. Colander regarding the priorities for next year's
23 accomplishments and achievements. And in that, the
24 200-member panel by consensus agreed to include
25 medical devices as a priority area for inclusion in

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

12 DR. SLOANE: That is correct.

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

20 MODERATOR KESSLER: Paul, did you want to
21 comment?

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

5 DR. HENSTEN: Thank you.

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

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

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

25 Building a new dental school with 100

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

14 Thank you.

15 MODERATOR KESSLER: Thank you.

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

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

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

17 Don?

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 beginning in 1992 which put together 16 regulatory
2 proposals for the new regulatory framework in Canada.

3 And in conversation with the FDA about a month ago, I
4 was happy to dust off one of our regulatory proposals
5 dated December 1995, which called for a bar code
6 identifier in Canada.

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

25 Message to the FDA: Please keep us

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

6 (Laughter.)

7 MODERATOR KESSLER: And, as Joe was
8 saying, we're probably a decade or more behind the
9 grocery industry. So it's easier for them to identify
10 that the 14-ounce box of Corn Flakes is on sale this
11 week and we can't figure out what implantible cardio
12 defibrillator went in someone last week at a cost of
13 \$26,000, so fascinating.

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

17 MR. WEININGER: Thank you.

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

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

25 And if you can't even figure out what the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

9 Thank you.

10 MODERATOR KESSLER: Thank you.

11 Bernie, last comment.

12 MR. LIEBLER: Bernie Liebler from AdvaMed.

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

25 MODERATOR KESSLER: Jon and then Marcel?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

19 MODERATOR KESSLER: Okay.

20 DR. SALIVE: Can I?

21 MODERATOR KESSLER: Marcel?

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

16 So this is true. It was brought up at the
17 very beginning that people are not good at recording
18 in the record what device they have implanted into
19 patients or justifying why they chose among some
20 choices. And so you have to be able to track this to
21 know whether something is true, related to the
22 product, or not. And you need to be able to do that.

23 It's vital to your company's survival, frankly.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

3 MODERATOR KESSLER: Thanks.

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

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

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

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

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

22 (Applause.)

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

12 DESIGN AND IMPLEMENTATION OF A SYSTEM OF UDI

13 PANEL DISCUSSION

14 MR. FRANZ: Good morning.

15 MODERATOR KESSLER: Good morning.

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

20 And we faced this subject many years ago.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

19 I don't know how far we have moved in the
20 health care setting today, but it's still the problem.

21 The problem is having a global standard that all of
22 us as manufacturers, all of us as health care
23 providers can agree on, can support that ultimately is
24 going to benefit the whole health care supply chain
25 and patients in the end.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 This occurred about two to three years ago
2 at Cook, but we boiled it down to two different
3 things. We used bar codes in the late '90s and early
4 2000 or RFID. There were several things that we kind
5 of were looking at. Do we change over? How do we
6 change over? And what do we do?

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

13 If you think of the global health care
14 solution, we had better be thinking about everywhere
15 in the world. We had better be thinking about, you
16 know, Africa. We had better be thinking about Canada.

17 We had better be thinking about the U.S. We had
18 better be thinking about Asia. And is RFID, and the
19 systems and the cost, available today everywhere in
20 the world? So, again, our decisions were taken about
21 two to three years ago, but those were the kinds of
22 questions we asked ourselves.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

11 By April of 2002, we had converted over
12 all of those 17 to 25 thousand part numbers, let's
13 say, and then launched it globally to our customers in
14 2003. Okay? So, again, I'll go into a little bit
15 more detail on the amount of time that it takes and
16 the troubles that we had.

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

5 So far, again, in evaluating all the bar
6 codes out there, the EAN codes back in 2001, 2002,
7 2003 supplied far more information than the other bar
8 codes that were out there those days.

9 As you can see, it has an identifier on
10 the front end. It labels every manufacturer. The
11 00166 is actually a product number. And number 4 is a
12 check digit there on the very end. That's the basics:
13 manufacturer, part number.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

22 So if you are a very small manufacturer,
23 you would probably be on the lower end of that scale,
24 \$1,000 to get your EAN number, maybe \$5,000 for a
25 printer and a scanner, set up 2 hours validation a

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 helped them switch over their readers.

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

4 Thanks.

5 (Applause.)

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

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

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

20 Radiance has deployed approximately 20 to
21 30 hospital-wide implementations of active RFID
22 systems to track things. So we can talk about that if
23 you're interested, but that's not really what I'm here
24 talking about here today. I'm here representing
25 Partners Health Care.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

25 So now a clinician, for example, can walk

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 by any means within the Partners Health Care system,
2 but there are some early very positive outcomes of it.

3 So if you want to talk more about it, grab me.

4 Thank you.

5 MODERATOR KESSLER: Thank you.

6 Lu?

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 MODERATOR KESSLER: Thank you.

2 John?

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

3 It has also been noted, I think, if you
4 look across medical devices, a great amount, maybe
5 even most, are already identified, bar coding. As
6 Paul Pandiscio mentioned, they are at 90 percent.
7 Other large manufacturers are probably in that range.

8 So much of the stuff is already identified today with
9 the UDI.

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 serialization approach.

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 hospitals.

2 Also, as I mentioned, a little about RFID.

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

18 I think it is also important to recognize
19 when the Universal Product Code came out in the early
20 1970s, it took over 10 years for it to be broadly
21 adopted in the industry. Now, all of us in this room,
22 for instance, say, "Well, it's always been there."
23 Not really true. It took about ten years to be really
24 ubiquitous.

25 I will share with you, though, two things.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 One, Business Week issued an article in the early
2 '80s that basically said the failure of the UPC. On
3 that one they ate their words. They were very wrong.
4 It just takes a while sometimes. So let's not forget
5 that.

6 Thank you.

7 MODERATOR KESSLER: Thank you very much.

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

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

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

25 This panel is really about implementing.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

6 John?

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

25 MODERATOR KESSLER: Thanks.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

7 MODERATOR KESSLER: Terrific. Thanks.

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

16 So I guess what I am asking is the
17 following. It sounds like many of the major
18 manufacturers already have systems in place to do
19 identification. But the hospital is now facing
20 multiple systems. They get one system from Cook, 2D.

21 J&J may be maybe single D. They want to employ the
22 Radiance RFID system. And that may work for certain
23 devices, not others.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

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

24 MODERATOR KESSLER: Please.

25 MR. DEMPSEY: We have been putting forward

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

14 John?

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

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

23 MODERATOR KESSLER: Thanks.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 yourself.

2 AUDIENCE DISCUSSION

3 MR. MONROE: I am Napoleon Monroe
4 representing Henry Schein.

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

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

15 (Laughter.)

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

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

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

25 What I'm looking at up there looks like a

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

16 I think there's a limit to the, shall we
17 say, effectiveness of creativity and of individualism.

18 And I'm just wondering what sort of is being done to
19 think about not just the data but how it is presented
20 in a way that would minimize misreading by sort of
21 engendering an organizational culture throughout the
22 whole supply chain where everybody is reading the same
23 stuff at the same place in the same order, left,
24 right, et cetera.

25 Thanks.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 MODERATOR KESSLER: Lu?

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

8 (Laughter.)

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

17 Over here?

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

25 Leighton has a comment. Do you want to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

3 MR. SOKOL: Yes, if I may.

4 MODERATOR KESSLER: You may.

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

14 MODERATOR KESSLER: Thank you.

15 Leighton?

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

15 MODERATOR KESSLER: Fair.

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

25 MODERATOR KESSLER: That's a great

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

12 Any response?

13 (No response.)

14 MODERATOR KESSLER: Okay. Jim?

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

8 MODERATOR KESSLER: Thank you.

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

4 At the same point I think a lot of the
5 value there is going to be, well, how much is it if we
6 did get to that point where the gloves are important?

7 Well, do we find every glove in the room and throw
8 them away and start from a new box that we know is
9 good, those sort of things that I think are going to
10 drive that.

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

4 Thank you.

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 will.

2 Other comments?

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

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

14 It would be impossible for people to do
15 self-checkout.

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

22 MODERATOR KESSLER: Michael?

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 that theoretically that is not correct.

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

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

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

16 MODERATOR KESSLER: Thanks.

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

11 Thank you.

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

10 So we have a chicken and egg problem here.

11 We have to very carefully ask the potential users of
12 the systems what would they do differently and what
13 could they do differently if the technology existed.

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 questions are asked the wrong way.

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

10 Thank you.

11 MR. SCHULMAN: Seth Schulman again.

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 efficiency, cost reduction, et cetera, are.

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

13 MR. TERWILLIGER: Sure.

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 bare minimum.

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

12 MODERATOR KESSLER: Leighton?

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

25 We have talked to industry a lot. And one

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 We are going to thank the panel in just a
2 minute. We're going to have lunch. It's now 10 after
3 12:00. I would like you to be back here promptly at
4 1:30. And we will convene on the next panel. 1:15?
5 How about 1:20? Give them five extra minutes. You'll
6 need it.

7 (Laughter.)

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

10 (Applause.)

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

13

14

15

16

17

18

19

20

21

22

23

24

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

2 (1:27 p.m.)

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

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

12 Thanks, Kathleen.

13 (Applause.)

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

18 THE DEVELOPMENT, MAINTENANCE, AND USE OF

19 A REPOSITORY

20 PANEL DISCUSSION

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 utility initiative.

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

25 And although the assignment of numbers

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

21 Now, I'm not saying that the PDU is the
22 answer for the FDA's UDI program. However, there are
23 many data elements, standard data elements, that will
24 be shared in UDI, as they are in many other programs.

25 And I see the health care data utility as one of the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 sources to feed the FDA's UDI.

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

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

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

14 They already use this process.

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

17 Universal product number I'm using there.

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

25 Another question that was raised in the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

25 So the right information. We're looking

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 prove to be terribly accurate.

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

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

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

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

25 Thank you for your attention.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 (Applause.)

2 MODERATOR KESSLER: Thanks, Kathleen.

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

11 MODERATOR KESSLER: Thanks.

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 Addressing the issue of minimum data set,
2 repositories, registries, those types of things, one
3 of the things that we are looking for in the
4 Department of Defense in the military health system is
5 the ability to automatically populate our catalogue
6 records, our property records, and our maintenance
7 records with accurate, clean, and current data. And
8 the only way that this can happen is through an
9 industry product data utility that is maintained by
10 the manufacturer with the most current data possible.

11 And that in terms of supply chain management is
12 something that the Department of Defense military
13 health system really would like to see happen.

14 I don't need to address minimum data set.

15 It's already been articulated. But I also
16 participate in a bar code workgroup within the
17 military health system that has been looking at point
18 of delivery of medicine within the hospital using a
19 bar code system.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

16 Thank you.

17 MODERATOR KESSLER: Thank you.

18 Jon?

19 DR. WHITE: Good afternoon. Good
20 afternoon.

21 MODERATOR KESSLER: Good afternoon.

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

10 Another process that I am involved with is
11 the ACQA, or Ambulatory Care Quality Alliance. This
12 is, if you can imagine this, America's Health
13 Insurance Plans, the American College of Physicians,
14 the American Academy of Family Physicians, and AHRQ,
15 so the government, doctors, and payers convening this.

16 It's quite a crowd. And the meetings are very
17 exciting. That is somewhat outside of the federal
18 process but has federal involvement. Okay?

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

3 So thanks.

4 MODERATOR KESSLER: Randy?

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

25 Over the years, the requirements have

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 regulations, other activities to address these
2 different requirements.

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

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

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

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

25 In our international discussions with our

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

14 MODERATOR KESSLER: Thank you.

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 thinking together about this system.

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

19 MODERATOR KESSLER: Comments from the
20 floor?

21 AUDIENCE DISCUSSION

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

23 MODERATOR KESSLER: First identify
24 yourself, please.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

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

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 identification code or nomenclature on the device.

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

7 So if you would like to make any comments
8 on that?

9 DR. LEVIN: At least from the drug
10 perspective, again, in our proposed regulations, we
11 are proposing that the National Drug Code be on every
12 label so that people could use that information to
13 have access to additional information that the
14 original national drug code was actually three
15 different codes. One was a labeler who was labeling
16 the product. One is for the product. And one is for
17 the packaging.

18 But these codes themselves really didn't
19 have any meaning within themselves. So you would have
20 to go and access information elsewhere to find out
21 what the codes stood for.

22 MR. SHERMAN: And that goes along with
23 what Dr. Kessler mentioned earlier, whether this is
24 going to be a smart number that can convey some
25 information about the piece of equipment or whether it

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 would be a dumb number, which then would lead you to
2 have to access the database of attributes in order to
3 determine what that item actually is, who manufactured
4 it, et cetera.

5 MODERATOR KESSLER: I think the home
6 health care issue is really very challenging for us.
7 I didn't realize 364 languages were spoken. You said
8 in Montgomery County?

9 MS. BERMAN: Yes.

10 MODERATOR KESSLER: Three hundred
11 sixty-four? Are you including FDA languages in that?

12 (Laughter.)

13 MODERATOR KESSLER: FDA-speak?

14 MS. BERMAN: Montgomery County is a very
15 diverse county. And I think it is because we have a
16 lot of military people stationed here and a lot of
17 people from the embassies here.

18 MODERATOR KESSLER: I'll repeat what she
19 said. She is just saying that Montgomery County is a
20 very diverse community, principally because of some of
21 the transient nature of the military around here, so
22 364 languages.

23 I don't think we have thought all the way
24 through that, but we recognize it as an important
25 challenge. Thanks, Sandy.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 DR. HENSTEN: Thank you.

2 Arne Hensten from Norway again. There are
3 two issues that I think I would like to see considered
4 here in the minimum data sets because the regulatory
5 requirements are different in the various countries.

6 The European Medical Devices Directive has
7 safety issues, both for the patient, also for the
8 users, which would be a different regulation here, I
9 guess. And also what we are seeing now very heavily
10 promoted in Europe is in the kind of environmental
11 issue that could be part of the product when it's
12 destroyed or when you're using it.

13 So when we talk about minimum data sets, I
14 think the number is going to grow indefinitely, but I
15 would like to see if you do have some kind of plan or
16 a system if you would like to include also the
17 international perspective for the occupational
18 problems and for the environmental part.

19 MODERATOR KESSLER: So let me ask you a
20 question about that. In terms of environmental
21 problems, I think, actually, we have a requirement in
22 the FDA if we are going to promulgate a regulation, we
23 actually have a little section where we have to think
24 through environmental consequences.

25 So you're suggesting that somewhere in the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 data system, I'm not sure it would be in the number,
2 you would be able to access whether disposal of that
3 kind of equipment or device would have environmental
4 impact.

5 Is that what you're asking?

6 DR. HENSTEN: Yes.

7 MODERATOR KESSLER: Okay. And then
8 explain more about the occupational risk issue. What
9 are you expecting or hoping to see in the data set?

10 DR. HENSTEN: Well, after working for 30
11 years with the various reactions to dental materials,
12 what we have to see in the first place to see the
13 reactions is in the occupational people, in occupation
14 with allergies or that kind of reaction.

15 So you need to be able to have
16 identification of the product for that reason also
17 because otherwise you have got 250 implant
18 manufacturers or 250 amalgam manufacturers. If you do
19 have a better system of identifying the various
20 products, you could minimize the number somewhat.

21 But we do see the occupational problems as
22 a very important issue. And for the European Medical
23 Devices Directive, that is written into the directive
24 very clearly, the risk-benefit also for the user.

25 MODERATOR KESSLER: Thanks.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 Okay. It looks like we're having a slow
2 moment. That's fine. Is break ready? Okay. So
3 we're going to take a brief break. It's about 2:15.
4 Break until 2:30.

5 Just so you know, we're going to come
6 back, do the last panel. Then people who have asked
7 to make presentations will be given a brief period of
8 time with their presentations. And we'll do a
9 wrap-up. So 15 minutes, please.

10 Thank you.

11 (Whereupon, the foregoing matter went off
12 the record at 2:20 p.m. and went back on the record at
13 2:40 p.m.)

14 MODERATOR KESSLER: Home stretch. We're
15 going to talk now with the last panel about the use of
16 automatic identification technologies. And we're
17 starting to address, again, some more technical
18 issues.

19 I am pleased to present one of my good
20 friends and colleagues: Jim Keller from ECRI. He
21 will begin with the first presentation. And we'll go
22 on from there.

23 Thank you.

24 THE USE OF AUTOMATIC IDENTIFICATION TECHNOLOGIES

25 PANEL DISCUSSION

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 MR. KELLER: Good afternoon, everyone.
2 Thanks, Dr. Kessler. It's really nice to be here
3 today. And I think this is an important topic that we
4 all are learning a lot from today from the different
5 comments from the folks today.

6 I was asked to do a couple of things to
7 start off this panel. I'm going to provide just a
8 little bit of background, some ECRI perspectives on
9 the topic, and then also to briefly review the ECRI
10 white paper, the white paper that ECRI produced for
11 FDA. And I will provide you a link to that. And then
12 we can go into the panel discussion.

13 Just real quickly, ECRI is an organization
14 that has been around for a long time. And some of the
15 things that we have done that are relevant to today's
16 discussion have to do with the problem reporting
17 system for medical devices that we have been running
18 for about 35 years. We have been for about the same
19 amount of time running a program to disseminate hazard
20 and recall information related to medical devices.

21 And then we also have developed and
22 maintained a universal medical device nomenclature
23 system that is a naming convention for all types of
24 medical devices, from reagents to Band-Aids to a
25 picture archiving and communications system.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 Some of the slides that I have will have
2 been touched on today. I was thinking as we got to
3 the end of the day, some of the subject matter has
4 been covered a couple of different times. But from
5 ECRI's point of view, there's clearly potential value,
6 significant potential value, in using a unique
7 identifier for medical devices and in the patient
8 safety realm, obviously assisting with recalls,
9 tracking medical devices, incidents, helping to
10 identify incompatible or counterfeit devices -- we
11 heard a little bit about the counterfeit devices
12 earlier today, I think -- and then in the inventory
13 management area.

14 I was reminded of one of my DOD
15 colleagues, who told me a number of years ago when
16 they were looking at inventories across the Department
17 of Defense during the Y2K days, when they were trying
18 to determine whether or not there were any Y2K
19 incompatibility problems with the medical devices in
20 their inventories, one of the folks that I have worked
21 with said, "I didn't know that there were so many
22 different ways to name a defibrillator." And I think
23 just within one database within an institution, there
24 were multiple names for a defibrillator.

25 And also getting to some of the values of

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 having unique identifier: cost containment. And
2 clearly you can help improve the supply chain. You
3 can ideally improve on costs.

4 Some of the challenges we have heard
5 about, the diversity among different types of devices
6 to be identified. And even within a device category,
7 that's a challenge. So using a defibrillator as an
8 example, is the device a manual defibrillator or an
9 automated defibrillator? With a pulse oximeter, is it
10 a standard pulse oximeter or is it a pulse oximeter
11 with motion artifact rejection?

12 And then another question is, is this
13 thing a device, a drug-eluting stent? How are you
14 going to handle that? And then diversity among the
15 different types of identification technologies, we
16 have been hearing a lot about bar code and RFID. And
17 I'll touch on some of the other things that are out
18 there that are intended to do some of the same things
19 that the RFID technology will do.

20 Nonstandard approach to device
21 identification and inventory management across
22 institutions. And I remember back in the Y2K days
23 when ECRI was helping hospitals to review inventories,
24 I couldn't believe how many different terms were used
25 for different devices within those inventories. And

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 then you have to think about the fact that hospitals
2 have multiple inventories within their own
3 institution.

4 So a computerized maintenance management
5 system is an application that's used in the clinical
6 engineering department that has much of the capital
7 equipment inventory but not necessarily all of the
8 inventory. And then you have the materials management
9 database. And then you have a separate database that
10 might be used in a purchasing area or a database in
11 the radiology department and so forth. So there is a
12 lot of complexity. And all of this ties into high
13 potential costs for implementation of the system.

14 Quickly, to review the white paper that
15 was produced by ECRI for FDA. First off, the most
16 important piece of information is the third bullet.
17 And that's the link to that document. And that is on
18 the FDA Web site.

19 The white paper was commissioned by FDA
20 for ECRI to provide an extensive overview on automatic
21 identification of medical devices. We did an
22 extensive review of the available literature and
23 provided an overview of the different types of
24 identification technologies that could be considered
25 for this application and then provided some commentary

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 from ECRI.

2 The white paper is organized with a
3 technology overview. So we covered an overview of bar
4 code identification systems and then described the
5 RFID systems. There was detailed discussion of
6 automatic identification technologies for medical
7 devices.

8 So we surveyed who is using the
9 technology, how it is being used, potential benefits
10 for the different types of technologies. You will
11 find information in the document on stakeholders'
12 position statements that do exist related to this
13 topic, relevant standards, existing classifications
14 for unique identifiers, discussion about nomenclature,
15 and what type of elements are built into nomenclature,
16 et cetera.

17 And so some of the content, as I said
18 before, described the bar code identification
19 technologies and pointed to the fact that these are
20 valuable but have some limitations in that they're a
21 line of sight reader with a limited range so someone
22 has to walk around the hospital with a hand-held
23 reader to get the information that you need.

24 Clearly they are widely adopted and are
25 the first choice in terms of reading a unique

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 identification number on a product. And they're
2 relatively expensive.

3 Regarding radiofrequency identification,
4 ECRI is in the middle of doing a comparative study of
5 some of the technologies in this class. And one of
6 the first things that we realized as we were naming
7 what we were going to write about in the publication
8 data research is going to be in is it's not just RFID.

9 We're doing a review of asset-tracking systems for
10 medical devices. And as we started to do some of the
11 research and evaluation work, we realized that there
12 were multiple different methods for doing the same
13 kind of thing.

14 So there's RFID. There are wi-fi systems.
15 There are ultra-wide band systems. There are systems
16 out there that use IR in combination with RFID. And
17 then there is an ultrasound-based system. So there's
18 a variety of technologies that are in this
19 classification.

20 With the RFID-type technology, it's a new
21 and emerging technology that can be used over a wide
22 range within the health care facility, but the cost
23 for the tags and the readers and the associated
24 software can be relatively high, especially compared
25 to the bar coding systems.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 Some of the perspectives from ECRI
2 regarding the topic of unique identification have to
3 do with the varying sizes of medical devices and the
4 different types that are out there, sterilization and
5 disinfection, issues of reusable medical devices, and
6 should you be labeling the packaging or the device
7 itself. If you're labeling the packaging and you're
8 talking about a reusable medical device, then that is
9 gone.

10 I've done many medical device accident
11 investigations over the years since I have been
12 working at ECRI. And one of the most common problems
13 that we run into is when you go in and do an
14 investigation in the hospital to find out what
15 happened, frequently the packaging for the device is
16 gone. And that is, the identifying information for
17 that device is gone.

18 There is a growing number of devices with
19 built-in software and interconnections. Dr. Kessler
20 referred to that. And from one day to the next,
21 computer-based medical devices is not going to be the
22 same thing.

23 A medical device manufacturer may push out
24 a patch to correct a bug or they may push out a patch
25 to correct a security issue. And then a patient

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 monitor, for example, may be completely different from
2 one day to another because it's a modular-based
3 device. And it may have pulse oximetry in it as an
4 adjunct piece of monitoring and then may have entitled
5 CO2 added to it. So these devices will be changing
6 over time.

7 Some of the things we need to think about
8 in terms of applying a unique identifier -- and we
9 heard about this earlier -- is whether or not to apply
10 human-readable versus a machine-readable identifier.

11 And then I touched on the fact that there
12 is rapid evolution of the reader technologies. And
13 you're not going to be able to establish one reader
14 technology and have that stick for a number of years
15 going forward.

16 So additional perspectives. Automatic
17 identification of medical devices has tremendous
18 potential. The diversity on a variety of levels is
19 going to make universal implementation of this very
20 difficult and costly. And one of the things that
21 might be considered is to address high-value
22 technologies first. And what I mean by high-value
23 technologies is things that have the most patient
24 safety implications, for example.

25 So infusion pumps are an example

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 technology that might be looked at first from a unique
2 identifier and how a classification or a requirement
3 from FDA to touch on infusion pumps and maybe
4 implantable devices, things where there is high risk,
5 where the patient may die if the device fails and then
6 see how that works and then evolve it to be more
7 widespread.

8 So some of the facts that the rapid
9 evolution of the identification technologies is going
10 to limit your ability to standardize on one method may
11 allow us to address a small number of devices first
12 for unique identification, get it right on a small
13 number of devices, and then expand it beyond the rest
14 of the system or to the rest of the different
15 technology devices.

16 So, with that, I'm going to pass it on to
17 Dr. Kessler and the rest of the panel and for
18 discussion. Thank you very much.

19 MODERATOR KESSLER: Thank you, Jim.

20 (Applause.)

21 MODERATOR KESSLER: I'm going to ask
22 Julian Goldman of Partners to speak first. I'm just
23 going to stand up. And we'll try to keep them to
24 20-30 minutes.

25 DR. GOLDMAN: This was a last-minute

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 suggestion so that, instead of just reading a page of
2 notes, I would project it. I don't have any slides,
3 just a quick set of notes. There we go, almost like
4 magic or like interoperability.

5 Well, my name is Julian Goldman. I'm an
6 anesthesiologist at Mass. General Hospital. I am a
7 physician adviser to Partners Health Care Biomedical
8 Engineering.

9 I have been also directing a program on
10 medical device interoperability for the last few
11 years. And that program has been coordinated with
12 many of the folks in the audience as a part of the
13 broad collaboration.

14 That is moving all over. Sorry. We have
15 been working on a program. I'm going to try to fix
16 that so no one gets too dizzy. Is that okay?

17 We have been working on a program on the
18 operating room of the future that opened in the Summer
19 of 2002, which has given us an opportunity to try many
20 innovative technologies in a clinical environment.

21 The OR of the future is sort of like a
22 living laboratory for technology. We don't do
23 experimental surgery, but we do have a chance to use
24 many devices, such as rolling out an indoor
25 positioning system using active RFID, innovative

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 RF-based cabinets for storing devices, and many things
2 like that.

3 I just organized my thoughts here in this
4 document. And so I would like to share it with you.
5 The first thing I would like to point out is to share
6 the mission for Partners Health Care Biomedical
7 Engineering, which, to paraphrase, is that no patient
8 shall be harmed by any medical device.

9 And so we have to keep remembering that
10 our business here really is to take care of patients.

11 It may be to improve the quality of the delivery of
12 health care. It may be to reduce adverse events. It
13 may be all the different things that we know that we
14 can do, but we certainly want to keep remembering that
15 that is the purpose. It's to prevent that, prevent
16 harm, and to help heal disease.

17 So what is the goal of this work in unique
18 medical device ID? From our perspective, this is one
19 piece of the puzzle. You have to take a systems view.

20 And this provides a capability to support other
21 solutions in the health care systems base.

22 Which devices should it apply to? I don't
23 know the answer but probably all devices above a
24 certain threshold, certain threshold for risk, for
25 cost, for size. And that will be figured out. The

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 military I think has done that with a \$5,000 price tag
2 or something like that. So that will get sorted out
3 but probably for most devices.

4 But don't forget that we're not only
5 talking about the hospital. As it was mentioned in
6 previous conversations or presentations today entering
7 Q&A, there is a dramatic movement of caring for
8 patients in the home environment.

9 And when we see the kinds of activities
10 that are coming together, such as the Continual Health
11 Alliance, which was formed in June of this year, now
12 has, I believe, 50 or so companies that are members of
13 continuum, pushing for a logo compliance of
14 interoperability, there is a need to inventory devices
15 in the patient's home.

16 And a use case was mentioned earlier by
17 someone who had a comment that there are hundreds of
18 languages and how will we deal with that. I don't
19 know the answer to that, but I want to point that out
20 as the kind of question that needs to be captured as a
21 use case.

22 The use case is an example of a patient at
23 home who speaks another language who may have to read
24 a devices ID and then report that. Is that a valid
25 case? I don't know. If it's just a number, does it

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 make it easier to do that? I'm not sure. Is the
2 solution to take a photograph and to e-mail it? I
3 don't know.

4 But I think that most of the time, as
5 technology moves forward, it will be reading the
6 information automatically over the network. We won't
7 be asking people to report back a 30-digit string in a
8 language that we don't understand or over a poor
9 connection.

10 Do we need this process? Do we need FDA
11 leadership? Well, can we just do this on our own?
12 Well, we are doing it on our own. We're doing it on
13 our own in our hospital. People are doing it on their
14 own hospital.

15 We buy devices. We apply new numbers and
16 new stickers. We bind the things together in our
17 homegrown database. And it's terribly inefficient,
18 and it's a good source for errors. And it prevents
19 the collection of data at a national level for
20 national investigations and for pursuing potential
21 device problems nationally.

22 So sure, we can do it ourselves. And we
23 can keep doing it poorly. It's as if we didn't have
24 Social Security numbers or passport numbers.

25 We also have the potential problem of

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 having the same serial number from two different
2 manufacturers. And then we have to sort out the
3 difference. So for all the reasons that anyone who
4 knows anything about databases knows, yes, we can do
5 it, but it's a bad idea.

6 Now, how many devices are we talking
7 about? Well, I don't know the universe of medical
8 devices, but I can provide some numbers for you. Let
9 me scroll down to bring that up higher on the page.
10 There's a reason that people use PowerPoint, instead
11 of Word.

12 The Partners Health Service Health Care
13 manages 33,918 devices as of September of 2005. Those
14 are the numbers of medical devices we actively track.
15 It does not include implants and things like that.
16 It's things that biomedical engineering tracks in our
17 database.

18 Last week we had a scientific exhibit at
19 the American Society of Anesthesiologists' annual
20 meeting. As part of that exhibit, which was a
21 collaboration of a number of interested parties
22 helping to move medical device interoperability
23 forward, Kaiser Permanente presented data for the
24 first time in a public forum. And they disclosed that
25 they managed 300,000 medical devices. Again, this is

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 just management from a biomedical engineering
2 perspective.

3 Let's talk about the benefits and
4 applications of this type of technology or this type
5 of infrastructure. Well, unique medical device ID is
6 a key element of a larger infrastructure. And many
7 applications will be part of a framework that require
8 UID functionality to be effective.

9 We have been using indoor positioning
10 system technology to track patients, to track things,
11 to look at associations between things. And Mike
12 Dempsey talked about that this morning. Well,
13 naturally it's pretty difficult to use that if you
14 can't identify the things initially and bind them
15 together in the database.

16 We need to be able to support preventive
17 maintenance and servicing of devices. It is
18 tremendously difficult to find devices and then be
19 sure that they have been upgraded and one is compliant
20 for JCAHO purposes.

21 Now, one of the key messages I would like
22 to leave you with is the need for this work to be
23 driven by requirements. And a good requirement was
24 the example from earlier today. And we have been
25 working on obtaining clinical requirements over the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 last two years from clinical groups and from clinical
2 engineers in various national forums.

3 I took a look in our database to try to
4 pull out some of the clinical requirements that I
5 thought fit with the discussion today. And here are
6 eight of them. And they're not all unique. Some of
7 them apply to the discussions that we have had.

8 Number one is the need for device IDs to
9 support network medical device systems that are to
10 support safe networking of medical devices to
11 accomplish new tasks; for example, for safe medication
12 administration or to verify that an IV pump that is
13 being used as part of that system actually is a device
14 that can support that use because, for example, some
15 infusion devices aren't accurate and within certain
16 infusion ranges.

17 And those things are known ahead of time.

18 And one can prevent potential errors or adverse
19 events just by making sure that the wrong device isn't
20 selected for an application.

21 Number two, to verify device patches and
22 upgrades are performed correctly, this is a major
23 challenge for us now in the hospital.

24 Number three, closed loop control. Closed
25 loop control using physiological data, closed loop

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 control, for example, to improve the safety of PCA
2 opioid administration, you know, push the button, get
3 the pain shot on the hospital ward.

4 That system is a system fraught with
5 problems. And patients are being injured. That was a
6 focus at a Anesthesia Patient Safety Foundation
7 meeting a week ago. And to do that well, we have to
8 network devices together. And then we have to know
9 the capabilities of those devices, if they can support
10 the algorithms that will be used clinically.

11 Number four, we all have discussed that
12 there is a need for comprehensive population of the
13 electronic medical record. And the need for that is
14 to support many activities, including, of course, CQI.

15 Automated inventory for system readiness.
16 It would be very helpful if one could look at a
17 hospital inventory, rapidly take a snapshot, identify
18 the devices that are in use. And then if Hurricane
19 Katrina is bearing down on that hospital, we know
20 which devices have to be set up elsewhere to support
21 that patient population; again, very difficult to do
22 today but quite possible if we can interrogate over
23 the network, ID the devices, and know what is being
24 used, identify devices that are being used in the
25 wrong environment, integrate IPS, indoor positioning

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 systems -- I mentioned that before -- and also to find
2 urgently needed devices. Believe it or not, this is a
3 big problem.

4 You need a pacemaker quickly somewhere in
5 the hospital. You need to be able to find it. One
6 way to do that is by having unique IDs on the devices
7 and tying that in with another system. Again, that's
8 a system problem. It's a system solution. This is an
9 element of the system.

10 In terms of specific technologies, I don't
11 have specific recommendations except to say we have
12 tried a bunch of them: active and passive RFID and
13 various solutions. And that is not for us to think
14 about today.

15 In conclusion, --

16 (Laughter.)

17 DR. GOLDMAN: -- the demand for
18 interoperability to improve patient safety and health
19 care efficiency can benefit greatly from unique
20 medical device IDs. I think it's time for us to act.

21 And, like Legos, it's a matter of producing the
22 building blocks and then letting other people build
23 the solutions. And we have to look forward. We have
24 to be innovative. And, frankly, I think that the FDA
25 can provide significant leadership in this area,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 Larry.

2 Thank you very much.

3 (Applause.)

4 MODERATOR KESSLER: Thank you.

5 The rest of the panel includes Ilisa
6 Bernstein from the Office of Policy at FDA; Ann
7 Ferriter from the Office of Device Evaluation at FDA;
8 and, again, two familiar faces: John Terwilliger and
9 Lu Figarella.

10 Ilisa?

11 MS. BERNSTEIN: Thank you. Hi. Thank you
12 for inviting me here today.

13 I know Randy on the last panel said that
14 he was a token drug person. He was actually the token
15 drug guy. I'm the token drug girl here. So my
16 experience in this area is with drugs. And I'll tell
17 you a little bit about it.

18 I'm sorry. Unfortunately, I was unable to
19 attend the earlier part of this meeting. And I don't
20 want to repeat anything. So the two areas in the drug
21 side of FDA that were using these technologies is for
22 the bar code rule and for electronic pedigree or for
23 pedigrees for creating a chain of custody for a drug
24 or a document or a chain of custody document.

25 So for the bar code rule -- did you cover

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 that already? No? Well, I'll just briefly give a
2 brief overview. What the bar code rule does is it
3 went into effect in 2004. And, as of April of 2006,
4 all drugs that are used, prescription drugs that are
5 used in hospitals and OTC drugs that are used in
6 hospitals pursuant to an order or a prescription, have
7 to have a bar code.

8 In the rule, we required, at a minimum, a
9 linear bar code. At the time when we were doing the
10 proposed rule and the final rule, the only information
11 that we had when we did the economic analysis, the
12 cost-benefit came out in favor of a linear bar code at
13 the time.

14 We had said in the proposed rule that at
15 some point once the bar code rule is in effect, we're
16 going to look at other automatic identification
17 technologies and look at their use as well. And right
18 now it may be a little too early to evaluate that now
19 that that April 2006 went into place, but we'll
20 probably start thinking about this very shortly.

21 In the area for pedigree, I know this is
22 mostly a device crowd. So, just in summary, there is
23 a pedigree requirement for prescription drugs that for
24 certain wholesale distributions of prescription drugs,
25 not all wholesalers have to pass a pedigree. And I

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 won't go into the whole thing. That would be a whole
2 other two hours here. But for certain wholesale
3 distributions, a pedigree has to be passed. The
4 regulations and the law do not specify whether it's a
5 paper pedigree or an electronic pedigree.

6 In 2004, FDA put together a big
7 counterfeit drug task force to look at the issue of
8 counterfeit drugs in the drug supply chain and to
9 identify vulnerabilities in the drug supply chain and
10 try and identify ways that we can minimize those
11 vulnerabilities to create a safe and secure supply
12 chain.

13 One of the key elements of that initiative
14 was it was calling for a widespread use of an
15 electronic pedigree for all transactions involving
16 drugs from the time it leaves a manufacturer all the
17 way until it gets to a pharmacy. We have no
18 requirements here, but this is what we called for as
19 our action plan for the drug supply community to put
20 this in place.

21 And so we put out a report. And we have
22 said this many times in several reports -- it's all on
23 FDA's Web page at www.fda.gov/counterfeit -- that in
24 order to get to an e-pedigree, the most promising
25 technology is RFID. But that's not the only way to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 get there.

2 So we have said that other technologies,
3 auto-identification technologies, could be useful.
4 But we are putting a lot of effort in trying to move
5 the pharmaceutical community and manufacturers,
6 wholesalers, and pharmacies to use RFID. But the
7 ultimate goal here is an e-pedigree. So that you have
8 a document that shows who has had that drug and in the
9 supply chain as it moved.

10 And so just an update on where that is in
11 the drug side, there is a great deal of effort by UPC
12 Global within the UPC global community to create
13 standards from an electronic pedigree for track and
14 trace, for use of RFID on drugs, prescription drugs.

15 There are a number of pharmaceutical
16 companies who already have put some tags, RFID tags,
17 on individual units. And the key here is mass
18 serialization so that each individual product would
19 have its own unique number, just like you're talking
20 about here.

21 And there is still talk about doing
22 standards. As many of you know, we're not there yet,
23 but this is the ultimate goal. And there is a lot of
24 effort moving in that direction to get there.

25 We at FDA are very hopeful that if we all

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 work together to get there, that this would be useful
2 and extremely beneficial to secure our drug supply
3 chain.

4 So I'll stop there.

5 MR. FERRITER: Hello. I am Anne Ferriter.

6 And I work in the Center for Devices. So this is our
7 device meeting to talk about unique device
8 identifiers, but there are device identifiers already
9 in use in the market.

10 There are bar codes and RFID on many
11 things. Bar codes are present on almost all medical
12 device labeling and packaging. It's also used on
13 patient identification bracelets.

14 RFID devices have been cleared through the
15 510(k) process. There are two patient identification
16 devices: implantable VeriChip and the adhesive Surge
17 chip. RFID is also integrated into medical devices,
18 like wireless monitors, for device identification.

19 So the technology is being used, not in a
20 standard way, but it's out there. RFID is also used
21 on health care-related items that aren't considered
22 medical devices. There's been some work on blood bag
23 tagging, for example, with RFID to limit the number of
24 incorrect transfusions.

25 Through our 513(g) process, we have

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 decided that that is not a medical device. And
2 neither is a device inventory cabinet. But CDRH is
3 looking at these uses of RFID and keeping an eye on
4 how they are being used in the hospitals.

5 We realize that one solution isn't going
6 to fit all devices. It's unlikely that FDA is going
7 to ask resorbable suture manufacturers to put an RFID
8 chip on a resorbable suture, but something like an MRI
9 machine, it wouldn't make sense to have the RFID on
10 the packaging or any unique identifier.

11 Even given that we're going to have to go
12 a lot of different directions on medical device
13 labeling, we do want to be compatible with both the
14 Center for Drugs, with DOD, and with EPC standards.
15 So we are talking to all of these people to learn what
16 is going on.

17 MODERATOR KESSLER: Thanks.

18 MR. TERWILLIGER: I'm back. A little bit
19 about automatic identification technologies. I want
20 to back up on one point, and that is, why do we do it?
21 And this is something I think most people maybe
22 haven't thought through.

23 The reason we do automatic identification
24 technologies, whether or not it's bar coding or RFID,
25 is about accurate data capture. That's why we do

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 this. It's not about pretty art work.

2 Also, another way I like to think about it
3 is if you think any process includes the phrases,
4 "Write it down, and someone is going to keypunch it
5 in," what it really, really says is, I'm going to
6 scribble it so no one can read it, and I'm going to
7 keypunch it in wrong again, again, and again.

8 So if we think we're going to get to
9 correct data in electronic health records that involve
10 anything about people typing data in, we're sorely,
11 sorely mistaken. And that's really what automatic
12 identification technology is about. And I think,
13 particularly for products used for patient care, it's
14 really about capturing them automatically. And I
15 think we should be very focused on that.

16 Also, there's been a lot of discussion
17 here about I know marking things. I know a couple of
18 providers or end-users talk about we mark them
19 ourselves. How sad. I don't know how else to phrase
20 that because the manufacturer is the absolute cheapest
21 place to put on automatic identification technology.
22 Anyplace else in the supply chain is very expensive.
23 It's just orders of magnitude more. So I think that's
24 one we should all keep in mind.

25 Another thing I would like to share with

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 you, I am unaware of any broadly implemented AIT
2 application that uses lots of data. So, actually, we
3 are the data carries all sorts of stuff or even smart
4 numbers, shall we say, again, broadly implemented.

5 Most all of them, even that I'm aware of,
6 use more of a kind of a license plate approach, where
7 it's kind of an identifier pointing back to data. It
8 is very difficult and expensive to carry lots of data
9 in an AIT approach. It's just not done that way.

10 And, like I said, I am absolutely unaware
11 of any broadly implemented system that works like
12 that. So I would like to share that, which really
13 comes down to this idea of smart numbers. Smart
14 numbers ultimately fail, ultimately, ultimately fail.

15 And I wouldn't use the word "dumb" numbers.
16 Unintelligent. They're really license plates back to
17 the real data.

18 And I think nothing we have mentioned
19 earlier -- the data points back to changes over time.

20 I think, as the community becomes more sophisticated,
21 things get added on. And things that used to be
22 important will drop off. So I think that's important.

23 And if you're bar coding all of that, it will always
24 never be right.

25 I think another thing I would like to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 point out, the creativity in automatic identification
2 technology is not an objective here. I really would
3 like to put this forth. Mass adoption implementation,
4 that's the objective. Unfortunately, the world is
5 littered with AIT technologies. Our providers have
6 great fun doing it, but they aren't broadly
7 implemented. It's not what we're after here. So I'll
8 throw that out.

9 And then probably the last little thing, I
10 really would like to encourage the FDA to promote the
11 adoption of existing standards -- you made mention of
12 a few of them -- which really runs kind of our product
13 identification lot numbers, expiration dates, and
14 serial numbers, and let the community work through the
15 various standards processes to adopt new automatic
16 identification technologies as they evolve because
17 there is no way that the rule will ever keep up with
18 what is going on in the industry. And I think that
19 the industry is in a good position to really better
20 reflect over a longer time frame what is the best
21 approach to collect data.

22 And, last but not least, our health care
23 user group, the HUG, as I mentioned earlier, has been
24 very focused on many of these issues. And we actually
25 have a road map for actually working through these.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 So many of the things that you talked about, like what
2 data should be bar coded and actually some of the
3 automatic identification technologies, we are really
4 kind of reevaluating to make sure we haven't missed
5 anything. So much of that is actually going on today.

6 Thank you.

7 MODERATOR KESSLER: Thanks.

8 Lu?

9 MR. FIGARELLA: Last time they told me to
10 project. So hopefully you can hear me.

11 I think the points are well-made. You
12 hear sort of a theme of "Well, we tried this system"
13 or "that system." When you look at the use of auto ID
14 technology, I think you have to -- and it was said
15 before. I'll reiterate it. You have to separate the
16 data from the data carrier. I think the data carrier
17 is all of the things that we talked about here,
18 whether it's RFID or 1D bar code or 2D bar code.

19 You know, for a while, one of my previous
20 jobs, they had a joke about the color of blue, which
21 was every two months, it seemed a new two-dimensional
22 bar code was invented, you know, because it was better
23 than the other one.

24 And the answer is that always continues to
25 happen. You want the standards that exist, you know,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 all the work that we have done with ISO and other
2 places, not just here but in Europe and other places.

3 You really want those standards to tell you how to
4 carry the -- not necessarily to have smart numbers but
5 to have a good rationale for how you came up to what
6 your unique identification is, rather than just, you
7 know, from 1,000 to 2,000, you got those. Those
8 things are I think well-understood, well-done.

9 Somebody mentioned in a previous
10 presentation the whole UID effort at the DOD, where
11 they clipped it off at \$5,000. But they've done a
12 tremendous service for all of us because part of what
13 the DOD did is essentially say, "Okay. These are the
14 issuing agencies for this UIDs."

15 And GS-1 is one of them. HIBCC is
16 another. Dun and Bradstreet is another. These are
17 people who have a data identifier that essentially
18 allows you to use.

19 As mentioned by somebody before, it's a
20 triad. Think of it as 1D bar code, 2D bar codes, or
21 RFID as those three legs of the stool. And you decide
22 which one you're going to use for a particular
23 application.

24 That's really my message to the FDA. I
25 think that we have to look at solutions that allow, if

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 possible, not necessarily give a manufacturer 20
2 choices but really give somebody a choice of -- in
3 this particular application, maybe it's a class 3
4 device, implantible, et cetera. We will mandate an
5 RFID or not, but these other applications are less
6 important.

7 Perhaps what you end up doing is you end
8 up saying, "Well, you could do it this way or this
9 way. This is the data we're going to require you to
10 have so that we can find it, whatever we decide to
11 look for it, but these are the choices of
12 manufacturer." Again, you know, somebody who makes
13 products.

14 You really hate to have anybody tell you
15 this is the only way you're going to do it because
16 instantly whoever is that solution, the price just
17 added a zero. It's amazing how it happens overnight.

18 The data size is important -- we talked
19 about it before -- because, again, you're not going to
20 get -- it used to be called label inflation. I need
21 another byte for something else. And before you know
22 it, you're wrapping the bar code around the package.
23 And you still can't read it.

24 So those are the things for us. Again,
25 keep on thinking of the data and the data carriers,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 two different entities. And really think about what
2 you want to mandate for data you have to generate and
3 then see if that maps to the data carriers.

4 It may be yes, for example, when you use a
5 HBIC number that you have a primary and a secondary
6 and two bar codes, which isn't a problem if you have
7 an MRI machine, but if you have something that is very
8 small, contact lenses or any other device like that,
9 what you really may want to end up doing is mandating,
10 well, we'll either have less data or you really will
11 have to go to this to the bar code or this RFID. And,
12 really, you know, this is your poison, but we want the
13 data tracked.

14 We thank you.

15 MODERATOR KESSLER: Thanks, Lu.

16 I am going to turn the mics open in just a
17 second. It's a very important comment. That you make
18 that the data system and the carrier, the number are
19 separate issues and that we don't have to confuse them
20 is something that I think we have learned along the
21 process.

22 And I really appreciate John's offer from
23 GS-1 of the road map. I would love a road map. And
24 if it gets me somewhere, it will even be better.

25 Where does the road map get us, John?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 MR. TERWILLIGER: The road map I am
2 talking about is our user group as they attack some
3 problems around standards and implementation of the
4 GS-1 system. There are a number of steps involved we
5 actually have posted on the Web site. Is it
6 gs1.org/hug? Yes, www.gs1.org/hug.

7 MODERATOR KESSLER: Does that include the
8 processes that we have been talking about today; for
9 example, implementation at the hospital level,
10 implementation at the health professional level.

11 I have the wonderful man who has come all
12 the way from Norway to build a dental system around
13 this. So is that going to help him as well? Does the
14 road map get to Norway?

15 MR. TERWILLIGER: Oh, absolutely. Well,
16 it's global. It's global. I think the thing is we're
17 still working more at kind of these fundamental data
18 levels of making sure that we have things properly
19 identified and properly bar coded or automatic
20 identification analogies so you can see global, too,
21 and really get in and set the stage for some of the
22 things you have just asked about.

23 MODERATOR KESSLER: Mics are open if you
24 have a question or a comment to make to the panel.

25 I'm going to ask Ilisa something about

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 counterfeiting, leave it open for you. Then the next
2 plane is we have a series of presenters who are going
3 to come up, do very brief presentations. They have
4 asked for a few minutes on the floor to make some
5 comment about what we have done today.

6 And then we have a treat at the end of the
7 day of a few minutes and closing comments from Dr.
8 Daniel Schultz, who has come here. He's the Director
9 of the Center for Device and Radiological Health. He
10 has some of his own thoughts about this as well. So
11 you may want to wait for that. For those of you who
12 don't have airplanes, it would be worth a few minutes
13 of waiting.

14 Ilisa, I want to ask you about
15 counterfeiting because I know you have been enmeshed
16 in this with the drugs world because you are the drugs
17 gal here. To what degree has this been a problem? Is
18 it an emerging problem? I think we started to see it
19 in devices, and we just hadn't seen it before.

20 And is there some consideration about how
21 that might affect what you are doing in terms of the
22 device world because I think sadly it's a very current
23 problem for us?

24 MS. BERNSTEIN: Yes. Counterfeiting. I
25 mean, I guess I always qualify this when I say, well,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 talking about all these initiatives to secure the drug
2 chain from counterfeiting, our drug supply is among
3 the safest in the world, but counterfeiting is a huge
4 problem globally. We have seen it in the United
5 States. We have seen it in our own drug supply. And
6 even one case is too many. So the efforts are worth
7 what we are doing.

8 What we are doing on the drug side, I
9 guess what you are asking is, can it be used for the
10 devices as well? It could. I know that within the
11 community that's looking at the standards, they're
12 setting up a device working group to look at some
13 things as well.

14 Right now I would say that most of our
15 efforts, though, are on the drug side. And because
16 that is where a lot of -- at least for the pedigree,
17 there is a prescription Drug Marketing Act, which is
18 under the Food, Drug, and Cosmetic Act, which governs
19 prescription drugs and pedigrees there. So that's
20 where a lot of our efforts are focused right now.

21 MODERATOR KESSLER: Thank you.

22 Brad?

23 AUDIENCE DISCUSSION

24 MR. SOKOL: I'm Brad Sokol from Fast Track
25 Technologies.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 A case could be made for medical device
2 pedigree. I just wanted to point a couple of areas
3 out in where we could as an industry point to those
4 like the pharma did, the pharma industry did.

5 Number one, the medical device record,
6 under the Federal Food and Drug and Cosmetic Act, any
7 use error states that, frankly, one should report that
8 use error. Now, it's not enforced, although it could
9 be. So that's number one.

10 Number two, when you're looking at 21 CFR
11 820.7(g), which is the installation and qualification
12 of successful process verification for devices, -- and
13 this means equipment and maintenance calibration --
14 this is another area that states that there should be
15 a pedigree, could be interpreted as a pedigree exists
16 for medical devices.

17 And, finally, there is a movement going on
18 right now for hospital-associated infections, where
19 states are requiring the reporting of these infections
20 and how those infections came about.

21 In fact, there are 27 factors, which I
22 will not go into at this point. One of those happens
23 to be instrumentation and devices. So those are the
24 three areas where pedigree if we wanted to make a case
25 and interpret the existing regulations on the books,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 that's one way we can interpret the medical device
2 pedigree.

3 MODERATOR KESSLER: Comments? Ann?

4 MR. FERRITER: Yes. I would like to
5 comment on the NDR reporting. I think that's a great
6 use for unique device identifiers. What unique device
7 identifiers could also give us would be the number of
8 devices that are out there. If we get 100 NDRs, we
9 don't know at this point whether that's for 100
10 devices that were implanted or several thousand. So
11 it is a very interesting use.

12 Thanks.

13 MODERATOR KESSLER: Other comments from
14 the floor?

15 (No response.)

16 MODERATOR KESSLER: I want to thank the
17 device panel.

18 (Applause.)

19 MODERATOR KESSLER: I'm going to ask the
20 following people to come up one at a time, a very
21 brief presentation. And then we'll begin doing
22 wrap-up. And the mics will be open for some comments
23 at the end of this.

24 So Cathy Denning from Novation, please.
25 And then in order just get ready: Michael Dempsey,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 Richard Eaton, Fred Freedman, Dr. In Mun, Mark Piper,
2 Jeff Schaengold, Elliot Sloane, and Brad Sokol.
3 Cathy?

4 One more thing to the presenters. I'm
5 going to sit down. When I stand up, five minutes are
6 over. And I'll just sort of quietly slide this way.

7 MS. DENNING: I use my watch. I was a
8 trainer.

9 MODERATOR KESSLER: Good.

10 OTHER PRESENTATIONS FROM PUBLIC

11 MS. DENNING: Good afternoon, everybody.
12 I am Cathy Denning, and I work for a company that's
13 called Novation. We are the supply company. We do
14 contracting for about 2,500 member hospitals for VHA
15 and UHC.

16 In addition to that, this is what we
17 represent from a statistical perspective. VHA has
18 over 2,400 members. UHC has 200 members and
19 represents a large percentage of the university health
20 systems throughout the country.

21 In addition to those two, we also have a
22 sibling company called HPPI, which stands for
23 Healthcare Purchasing Partners International. And now
24 we also are part of a company that is called Novation
25 U.K. We are the contracting side of the U.K. as well

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 for the device perspective, not for the pharmacy side.

2 Nationally Novation purchases are \$29.7
3 billion through these different entities. It
4 represents 26 percent of community hospitals, 70
5 percent of academic medical centers, 26 percent of the
6 staff beds, 30 percent of admissions, and 29 percent
7 of the total surgeries in the country today.

8 We would like to advocate from a public
9 health and safety benefit perspective for unique
10 device identification. We believe that it would
11 positively impact patient safety and quality in
12 addition to the health care supply chain efficiencies
13 that I will go into in a little bit. And I will stay
14 within my five minutes.

15 From a medical accuracy perspective, it's
16 interesting that the last comments around counterfeit
17 products and drugs were mentioned. In one of our VHA
18 facilities, we had patients and implanted 30 of them,
19 to be exact, with counterfeit mesh.

20 I would like to think that if we had a way
21 of uniquely identifying products as they enter that
22 hospital, we would know whether or those products
23 potentially were counterfeit.

24 And I do realize how wily some people can
25 be when they want to be dishonest, but just last week

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 I think we also heard about the blood glucose
2 monitoring strips that are also counterfeit.

3 From a product substitution perspective,
4 when we have large recalls and backorders, when we
5 have disasters across the country, certainly from a
6 product substitution perspective, being able to
7 identify when a product is both functionally and
8 actually equivalent to another product would certainly
9 provide for the easy movement of one product from here
10 to here and, consequently, not interrupt the care of
11 that particular patient.

12 Product shortages are an ongoing issue
13 again. It goes all the way back to raw materials.
14 But I do believe that from the standpoint of being
15 able to look and to aggregate the different products
16 again from a safety standpoint as well as supply chain
17 efficiency, that would bring some benefit as well.

18 Recalls and product withdrawals. Of
19 course, as you can see from the previous slide, we
20 have a lot of hospitals who have to manage large
21 numbers of both device as well as drug recalls on a
22 daily basis.

23 I think there was an article last week
24 that was published that said that hospitals have had
25 to manage over 600 drug recalls on average, which

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 would mean that that is more than one a day across the
2 country.

3 From a supply chain efficiency
4 perspective, unique device identification would enable
5 inventory management, item master management, recall
6 management, charge master management, and electronic
7 medical record, being able to track and trend which
8 device made it into which patient, how much it cost.
9 Whether you're paying for a product that went into
10 that patient or got charted on somebody else is
11 certainly something that I would think that all
12 payers, including CMS, would be interested in.

13 From a charge master and recall management
14 standpoint at the end of the day, it also is about
15 bringing efficiencies and being able to track and
16 trend.

17 Inventory management. You know, right now
18 there are disparate systems. And I have heard a lot
19 today about why hospitals don't adopt those coding
20 systems that are out there. We right now are
21 gathering information. We have a survey that is in
22 process. And we will provide those statistics and
23 data to the FDA.

24 What we have preliminarily looked at is
25 that and what our members have told us is that at the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 end of the day they have disparate coding systems that
2 come into them. And they have to figure out some way
3 of making sense of that.

4 When they get it, they then have to turn
5 around and code it so that it's recognized across
6 their system. So we would like to have a call,
7 really, for a mandatory system that is consistent
8 where the nomenclature is recognized globally.

9 In order for us to really be able to make
10 this work, we believe that that is what we have to do,
11 is come together from a collaborative perspective and
12 really advocate on behalf at the end of the day on the
13 patient.

14 (Applause.)

15 MODERATOR KESSLER: Thank you.

16 Michael? Michael Dempsey again from
17 Partners Health Care.

18 MR. DEMPSEY: Hello again. I prepared
19 this presentation, really, for a different context,
20 but after sitting here for the day and listening to
21 all of the expertise in the audience, I am quite
22 humbled by the amount of thought that is going into
23 this. So I am going to change it up a little bit.

24 What I would like to do is just share with
25 you a vision, maybe something to get people excited

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 by. Partners Health Care has our own version of a
2 unique ID. As I mentioned on the panel discussion, we
3 ended up here. We ended up with this originally
4 starting with patients and then moving on to
5 medication safety. It's not deployed ubiquitously,
6 but it does exist in some of the practices.

7 So you can imagine that once we
8 collectively decide what the unique ID is for medical
9 devices, that in a couple of years, we might be in the
10 same spot that Partners is today, some limited
11 deployment but something that works.

12 And now is where it gets interesting. We
13 deployed it, started talking to clinicians, and
14 clinicians came up with amazing and fun and exciting
15 and very invigorating ways to use it. And I'm going
16 to share with you one of those.

17 So that is nearly impossible to see, but
18 down at the bottom there in that white box is the
19 unique ID. It's self-identifying. That happens to
20 identify a drug, and it identifies the dosage and so
21 on. And it's all encoded in that 2D bar code.

22 So these are some of the records that are
23 included in there. And you can see it's quite
24 complex, has versioning numbers, has care area
25 information. Different drugs are used differently in

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 different care areas, bolus rates, and so on. I can
2 share with you the details of this. If you're
3 interested, contact me. This really isn't important.

4 But here is the unexpected benefit. We
5 realize that this unique ID could become a speed dial.

6 So, in fact, it was in one of the outpatient clinics
7 with a medical assistant. So this is a
8 paraprofessional, typically has gone through 16 weeks
9 of training, not a rocket scientist. And they came up
10 with this notion of capturing vital signs and putting
11 it into the electronic health record using the speed
12 dial.

13 So, effectively, what you see there is the
14 vital signs monitor. It's a CASS 740 vital signs
15 monitor that has no network connectivity, never has,
16 and probably never will. It's inexpensive. It's
17 typically found in a doctor's office.

18 On the front of it is literally taped that
19 2D bar code that says, "This is a CASS 740," its model
20 number, and its revision number. And you communicate
21 to it with whatever, infrared, Bluetooth, however you
22 communicate with it.

23 So then the clinician uses her PDA, which
24 has a bar code scanner; scans that 2D bar code. And
25 the PDA says, "Oh, I know this is a vital signs

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 monitor. So I'm expecting to capture vital signs.
2 And I know how to communicate with it." So it sucks
3 the vital signs out of the PDA and pushes it up over
4 the wireless network into the longitudinal medical
5 record.

6 Now, what are the benefits of this? One
7 and most significantly is it's work flow-sensitive.
8 So if you scan a vital signs monitor, it does
9 something different, the PDA does something different,
10 than if you scan a smart IV pump. Right?

11 The smart IV pump scan tells the PDA that
12 you're dealing with drugs. There must be a drug
13 someplace. And, in fact, since we have this notion of
14 unit-specific identifiers, you can have a smart IV
15 pump in an oncology unit perform differently than the
16 identical smart IV Pump that's in the pediatric unit
17 or in the OR because they have different care
18 practices.

19 All of this is enabled by the unique ID.
20 The important point of this is that the unique ID has
21 all of the advantages that we have been talking about
22 that are obvious. But I believe that once we as a
23 group of caring medical professionals implement it,
24 our clinical teams will figure out a lot more
25 applications of it in ways that we haven't

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 contemplated today that will make it very powerful and
2 important.

3 Thank you.

4 (Applause.)

5 MODERATOR KESSLER: Thanks a lot, Michael.

6 Richard Eaton from the National Electrical
7 Manufacturers Association.

8 MR. EATON: Good afternoon. Are we
9 holding up? I'm from the National Electrical
10 Manufacturers Association, NEMA, in Rosslyn, Virginia.

11 I want to tell you a little bit about NEMA, also
12 share some views with you that we have on UDI, talk
13 about some problems and issues that we see with the
14 potential system, suggest some next steps, and some
15 essential requirements.

16 What is NEMA? NEMA is the primary
17 standards development organization for medical imaging
18 and therapy systems equipment. Our Diagnostic Imaging
19 and Therapy System Division members manufacture over
20 90 percent of the market for all these big ticket
21 capital equipment items: X-ray, includes mammography;
22 CT; radiation therapy, which includes linear
23 accelerators; magnetic resonance devices; nuclear
24 medicine imaging, which includes PET; diagnostic
25 ultrasound devices; and medical imaging informatics

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 devices, or PAX.

2 NEMA generally supports a UDI system,
3 which is practical, cost-effective, and improves
4 patient safety. The link with patient safety is
5 absolutely essential.

6 We are ready to work with FDA and all key
7 stakeholders to achieve this goal. And we believe all
8 key stakeholders must become involved in this process
9 to ensure success. Everybody who is going to touch
10 this system needs to be involved in it or, else, it
11 will not work.

12 Let's talk about some problems. The first
13 and most important problem is, what are we trying to
14 fix? What problems are we trying to solve? We can't
15 develop a fix if there needs to be a fix unless we
16 define the problem first.

17 Now, on capital equipment, we already have
18 identifiers. Many of our members already have bar
19 codes on their devices. Some of our capital equipment
20 is already marked with serial numbers. And this is
21 used to track products for recalls and adverse events.

22 And the tracking of these begins in manufacturing
23 through installation.

24 The RAD Health Act requires identifiers on
25 X-ray components. Our concern is that a new UDI

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 system would conflict with the existing requirements
2 that our X-ray equipment manufacturers already have to
3 adhere to.

4 I want to emphasize that the same
5 regulations if a UDI regulation is passed have to
6 apply to both users and manufacturers.

7 Other issues of importance, who is going
8 to train the users to utilize this system in the
9 hospitals, doctors' office, or wherever they are
10 installed? We need to know what the cost impact of
11 increases in user and manufacturer infrastructure.
12 And there will be infrastructure changes in the
13 manufacturers to develop these codes, to revise them,
14 maintain them. We need to be aware of electronic
15 medical records and privacy issues.

16 I don't have the answers about the
17 identification technologies, but, as you have heard
18 today, there are many different identification
19 technologies that could be employed. Which are the
20 right ones?

21 And, as already alluded to, the software
22 revisions, how do we accommodate this on our devices,
23 which are constantly receiving software revisions?

24 Now, what essential requirements would we
25 want in a UDI system? The most important one is that

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 it must and must enhance patient safety. That is the
2 primary reason for being for a UDI system. It may
3 have a lot of other benefits that we have already
4 heard about, but patient safety is primary.

5 We're also very much believing that we
6 have to have harmonization with the systems and
7 regulations around the world. Global harmonization is
8 our absolute goal. We need one worldwide system. You
9 have heard today there are a lot of systems that are
10 already out there. We don't want a proliferation of
11 systems. We want to move toward one system.

12 We also need to have the identifier
13 provide only essential information, which is related
14 to patient safety. Again, the needs of FDA
15 manufacturers and users need to be satisfied and
16 should, as I said before, require compliance from both
17 manufacturers and users.

18 A UDI system also has to be flexible. It
19 has to adapt to changes in technology. And our goal
20 there is to achieve a least burdensome system, which
21 does not impose onerous, regulatory, or financial
22 burdens.

23 Next steps. I believe we should form an
24 interdisciplinary task force representing users,
25 industry and FDA. We can develop potential

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 approaches, identify the process and the next steps
2 through the task force and Federal Register. And I
3 understand FDA will be publishing a summary of this
4 meeting.

5 In conclusion, we support a practical,
6 cost-effective UDI system which enhances patient
7 safety. But, again, problem definition is essential
8 before we embark on this.

9 Phase-in process of five years is what we
10 are recommending. We must resolve critical details
11 and issues, proposing grandfathering existing devices.

12 And last, but certainly not least, we need
13 a mechanism to evaluate the system as we develop it,
14 involving all key stakeholders, and revise the system
15 if needed. We should link this UDI system to
16 performance goals and safety-related goals, like
17 recalls and adverse event reporting. In other words,
18 how is the system working? And we need a system which
19 will be able to do that.

20 Thank you.

21 MODERATOR KESSLER: Thank you.

22 (Applause.)

23 MODERATOR KESSLER: Fred Freedman from the
24 Dental Trade Association.

25 A couple of comments while Fred is coming

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 up here that Richard made. We're very cognizant of
2 the issues, some of the issues, he has raised, some
3 very challenging ones, specifically things like
4 software versions and how to keep that fresh and into
5 a data system that is accurate. That is a very
6 challenging problem.

7 The other problem he also mentioned is
8 legacy equipment because there are many, many
9 thousands of items on the floors of hospitals today or
10 in patients. And the question is, how do we handle
11 that? That is a challenging issue for us.

12 DR. FREEDMAN: Thank you, Dr. Kessler.

13 I just want to start off by saying thank
14 you for providing this forum today for all of us. I
15 found this very useful. We have been represented by a
16 few people here from the dental trade. And we're
17 grateful to have the opportunity to speak. We have
18 heard a lot of common sense spoken in the room today.
19 And we hope to contribute as we go forward.

20 The Dental Trade Alliance, an association
21 comprised of 220 members, represents manufacturers,
22 distributors, and laboratories providing medical
23 devices to the dental industry, including many of the
24 largest and smaller manufacturers.

25 Since unification of the highly respected

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 Dental Manufacturers of America and American Dental
2 Trade Associations, DTA members have been involved in
3 all aspects of dental, including manufacturing,
4 distribution, export, import, and international
5 commerce. The public's overall oral health and
6 patient safety are priorities for all DTA member
7 companies.

8 DTA applauds FDA for promoting public
9 health care and encouraging full disclosure of medical
10 devices. Because dental-type medical devices offer
11 little risk to the public, the dental trade agrees new
12 regulations for identification of medical devices
13 should be instituted in a way that is very practical,
14 flexible, and not burdensome to small companies. The
15 DTA position refers to these following points.

16 DTA does not believe UDIs will prove
17 particularly practical for dental offices and their
18 patients.

19 Time is a factor in implementing UDI
20 requirements. DTA believes a five-year period is the
21 minimum time required for manufacturers to implement
22 new regulations. Five years provides flexibility
23 without undue hardships for the industry.

24 Neither the use nor the format of unique
25 device identifiers should be mandatory except where

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 their absence would result in a major health care
2 risk.

3 UDI should be based on existing standards
4 which are well integrated into the marketplace and
5 meet basic requirements.

6 UDI will add cost and may be onerous for
7 small manufacturers, distributors, and users. A
8 general information campaign is required, particularly
9 geared towards the general public.

10 Elements should be limited to
11 manufacturer's number, product number, lot number, and
12 expiration dates when necessary.

13 UDIs should be only required on the sales
14 packaging unit except for large equipment.

15 Government efforts to require UDIs should
16 include Centers for Medicare and Medicaid Services,
17 Department of Defense, and others.

18 Any development of a UDI requirement
19 should be closely aligned with international global
20 harmonization.

21 DTA strongly urges consideration of these
22 important criteria when implementing new procedures
23 for identification of medical devices. Thank you.

24 (Applause.)

25 MODERATOR KESSLER: Dr. Mun from HCA,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 Hospital Corporation of America. Great.

2 DR. MUN: Good afternoon. I would like to
3 share some of the work we have done with medical
4 device marking using RFID and bar code. We start
5 basically when the IOM report came out in 1999. There
6 was a very fine line at the report saying that bar
7 code is a very important factor to reduce medical
8 errors.

9 So if you look at bar code in health care,
10 I guess bar code was invented much, much earlier than
11 1983, but year 2005, which was last year, there is
12 only about 9.4 percent of hospitals using bar code for
13 medication delivery.

14 And so in terms of identification
15 technology, obviously bar code was earlier one. It's
16 easy to use. And it's quite well-known technology.

17 So in HCA, we actually implemented a bar
18 code point of care system. The steps we have taken,
19 we started February 2000 as one of the major patient
20 safety initiatives. And then at that time, our
21 expectation was that we would implement the system
22 throughout our facilities by the year 2010. And that
23 was because the cost we were aware of was \$400,000 to
24 \$1 million per facility. However, after we installed,
25 we realized it wasn't as bad as it appeared. And so

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 we have accelerated implementation.

2 So by 2005, we actually have implemented
3 throughout our system. We actually delivered 115
4 million transactions. So even though the GS gentleman
5 says that we are clueless, we have slightly a little
6 bit of idea about what ID is.

7 Lessons we learned from BTOC is that it
8 definitely does reduce the errors and it helps to make
9 complete documentations. And there's definitely
10 improved patient safety.

11 However, bar code does have certain
12 problems. One is everybody must be engaged. And our
13 nurses are much smarter than we are. They know how to
14 get around occasionally.

15 And so at the same time we have looked at
16 RFID. And RFID, we decided to look at asset
17 management. The reason is that I work for a
18 for-profit hospital. So we have to get numbers met at
19 the end of the day.

20 And so we are looking where we could use
21 RFID. And we found the RFID for the device management
22 actually would work out very nicely because we
23 realized that there was data before us saying that
24 mobile equipment utilization is 45 percent. Hospital
25 loses quite a bit of money once in a while. And at

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 the end of the year, we have a problem with inventory
2 management. And, of course, there are always
3 complaints when there are infection rates that we are
4 not doing very well.

5 And so steps we're taking, we started
6 looking at the year 2000. And we have looked at the
7 bar code, passive RFID, active RFID. And then about
8 2003, we decided we will go with active RFID, for two
9 reasons: reliability and automation. That is,
10 passive RFID, we found out it will not work when we
11 really need it. And active RFID, we know when it
12 works. So that was one of the major criteria.

13 And then we selected vendors out of nine
14 vendors we have investigated about a year or two. The
15 criteria was the battery life because we wanted to
16 last much longer than a few months, then size of tag
17 because we wanted to be able to track as many
18 equipment as possible. And we also want to know what
19 resolution we can find the equipment.

20 And so we implemented a pilot system in
21 2005. And this is a configuration. We are using
22 basically 433 megahertz tag, and we are tracking
23 currently 2,500 items in a hospital.

24 These items we tagged, almost everything,
25 anything which can move. We don't do it based on

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 price. MRI is very expensive, \$2.5 million. We don't
2 tag. It doesn't move hopefully.

3 (Laughter.)

4 DR. MUN: However, the thermometers, which
5 are maybe 50 bucks, we do tag because that's something
6 the nurses need.

7 And we have found out some interesting
8 things right after we installed. About 30 percent of
9 infusion pumps simply don't move, despite the fact
10 that nurses insists we must buy pumps every time. So
11 we have some idea. Now we can go back and talk with
12 nurses, why they don't need any more.

13 And this is data from one of the
14 institutions where they have done the work a little
15 bit earlier than us. They were basically able to
16 demonstrate a cost saving of \$1.5 million. This
17 excludes cost avoidance or such savings.

18 The current status is that we have done
19 all of these things, and there are a few hiccups, as
20 you may expect. We found out that some of our nurses
21 are much smarter than we are.

22 And then we have interfaced the biomedical
23 service database. So now we know exactly when the
24 device is serviced and when it should be serviced.

25 We are also getting some interesting

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 information. For instance, as I mentioned, some of
2 the items simply don't move. And they say they don't
3 have it. So we know we need to manage these things
4 better.

5 And also we found out some interesting
6 relationships among items, like rental equipment and
7 discharge. We rent equipment when patient comes in,
8 but we don't know when to stop that rental because
9 when discharge, we don't tell the guy, "We no longer
10 need it." So we see huge savings at that side.

11 And also because we have seen a lot of
12 work flows we can improve using this technology, we
13 are looking at the surgical chart tracking in OR,
14 improvements in ER as well as ICU. And also we will
15 be able to give information on physicians' PDA where
16 the patient is so when he rounds, he doesn't have to
17 waste his time going in the wrong place.

18 And what we have learned is that equipment
19 or any technology you put in, it's just a cost. You
20 have to sweat it out. You have to work at it. You
21 have to make sure that your workload is matching with
22 what you do. And if it doesn't, then we have to
23 change it and make sure everybody works at it.

24 The lessons we have learned is that RFID
25 medical device, asset management using active RFID is

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 cost-effective. However, there are a few other issues
2 which we have identified.

3 One of the worst problems is, what do you
4 do with the database? This is one entry in the
5 database. It's the same equipment. This equipment is
6 known as a patient lift. But nurses call it agile
7 lift. And common name used by industry is
8 lift/patient. So if you search this database, as
9 previous speakers talked about, it's a mess.

10 So we decided, why can't you use 2D bar
11 code? So the reason is that it's cheap, at least
12 compared to RFID. And there are less physics
13 problems. And we can address item level very easily.

14 And also it provides lots and lots of data.

15 Now, some people say we don't want to give
16 data to the end users. Come on. We are the guy who
17 has to manage patients. If you don't have any data,
18 how do we manage them? We must have data. So please
19 don't insist not giving us data. Please give us data.

20 So, for instance, we can put a 2D bar
21 code, human-readable information. Current tag can be
22 put into 2D bar code and put right next to it. And I
23 believe this helps considerably in managing.

24 And I don't know about DOD, but for our
25 hospital, some of the guys who are looking for

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 equipment, they are the lowest-paid people in the
2 hospital. They really don't know one from the other.

3 And it's vital for us to provide additional
4 information to these people.

5 What we would like from FDA and everybody
6 else from here is that we would like to have a
7 cost-effective unifying standard which will cover
8 staff budgets, patient restraint, IV medication,
9 non-IVs, medical devices, and blood products if it is
10 possible. It may not be possible. So this is just my
11 shopping list, shall we say.

12 And so we are looking at a couple of other
13 different documents to figure out what to do. And we
14 are extremely interested in what Partners is doing.
15 And hopefully we will be able to work with them.

16 Thank you very much.

17 (Applause.)

18 MODERATOR KESSLER: Mark Piper is next
19 from DOD. And those of you who will be watching the
20 FDA Web site will see that Dr. Mun will become a
21 visiting member of FDA soon, nothing to do with the
22 fact that he has got all the right answers for me.

23 (Laughter.)

24 MR. PIPER: Hi. I am Mark Piper. I am
25 with the Department of Defense Unique Identification

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 Program Office. And I am here specifically to talk
2 with you about item unique identification.

3 I actually work for Keane Systems. We are
4 one of the management consulting companies to the DOD
5 with regards to unique identification.

6 Just to give you a little bit of
7 background about the DOD's item-unique identification
8 program, it is approximately five years old. It was
9 launched in 2002 formally with policy guidance that
10 came out then. And if you take a look at some of the
11 business drivers that we found, such as better value
12 for the dollar spent, full accountability, and asset
13 management, adverse event tracking, personnel safety,
14 they are similar to the business drivers that we have
15 all heard here today with regards to health care.

16 And certainly the Department of Defense
17 item-unique identification program includes health
18 care system, health care items, health care devices,
19 as well as other types of Department of Defense
20 systems.

21 One of the things that we looked at was we
22 focused on the data and the processes that are
23 involved. Basically we looked at item-unique
24 identification as the information key. It consists of
25 the enterprise identifier lot, batch, or part number,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 as required, and also a serial number.

2 And within that, we chose a
3 two-dimensional data matrix as the data carrier,
4 adhering to international standards with regards to
5 syntax and semantics.

6 What we allowed for was the manufacturer
7 actually gets to select the methodologies for
8 serialization. We use the enterprise identifier in
9 their serial number or the enterprise identifier part
10 number, serial number, and the equivalent with regards
11 to GAIA, GRAI, and for serialized items, VIN number,
12 and ESN.

13 We looked at processes from the
14 perspective of we will have both operational and
15 business processes regarding manufacturing, repair,
16 the actual business of receiving, paying for material,
17 and then accountability for that material and where it
18 is located within an operation.

19 Today the item-unique identification
20 program has over 700,000 items entered into the
21 item-unique identification registry. Somebody asked
22 me earlier from one of the device manufacturers,
23 "Mark, are you going to get up and say, 'Been there,
24 done that'"? Yes, we have been there and done that.

25 And we very much want to thank the help

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 and participation that we have gotten from the FDA and
2 the support that we have gotten from people like Dr.
3 Larry Kessler as well as Mr. David Racene and also
4 from the Defense Logistics Medical Supply Center with
5 Kathy Garvin as well as the support that we have
6 gotten from the Defense Medical Logistics Standard
7 Support Service with Jon Sherman because we have been
8 able to integrate the requirements for medical items,
9 medical devices within all of DOD. I'll say items
10 that are purchased or procured and all items that we
11 have to manage.

12 Something that is interesting is 65
13 percent of the items that have been registered are
14 registered by small commercial operations. To us a
15 small operation is somebody who is \$250,000 in
16 revenue. And certainly we have other suppliers within
17 our supply chain that go up to \$30,000 billion as far
18 as corporations go.

19 We have done some cost analysis. And
20 whenever you work in a repetitive manufacturing
21 environment, the cost of marking an item can drop to
22 as low as 20 cents. And if you begin to look at
23 non-repetitive manufacturing, it could be as much as
24 10 to 20 dollars per item.

25 The UID program, item-unique

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 identification program, was built on certain
2 foundations. And we looked at this is a program that
3 has to be commercially robust in that our suppliers,
4 whether or not they're in other areas as far as
5 systems or within the medical and health care
6 industry, go through mergers and acquisitions. And
7 our item-unique identification program has to be able
8 to perform and identify items with regards to both
9 commercial mergers and acquisitions as well as
10 divestitures of operations.

11 We have a global supply chain. And, as
12 you know, many of you currently participate in that
13 global supply chain. We have to look at an item
14 through its complete life cycle management from the
15 manufacturer to the supplier, through the health care
16 provider, down to the patient. And you can translate
17 that in other defense systems to manufacturer,
18 supplier, distributor, and soldier.

19 Many types of devices have to be
20 identified within the Department of Defense program.
21 And we have to be able to operate and interact with
22 many different types of systems, both from our own
23 internal operations as well as commercial systems
24 throughout our supplier community.

25 What we looked at additionally were how do

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 we distinguish and enable identification, description
2 of the item, and location. And we made a distinction
3 between identifying an item versus describing it.

4 For example, I can give you the vehicle
5 identification number for my car. And then if you
6 took a look at it, you would say, "Okay. It's a
7 silver Ford Taurus." But there's a distinction
8 between identifying it and describing it. And then
9 you can say, "Okay. It's registered in the State of
10 Virginia."

11 Global unique identification has to
12 fulfill each one of these requirements within the
13 Department of Defense. And these are "or" type
14 statements. If the item is serial-managed within the
15 Department of Defense, then it has to have an
16 item-unique identifier. If it's part of our
17 controlled inventory, it has to have an item-unique
18 identifier or if it's a safety or
19 mission-essential-type item, it has to have an
20 item-unique identifier or if it's greater than \$5,000
21 in value. So I could actually have an item that costs
22 50 cents. And if it's safety and mission-essential,
23 it has to be uniquely identified.

24 So that's the conclusion of my
25 presentation. I wanted to thank everybody very much

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 for allowing us this opportunity to discuss things.

2 MODERATOR KESSLER: Thanks.

3 (Applause.)

4 MODERATOR KESSLER: Jeff Schaengold from
5 Siemens and then Elliot Sloane and Brad Sokol. Jeff?

6 And I promise you we will be out around 4:30.

7 MR. SCHAENGOLD: Good afternoon, everyone.

8 Actually, that was me before the meeting today.
9 Siemens is a leading device manufacturer, also a
10 leading symbology manufacturer. And we're very much
11 committed to mass serialization.

12 We look at the UDI program as really mass
13 serialization, not as much as a technology. And when
14 we look at mass serialization, we look at it globally.

15 And when you really look at a global effect, there is
16 a manufacturer out there of ink jet cartridges that
17 basically applies a unique serial number on every ink
18 cartridge they produce and they distribute. And they
19 track every one of them.

20 And the real question that comes to our
21 mind is if they can produce hundreds of millions of
22 these cartridges and track every one of them using 2D
23 bar code, why can't we do it with medical devices?

24 The other element that we have to look at
25 is that we have 420 million passengers who fly in the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 U.S. every year. And it's growing by six, seven
2 percent a year. That ticket number is a unique
3 identifier. We can track passengers through a unique
4 identifier, but, for some reason, we can't track
5 medical devices.

6 We have 13 billion parts a year that we
7 mark in the automotive industry. We do it with bar
8 code. We do it with RFID. We do it with data matrix
9 on metal, 13 billion parts. We somehow seem to manage
10 that, but we can't seem to manage it in a medical
11 environment.

12 So what we would like to do is we would
13 like to offer the premise that creating and
14 maintaining a UDI architecture is really all about
15 mass serialization. It's about designing the
16 identifier first and then utilizing prevailing
17 technologies in direct part marking, instead of
18 reinventing.

19 Now, what will happen is that once you
20 create that foundation, that infrastructure, that
21 cornerstone, pure economics and the ingenuity of man
22 will basically drive everybody around that
23 architecture.

24 So what we are looking at is we are saying
25 that the DOD, for instance, has a UID program that's

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 excellent. We see the AIAG has a program for medical
2 devices. GS-1 and EPC Global has one. From our
3 perspective, it's like, for Pete sakes, choose one.

4 When you look at it, the basic
5 architectures are relatively the same. There are
6 slight nuances. And we can go into some of the
7 particulars, where we say in many respects, you have
8 to pay a little bit more with GS-1 and EPC Global, you
9 have to pay a little bit less with DOD, but the
10 reality is pick and go with it.

11 Now, what we suggest is that we
12 respectfully would recommend to the medical device
13 supply chain community that you pick a structure. And
14 the second step is you create an adjudication body.

15 In other words, we have heard it all here
16 today. We have to define what is a medical device and
17 which is a medical device. We have to define what we
18 are going to use as a serial number, where we're going
19 to put the digit here and a digit there.

20 Decide. Get a group together. Get a body
21 that's basically going to be our court system. And
22 get everybody to come in and make their case. Decide
23 on the case. And continue to move forward.

24 It isn't really about the technology. The
25 technology is only a method. It's only a means to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 this. The reality is anybody who wants to can contact
2 me, and I'll send it to them. But when you look on
3 this, we do a matrix. 2D works well here, and RFID
4 works well here, and Locator works here. But at the
5 end of the day, it's about direct part marking.

6 Assign the bloody serial number to it.
7 And the rest of the world will figure out a way to
8 utilize that serial number in one way or another. We
9 will collaborate. We will be interoperable. We will
10 do all that stuff or we can spend the next 15 years
11 trying to figure out how to build a superhighway, an
12 intelligent highway, when all we want is a bicycle.

13 The reality here is that 2D bar code is an
14 excellent low-cost way of serializing everything from
15 latex to metals to aluminum to jet parts to CAT scans,
16 et cetera. And, by the way, we make every one of
17 those.

18 We can even track something that is so
19 small that it is barely visible to the eye. And we
20 can read millions of these in a matter of about two
21 and a half seconds. So we can read these in batch
22 because we use optical technology. As you have seen
23 out in the floor today, we can laser mark. We can
24 read these laser marks. And it's not expensive.

25 So what happens here is that UDI just

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 basically needs to have an architecture. Everybody
2 just basically say, "Let's go with the architecture"
3 and move forward.

4 So what happens here is that from a
5 Siemens perspective, you're looking at a company that
6 not only is one of the world's largest medical devices
7 manufacturers, but we're so committed to mass
8 serialization that also we have been 17 years in RFID.
9 We do RFID tag medical devices today.

10 We sold over 300,000 readers around the
11 world over the last dozen or so years. We bought
12 RBSI, which you heard earlier today from Lu, which is
13 one of the innovators in 2D bar codes. And we own
14 that now.

15 We are the most pronounced DPM competency
16 center. That's direct part marking. And we do
17 serialization of optical verification.

18 Now, this is kind of my presentation. I
19 have about 45 seconds, I believe. But the reality is
20 I also kept thinking during the conference some of the
21 things that analogous to what we are talking about.

22 Easy pass toll systems, 20 billion
23 transactions a year. Is that really that much
24 different than medical devices? Twenty billion
25 transactions. It seems to be working pretty well.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 And, by the way, if you pass through a toll booth and
2 it doesn't read your RFID, they take an image of your
3 license plate. And they send you a letter. We can do
4 the same thing in the hospital and in the medical
5 device world.

6 The thing from Siemens' perspective is I
7 can tell you it's kind of selfish. I do not want to
8 be the chairman of the board of Sony having to answer
9 to the board about why my market cap went down 14
10 percent because my batteries blow up laptops and I
11 can't decide which battery is blowing up which laptop.

12 If I do a really good job of serializing
13 my product, the product I produce, a catastrophic
14 event will have a less financially detrimental impact
15 to my market cap. So I have a vested interest in
16 making sure that I keep promoting serialization of the
17 product that I sell. And throughout my supply chain,
18 the more focused I am where my product is, the more
19 focused I am on being able to adjust to a recall.

20 And the last thing I want to say is look
21 at the linear bar code. Forget the bar code itself.
22 It's really the UPC, the Universal Product Code.
23 Thirty years ago the first one was at Wrigley's on a
24 Wrigley's chewing gum in March.

25 It took 10 years before anybody realized

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 that you really need to use it 100 percent because I
2 don't know about you guys, but I used to stand in line
3 in the mid 1980s at Home Depot for 20 minutes while
4 they said, "Plumbing, plumbing, price check" because
5 it didn't have a UPC code. And then we became
6 universal. And today everything has a UPC code.

7 So we are suggesting very strongly from
8 Siemens pick and choose an architecture and just move
9 on with it and just go with it and don't worry about
10 inventing new things. Everything has been invented.

11 Thank you.

12 (Applause.)

13 MODERATOR KESSLER: Elliot Sloane from
14 Villanova.

15 DR. SLOANE: Thank you. It is a pleasure
16 to be here.

17 I will weave a number of my Villanova
18 topics into this, the e-commerce, the
19 telecommunications, the database, the e-health, and a
20 whole bunch of other things.

21 And while I am simply a professor, I am
22 not just a professor. I have a little bit of another
23 background. I was Vice President, CIO, and COO of
24 VCRI for 15 years: from 1975 to 1990. I was
25 responsible for building, my team was responsible for

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 building, the recall system, the health advisory
2 alerts, the UMDNS system.

3 I had the pleasure of working with John
4 Vilforth, Jim Benson, Walt Gonderker addressing these
5 things quite a while ago. And we are hopefully more
6 than halfway along this discussion. Hopefully we are
7 getting to the end of this discussion.

8 The next ten years of my life I worked at
9 MedEx. I spent ten years trying to stay out of the
10 FDA's radar screen. MedEx was a medical device
11 manufacturer.

12 At its peak, we owned 500,000 pieces of
13 medical equipment, which we rented to hospitals
14 throughout the United States. We owned nearly 100,000
15 infusion pumps, 25,000 ventilators. We managed all of
16 that with a bar code system with our own unique device
17 identification system. And if I have anything to
18 claim about my ten years at MedEx, it's that we were
19 never sued for injuring or killing a patient.

20 We did get a chance to work with the FDA
21 at the end of that period for working with Phil
22 Phorpolo and the other Dr. Kessler in terms of medical
23 device safety, maintenance, and the like. And today I
24 teach in Villanova and work in the areas of health
25 care information systems and related topics.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 Reality check number one, medical devices
2 really do kill people. I investigated my first
3 medical device death in the late '70s and almost every
4 year since then have been involved in medical device
5 death investigations, including, unfortunately, some
6 involving MedEx devices in the early '90s.

7 It turned out it wasn't MedEx devices,
8 actually. It was an accessory, a \$500 accessory, part
9 of a manufacturer's device in the bed next to where
10 the MedEx equipment was. I got to meet some very nice
11 folks from the FDA with shiny badges that weekend.

12 Reality check number two, nearly 30
13 percent of all health care is occurring outside of
14 hospital walls already. That number is actually
15 ancient. It's too low. That's just the home care
16 piece. It doesn't count physician offices. It
17 doesn't count all of the other allied health and the
18 self-health that is going on.

19 Durable medical device firms, of course, I
20 was part of that at MedEx. MedEx is now part of
21 Hillrom. Other big organizations like Modern Medical,
22 big organizations like UHS, there are hundreds of
23 thousands, if not millions, of medical devices on rent
24 in hospitals day in, day out.

25 To give you a sense of that, with MedEx's

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 inventory seven years ago now, we had on any given day
2 60 to 100 thousand pieces of life support equipment in
3 hospitals, home health care, and other settings. That
4 was day in/day out 365 days a year.

5 So there's a lot of change happening
6 pushing this even further. And if you don't believe
7 that, I went shopping. I just wanted to see what was
8 happening out in the world. And I thought I would
9 just check out the market.

10 I went to my favorite shopping emporium
11 online, Amazon. In Amazon -- you can't read this --
12 in addition to AEDs up here of various brands,
13 glucometers of all sorts, it gets rather interesting
14 when you get down to devices like pulse oximeters of
15 different sorts, a tens units. And, in fact, down
16 here is even a diathermy ultrasound treatment device.

17 There's a number of physiologic monitoring. These
18 are non-invasive blood pressure monitoring
19 technologies, almost every brand and manufacturer.

20 And, by the way, the prices on these range
21 from about 100 to 200 dollars, on up. It doesn't stop
22 there. Full-out medical monitoring systems, \$1,300,
23 goes down into a CPAP, continuous positive airway
24 pressure, devices -- I'm the only guy in the business
25 school that understands what all this stuff is -- and

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 moving into pulse oximeters of various sorts and even
2 a 12-channel ECG monitor and recorder that's available
3 from Bertech price is about \$3,200.

4 So I'm a pragmatic person. I go right to
5 where the things are happening on the World Wide Web
6 to see what's happening.

7 Accessories of all sorts. One minute.
8 Accessories of all sorts out there as well. Ponder
9 medical device recalls. How are all these recalls,
10 maintenance support things being done for all of those
11 devices out in the non-hospital settings? If we don't
12 have a unique device identifier, we won't be able to
13 get to them and support them.

14 Reality check three, a third of every
15 health care dollar is wasted, not my numbers. Those
16 are the government's numbers or at least the Institute
17 of Medicine and National Academy of Engineering. So
18 process improvement is a big, big plus.

19 RFID, as only one part of RF
20 proliferation, every medical device for a few dollars
21 has the ability to be tracked, to communicate. And
22 they're putting batteries and wireless in our pockets.

23 Why aren't they putting it in medical devices? Well,
24 in fact, they are. Most next generation devices will
25 all feed to a telecommunications network. And they

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 all use IEEE standards of various sorts. The devil is
2 in the details.

3 Reality check number four, this I talked
4 about. I won't go into it now. The electronic health
5 record is unfolding. We need it. It is in order to
6 implement the electronic health record with medical
7 devices, every device, just like our cell phones, has
8 to have a unique identification. In order to keep
9 track of each device, there has to be a unique code to
10 allow that data to transfer reliably and accurately
11 into an electronic health record, a telemedicine
12 system, and the like.

13 Quick lessons here. Manual data entry is
14 not going to work. It has to be readable. There has
15 to be a human-readable form for everything. And it
16 can't just be manual data entry. Two percent is the
17 best you can get for manual data entry. You heard
18 about the millions of transactions that go into just
19 individual organizations, work at two percent. That
20 error rate is far too high. You have to have each
21 piece of medical device.

22 I put on the bottom, "Check digits."
23 "Check digits" means you can't make a mistake when you
24 enter something. My checkbook, my account has a check
25 digit on it. One of those numbers make sure if I get

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 the digits wrong, it will not enter the data.

2 So one of the mistakes we made in creating
3 UMDNS is we didn't create a check digit. It's cheap.
4 It's easy. NIST right down the road can give us
5 algorithms for that.

6 Lay persons' English description because
7 people have to be able to say what it is, not a
8 multi-polysyllabic sentence or phrase.

9 Wireless technology I already talked
10 about. In addition to UDI, each device has to be
11 assigned a clear permanent electronic product
12 classification. We need to know what it is. Dr. Mun
13 made that point. We'll leave it at that.

14 And each of these -- redundant.

15 If you need to find me, Google me. I'm
16 out there. And thank you for the opportunity to
17 present.

18 (Applause.)

19 MODERATOR KESSLER: The last of our
20 presentations is Brad Sokol. Then we'll let the mikes
21 open for a couple of minutes if there are any other
22 comments that we have not yet heard today. Then we'll
23 do a closing.

24 MR. SOKOL: Thank you, Dr. Kessler, Jay,
25 Dave. Thank you very much.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 Just to tell you a little bit about what I
2 am going to talk about today is just I'm going to
3 catapult you into the future about two years and talk
4 a little bit about patient safety and infection and
5 how does that relate to the UID.

6 After doing studies for the last three
7 years, I would be happy to talk with anyone after
8 about these numbers. Thirteen thousand to 26,000
9 mortalities a year are directly or indirectly
10 attributed to medical device procedures, processes,
11 infections, saving approximately \$3.1 billion a year.

12 We need to develop a comprehensive
13 interoperable health care model to include medical
14 non-electrical instruments and supplies. These
15 numbers were verified by two epidemiologists out of
16 UIC.

17 The factors to consider for a system we'll
18 talk about next; the drivers; the impact of the UDI;
19 and then, finally, the concluding comments.

20 The ability to incorporate the UDI system
21 into an interoperable health care model. When we talk
22 about the interoperability, we're talking about that
23 now with the patient record.

24 We need to address the patient record. We
25 need to address the medical devices. It all needs to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 operate together. It's fine for electronic medical
2 devices under IEEE 1073.3, but we don't have anything
3 for instrumentation or supplies.

4 There are some very unique life cycle
5 events experienced by a medical device that may not be
6 experienced by other devices or other methods in
7 medical industry. One is the reprocessing of medical
8 devices and associated regulations.

9 Recently the FDC passed something called
10 502.u, which happens to be the labeling of a
11 reprocessed device. Well, there is a little bit of a
12 problem there. You have to keep the manufacturer's
13 name on it. And now you have to have the
14 reprocessor's name on it in one of three scenarios. I
15 won't get into it that much.

16 Distributor relabeling. Rentals, loaners,
17 sterilization cycles, maintenance cycles. I mentioned
18 earlier medical device reports and history reports.

19 Adverse event reporting. We haven't
20 talked about that today yet. And it's really
21 something that's quite important. And, finally, state
22 reporting.

23 One of the things that I think we all
24 really need in this industry if you're looking at both
25 the patient side and the medical manufacturers' side

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 is you need a de-referenced database environment where
2 all queries have confidentiality, integrity,
3 authentication, and anonymity because we fear as the
4 medical device manufacturers the liabilities. On the
5 other side, though, the patients fear that their
6 privacy is going to be interrupted. So anonymity is
7 very important in a de-referenced database
8 environment; in other words, a hidden database
9 environment.

10 Patient privacy. I just talked about
11 that. Focus on infection control. And this is very
12 important. Design a model to increase our abilities
13 to better detect the chain of transmission of
14 infections by integrating the UDI procedure and
15 patient record. Currently there is nothing to
16 integrate the procedure and the patient record.

17 Finally, I've got to tell you as an
18 independent researcher and a consultant but mostly,
19 half the time, an independent researcher, I've been
20 blessed with being able to talk with a lot of people
21 around the world. And for the last eight months, I've
22 tried to see if there was a way to get these different
23 nomenclatures together and people together. I am here
24 to report that, unfortunately, I was unsuccessful.

25 So getting past the vested economic and

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 political bias of the current players, be it medical
2 devices, be it patients, be it the nomenclature
3 societies, is absolutely important to look at that
4 side. All I can say is that it's a very difficult
5 problem we face here. I won't say that much more on
6 it.

7 Device maintenance. We just talked about
8 that. We need to look at the proper chain of
9 transmission. We talked a little bit about theft and
10 counterfeiting.

11 We need to enable a process to track
12 reprocessing, recalls, rentals, loaning of medical
13 devices, and reducing the counterfeit of instruments.

14 There are ways to do that. I happen to know there
15 are several esteemed colleagues that I have been
16 working side by side with but not with exactly,
17 sharing information from an intellectual point of
18 view, that these things are possible.

19 Increased supply chain acid visibility,
20 you heard that probably from hearing Joe. Matching
21 patient record to diagnostics, to device to patient,
22 scheduled procedure, and infection cause, very
23 important.

24 Again, I keep coming back to infection.
25 Reducing the stay of hospital-associated infections

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 and length of stay, reducing mortalities, and ensuring
2 sterilization, ensuring sterilization, the process and
3 the work flow, through proper device usage on the
4 correct patient.

5 Finally, the issue. Lack of informatic
6 tools. We have all agreed on that today. I put to
7 you that the solution is actually to look at something
8 called the seven device L's, that I call them: last
9 manufacturer, very simple; last maintenance; last
10 sterilization; last location; last user; last
11 procedure; and last patient, just seven things, but
12 there are a lot of things that go into those seven
13 things.

14 That will inevitably help prevent 13,000
15 to 26,000 mortalities a year and save us \$5 billion a
16 year. As I mentioned before, the next issue, 11
17 nomenclatures, I suggest a universal translator. If
18 you remember Star Trek, that's what I suggest.

19 Finally, the confidentiality. Let me just
20 go to the conclusion here. The failure to incorporate
21 comparative relationships with a medical device,
22 nomenclature, error reporting, patient record, and
23 procedure will yield in an unstable interoperability
24 health care model.

25 If we wait until infection control yields

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 an immediate ROI or until we reach a global political
2 compromise, it may be too late. All I can say to you,
3 let's not wait for catastrophic disease outbreak to
4 implement UDI, which inevitably can reduce those
5 mortalities.

6 Thank you.

7 (Applause.)

8 MODERATOR KESSLER: With all those L's,
9 how appropriate for Brad to be our last speaker.

10 Is there anybody else who would like to
11 make a brief comment before Dan and I close? Don't
12 forget to identify yourself.

13 MS. FRAHLER: Good afternoon. My name is
14 Jori Frahler. And on behalf of the innovative and
15 entrepreneurial companies that the Medical Device
16 Manufacturers Association represents, I would like to
17 thank FDA for convening this meeting to discuss this
18 issue of unique device identification systems for
19 medical devices.

20 MDMA has met with FDA and other
21 stakeholders to begin discussions about this issue.
22 However, we believe there are many unanswered
23 questions that need to be addressed before moving
24 forward with any UDI initiative.

25 While MDMA supports the universal device

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 identification system, we strongly believe that it
2 should be a voluntary process. Much has been made of
3 the potential health and safety benefits of UDI,
4 comparing it to the mandatory drug bar coding system.

5 However, this analogy does not hold up
6 when looked at closely. Unlike pharmaceuticals, there
7 are very few, if any, compatibility issues that exist
8 between two devices that would impact safety or
9 efficacy. Therefore, the policy justifications that
10 exist in the pharmaceutical industry for a universal
11 bar code system do not exist for medical devices.

12 If, however, FDA can provide data that
13 suggests compatibility issues for particular devices,
14 mandatory UDIs for those devices may be warranted.

15 In closing, MDMA does look forward to
16 continuing this dialogue with FDA and other
17 stakeholders to answer the many questions that remain
18 about a universal UDI system. And we would like the
19 FDA to form a UDI task force with efforts of everyone
20 in this room. With a UDI task force, I am confident
21 we can develop a globally harmonized, yet voluntary
22 UDI system that will benefit all stakeholders.

23 Thank you.

24 MODERATOR KESSLER: Thanks.

25 Any other comments? You will get your

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 chance. First of all, if you don't mind, I would like
2 to thank all of the presenters, both the people we had
3 on the panel and the people who just did the last
4 presentation. So let's give them just a very brief
5 round of applause.

6 (Applause.)

7 MODERATOR KESSLER: All the presentations
8 you saw today will be soon on our Web site. That's
9 first.

10 Second of all, allow me to thank the
11 people who helped me organize this: Jay Crowley, who
12 is standing up in the back; and Dave Racene. And we
13 had some help from Ann Marie Williams putting this
14 together. I want to thank all of them for the hard
15 work they did to put together this meeting.

16 So you're probably wondering a little bit
17 our process and what we are thinking. So I am going
18 to give you a little bit of that process and a couple
19 of thoughts and let Dr. Schultz close in terms of the
20 global thoughts where the Center for Devices is going.

21 First of all, as most of you know, there
22 is a deadline coming up November 9th for comments
23 about what we are talking about. We urge you to get
24 in your comments to us as soon as you can so we can
25 think about them.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 If you get a comment in a day later, it's
2 not like we won't look at it, but we would really
3 appreciate giving it to us because Jay, David, and I
4 will have to make a presentation, not only to Dan,
5 but, as you heard from Dr. Woodcock, this is of
6 interest not only at the agency level but at the
7 department level. So any decisions we take forward
8 we're going to have to vet at the very highest levels
9 of the department.

10 And you saw the broad interest from our
11 partners from Medicare and Medicaid, from AHRQ, from
12 DOD, the VA. And we're going to have to work with
13 them very closely. So if we take any solution
14 forward, it's in collaboration with them, not
15 something that's separate. So it's very important to
16 us to do that.

17 And we have to take this forward. So the
18 sooner you get comments to us, the better, the more we
19 can handle them in our decision-making process.

20 A couple of things we are thinking about.

21 Clearly we understand the diversity of the medical
22 device industry. We're aware that it is made up of
23 many, many companies, from very small companies, very
24 large companies that make a very diverse range of
25 products. So thinking through the solution has been a

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 challenge. We mentioned things like software
2 versions, legacy products, et cetera; so a lot of
3 issues that we have to handle.

4 Clearly we are going to tie this to issues
5 of safety and performance. Those are the issues that
6 we are concerned with. And I promise you that we are
7 going to keep those in mind very closely. We're not
8 going to try and create a solution that doesn't fit
9 the problems that we're facing. It is very important
10 to us.

11 And, finally, I would like to say one of
12 the things that we are trying to do is challenge
13 ourselves to think about the system for the future.
14 If we are going to be moving in this direction,
15 solving today's problem is only part of the issue. We
16 have to think through where is the puck going to be in
17 five years, not where is it today. And that is a
18 challenge for all of us in health care for us in a
19 regulatory environment.

20 So I appreciate your time and your
21 attention and will turn it over to have some closing
22 remarks made by Dr. Schultz. Dan?

23 (Applause.)

24 DR. SCHULTZ: Thank you, Larry.

25 NEXT STEPS, WRAP UP AND HOUSEKEEPING

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 DR. SCHULTZ: For sure I am not going to
2 take my five minutes. I promise you that. One thing
3 I'm pretty good at is looking at faces and sort of
4 gauging where people are. And as far as I can tell,
5 it's time to move from bar codes to barstools. So
6 we'll be out of here very, very shortly.

7 I do want to say thank you and thank you
8 to particularly Larry, who has been waging this war
9 for a long time, Jay, David, everybody who put this
10 meeting together, all the speakers.

11 And I want to say something to all of you
12 because we hear over and over and over again that
13 there needs to be collaboration. Well, there's only
14 one way you can get collaboration. And that's to have
15 people actually show up.

16 So, for me, looking at this audience and
17 seeing the diversity and the number of groups and the
18 number of individuals who are represented, the first
19 step in getting collaboration has been achieved by
20 getting this group together and discussing this issue
21 and putting things on the table.

22 Clearly we have got a ways to go. I
23 understand that there are complex issues that we need
24 to deal with. But getting everybody together is
25 clearly the first step.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 Larry said that I was going to discuss for
2 a minute how this fits in with our overall center
3 priorities. And clearly our priority in the past year
4 and in the coming year has been trying to "connect the
5 dots" in all parts of our post-market surveillance
6 program.

7 We look at unique identifiers as a
8 keystone to that effort. So very clearly we see this
9 as a major, major, major important initiative in terms
10 of being able to provide for the safety of medical
11 devices. And, therefore, it's something that we are
12 going to pursue vigorously, both now and in the
13 future.

14 We want to be able to do this
15 collaboratively. And, as I said, you know, I think
16 that the first step in that process has been achieved,
17 but we want you to continue to participate because
18 there are other ways to do this. But I think that the
19 way that we would prefer to do this is to get the
20 input from all of our stakeholders and try to do
21 something that wins for all of us.

22 And I also want to, finally, thank our
23 government partners. And there are a number of them
24 whom we have worked very closely with. And, again, we
25 want to continue to work with them and with our

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 partners around the world because I heard frequently
2 people talked about the idea of doing this not just in
3 the U.S. but on a global scale. And we certainly
4 agree with that. That is something that we will be
5 shooting for as well.

6 So, again, thank you very much. Thanks to
7 Larry. Thanks to Jay. Thanks to David. And thank
8 you. Have a safe trip home. And we will be talking
9 to you. Bye.

10 (Applause.)

11 (Whereupon, the foregoing matter was
12 concluded at 4:32 p.m.)

13

14

15

16

17

18

19

20

21

22

23

24

25

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701