

1 MR. THOMPSON: And that was an excellent point
2 you made, and I would highly encourage you to ask the
3 pharmaceutical insurance company that question this
4 afternoon.

5 MS. SHAW: Hi. My question is for
6 Dr. Cranston. And --

7 MS. DOTZEL: Could you provide your name,
8 please?

9 MS. SHAW: I'm sorry. It's Sherry Shaw, from
10 Aventis Pasteur. And just specifically somewhat
11 related to the sampling issue, but with vaccines,
12 almost all of the vaccines are administered within the
13 office setting as opposed to a hospital setting. And
14 in order for such a system to be effective, it really
15 would require physicians' adoption of the technology at
16 the office level.

17 What would you foresee uptake at the physician
18 level to be with regard to that type of technology?

19 DR. CRANSTON: Frankly, I don't have a clue.
20 I really don't know. I think that based on the major
21 discussion we're having here today and the slow uptake
22 by hospitals because of the lack of barcoding of the

1 products that are available commercially, you know, my
2 suspicion would be that it would be relatively slow.

3 But, you know, as we talk about computerized
4 order entry and the likelihood that that's going to
5 become mainstream in the not-too-distant future, and as
6 the cost of scanning devices, you know, are very low,
7 you know, I think that that will happen. But at this
8 time, I don't think it's been thought about.

9 MS. SHAW: Thank you.

10 MR. GALLAGHER: My name is Derek Gallagher.
11 I'm with Aventis Pharmaceuticals.

12 Is there any data that shows either the number
13 or the impact of medication errors due to dispensing of
14 expired product or recalled lots, as opposed to wrong
15 product or wrong dose?

16 MR. THOMPSON: None that I'm immediately aware
17 of, but that would certainly be something I would be
18 happy to look up and verify and get you the information
19 if it's available.

20 MR. GALLAGHER: Thank you.

21 MS. TABORSKY: My name is Jeanne Taborsky and
22 I work for SciRegs Consulting. We represent a number

1 of different kind of drug companies. I have two
2 different comments.

3 One is that while we've been talking about all
4 these products, one of the products where there have
5 been some MedWatch reports are nebulas. These are the
6 little plastic devices that have drug, and they're used
7 in nebulizers.

8 And FDA currently does not allow us to label
9 those directly. And they're currently packaged in
10 pouches, and then the pharmacist will -- at the
11 hospital scene will take them out of the pouches and
12 sometimes put them in bins. And there have been some
13 instances where the pharmacists have actually had
14 problems where they have mixed them up in bins.

15 One thing, we're going to need agency help in
16 trying to find a way to label nebulas where we can't
17 even put a label on them. Because I don't know of any
18 way to barcode something without a label. So that's
19 one thing to consider.

20 The other is, on OTC products where we have --
21 we're trying to put a lot of information on small
22 blisters already. I don't see where the person in

1 their home is going to gain advantage of having a
2 barcode on that small blister for an OTC product. And
3 a lot of these people are getting older, and as we're
4 getting older our eyes are having more trouble reading
5 small print. And so it's just something else to
6 consider, as to how we're going to put a barcode on
7 each individual blister of material.

8 Any comments?

9 DR. COMBES: The only comment I would make is
10 that we use OTC products all the time in hospitals.
11 And if we have an integrated system where we're doing
12 bedside scanning, including prescriptive medications as
13 well as over-the-counters, we would certainly like to
14 have the advantage of scanning the over-the-counters as
15 well.

16 And again, I don't know that you can predict
17 what the future is. And I agree the real estate on an
18 OTC blister pack may not be all that large. But the
19 symbologies are getting smaller, and there are kind of
20 unique ways.

21 I was at the recent packaging conference, and
22 everybody had blisters with lots of information on them

1 and barcodes on them. And I think we need to look at
2 it because you don't know where the technology is
3 going. And it may be at home people will be using more
4 of these kinds of devices in the future.

5 MS. TABORSKY: Thank you.

6 MR. BILLS: Hi. My name is Ed Bills, from
7 Hill-Rom. And my question is for Dr. Feigal.

8 We've been talking about the label and
9 concentrating a lot on the label. But it looks to me
10 like we're introducing a new medical device here. And
11 what do you see the product clearance process for the
12 barcoding system to be, and how long will that take to
13 get in place?

14 DR. FEIGAL: The thought occurred to me as
15 well.

16 (Laughter)

17 But there are a number of hospital information
18 systems that we have chosen not to regulate. Some of
19 them are actually Class I exempt. But we would look at
20 these and have to see where they fit into the
21 framework.

22 But in general, if you look at most

1 laboratories' information systems, things like that, we
2 historically have not chosen to regulate those.

3 MR. RACK: Bob Rack, RDG Barcode America.

4 This is particularly directed to Dr. Combes.

5 You've indicated that NDC is a first step.

6 Okay? And you can do that with your existing scanners.

7 It's also been indicated here that only 1.1 percent of

8 hospitals are using any scanning technology. You've

9 indicated that you want to stay with existing scanning

10 technology, even though you also indicated that over

11 four to five years, these existing scanners will cycle

12 out.

13 At the same time, you've indicated that you'd

14 like to see the expiry date and lot code put on there,

15 and to accomplish that, you need to go to either RSS

16 codes or data matrix codes, particularly on your small

17 packages. At the same time, you've indicated your

18 resistance to data matrix multiple times. And you're

19 trying to do two things that they're exclusive to one

20 another.

21 And my other point, you've made reference

22 multiple times to the extreme cost of data matrix

1 reading devices. They can be had for under \$500.

2 DR. COMBES: What I was saying to you was that
3 we have made -- maybe only 1 percent of hospitals are
4 using scanning at the bedside. But we're using
5 scanning all throughout the hospital. We're using
6 scanning for inventory control. We're using scanning
7 for laboratory specimen identification. We have
8 scanners available in the institution.

9 My understanding -- and I may be wrong on
10 this, and we've spent some time trying to understand
11 it -- is that an RSS code can be read by the current
12 generation of scanners that we have in the hospitals
13 that are not optical scanners, and that what I was
14 saying is that the older scanners that are not current
15 generation will be cycled out, will be replaced, by the
16 current generation, which can read RSS, can read
17 composite barcodes.

18 So what I'm trying to say to you is we don't
19 think we should move to the next order of magnitude of
20 scanners, replacing the scanners we currently have in
21 the institution. And some of them are current
22 generation scanners that we're using in various

1 different departments within the hospitals.

2 We are not scanning at the bedside precisely
3 because we don't have the barcode on the medication,
4 and that's what we're asking for.

5 MR. RACK: But when you're talking about
6 inventory control, you can do that with current
7 existing technology. When you're going to small
8 packages, you have to go to the next step. When you
9 talk about reprogramming existing scanners that you
10 have, okay, that can be done to read certain subsets of
11 RSS. But they may not be the subsets that can fit on
12 this information that's required.

13 If we're only doing the NDC number, you're
14 right. But if we're going to do the expiry date and
15 lot code, it's not right.

16 DR. COMBES: That's why I said the expiration
17 date and the lot number needs to be phased in because
18 there are technical issues there. And I've heard all
19 sides of this argument, and I don't think we're going
20 to be able to resolve it today. It's going to take
21 some time in sitting down with people who know a lot
22 more about this than I do to figure out how you can do

1 this.

2 But my understanding, that there's a
3 possibility it can be done using the current generation
4 of scanners that we have in the hospitals. Again, I
5 think there's going to be a lot of technical work that
6 has to be done around this issue. I certainly don't
7 have the expertise to answer it today, but I do think
8 people do have it, and I think if we take a measured
9 approach, we'll get to that point.

10 Our concern is just, let's get something on
11 the label that we can start to work with. We don't
12 scan at the bedside because there's nothing to scan
13 right now.

14 MR. RACK: Okay. I guess my point is, if you
15 stay at NDC number, you're okay. Thank you.

16 MR. GROSS: Hello. My name is Michael Gross,
17 from Aventis Behring.

18 I'd like to ask the healthcare provider panel
19 what thoughts they have about how this is going to
20 impact the use of diluents that are used to
21 reconstitute dry products for injection. What
22 complications are going to be derived from this, the

1 labeling of those products?

2 MR. THOMPSON: Expand a little bit. I'm not
3 sure I understand your question. Now, we would support
4 diluents are pharmaceutical products also being
5 barcoded.

6 MR. GROSS: I believe that not all of them
7 contain NDC numbers. Some of them are sort of
8 customized diluents for particular products that really
9 go with the product. Sometimes, as I understand it, in
10 practice, the diluent can get separated from the actual
11 drug that it's used for, I think, in practice. You
12 might know more about that than I do, but this is what
13 I hear.

14 So I think there's some complications around
15 diluents. And I guess I'm asking if you've thought
16 this through and how this might work.

17 MR. THOMPSON: Not in any great detail related
18 to diluents specifically. However, one thing that we
19 have recognized as hospital/health system pharmacists
20 is that even if we get manufacturers producing all
21 products in unit dose packages and making those
22 available to hospitals, we're still going to have to do

1 some repackaging within the pharmacy department and
2 some barcoding at the pharmacy department level.

3 We heard about pediatric institutions and
4 children's hospitals and the specialized dosage forms
5 there. So the capability to barcode at the hospital
6 level is still going to have to be there for some
7 products.

8 And I don't know if I'm addressing diluents in
9 that or there's some other technical issues or
10 regulatory issues associated with that. Perhaps the
11 FDA can help answer that one.

12 MS. CIPRIANO: Let me just comment on your
13 statement that the diluent gets separated from the
14 medication.

15 MR. GROSS: That's what I understand that
16 happens.

17 MS. CIPRIANO: Well, I would hope that's
18 really not happening, I mean, because the final
19 preparation, all of those contents should accompany it
20 through all of the system checks that are done before
21 that medication would be released.

22 So that part of the medication cycle would

1 really need to be examined if in fact it was separated
2 before all of the final checks. I mean, again, every
3 institution has its system. But I would be surprised
4 if that is happening to any great extent.

5 MS. DOTZEL: Before you ask your question, let
6 me just ask that everybody who's standing up to ask a
7 question, we'll go through those questions, and then
8 we'll probably break after that.

9 MS. ALLINSON: Hi. I'm Jen Allinson from
10 Procter & Gamble Pharmaceuticals.

11 I have a question about whether or not the
12 rule would be extended to repackagers.

13 FDA PANELIST: We haven't made any final
14 decisions about the rule. We're here to get input
15 today. Do you have something you want to say about
16 that?

17 MS. ALLINSON: Well, I guess what I want to
18 say is mostly what these folks are using are items that
19 are coming from repackagers. So if that rule is not
20 extended to those folks, then there is a great
21 possibility that you're still going to be dealing with
22 the same issues.

1 DR. COMBES: We would like to see it extended
2 to repackagers. We'd like to see a common standard
3 that everybody uses so that there is no confusion about
4 what scanning device to use or where to use it or what
5 information is in there, so certainly any time a
6 pharmaceutical comes into the hospital, either
7 repackaged or packaged originally from the
8 manufacturer, there's a barcode on it that we could
9 read at the bedside.

10 MS. ALLINSON: Thank you. Second question:
11 Regarding your comments about not wanting to see data
12 matrix because of barcode scanners, et cetera, that
13 could potentially increase the costs to all the
14 manufacturers because we would potentially have to go
15 to one standard now.

16 And then if we want to add lot number and
17 expiration date later and have to go to, you know, data
18 matrix, now we're making a whole second change in terms
19 of all of our labels, all of our, you know, printing
20 capabilities, et cetera, et cetera. So you may be
21 actually creating a barrier for the pharmaceutical
22 industry to provide the data that you need.

1 DR. COMBES: I recognize that. But there are
2 some manufacturers right now that will put a barcode on
3 with the NDC and then add the composite afterwards in
4 the last step of the manufacturing process so they can
5 get into the lot number and expiration date because you
6 don't have that information until you're coming off the
7 line, basically.

8 And so if the technology is there -- and this
9 is why I say we think it needs to be phased in -- it
10 may be possible to have it linear coded, and then have
11 a barcode either adjacent to it in the composite form.

12 MS. ALLINSON: You're right. That is a
13 possibility. But it is something that's even less
14 developed and more uncertain for high-speed lines. So
15 I would just keep that in --

16 DR. COMBES: And I understand that. And
17 again, that's why -- but if we wait till we get it
18 perfect and get the right scanners to get all three
19 elements on, we might be sitting around for the next
20 several years being right where we are today.

21 MR. HANCOCK: Ed Hancock, American Health
22 Packaging.

1 What we're talking here today is an issue
2 that's significant enough for regulation, for federal
3 regulation. And there's a lot of discussion about what
4 is critical and what is nice to have, questions focused
5 around that.

6 I think Dr. Crawford set the scene this
7 morning when he spoke of 100,000 deaths annually
8 through -- and many through medication administration
9 errors. So it's critical that we figure out this,
10 what's critical and what's nice to have.

11 My question to the panel, to each and all of
12 the panel, and I think it can be answered in a yes or
13 no: Does the content of the NDC, which defines the
14 medication, manufacturer, and strength, coded on the
15 package provide sufficient information by itself to
16 address the five rights -- right patient, right
17 medication, right dose, right time, right route?

18 MR. THOMPSON: The answer is yes. But that's
19 one part of the medication use process which is an
20 extremely complex process. So also the ability of
21 having lot number and expiration date for product
22 tracking, recall, and identifying whether a product is

1 in date or out of date would be very useful.

2 I mean, you mentioned the 100,000 deaths
3 associated with medical errors. A subset of that in
4 the IOM was 7,000 related to medication errors. Do we
5 have to wait until an expired product caused a patient
6 harm? Do we have to wait until we have a product
7 recall that we really need to be able to track who got
8 what and when?

9 I completely agree, the NDC has the necessary
10 data elements. It is the primary element within the
11 code that will be the most useful at the bedside for
12 preventing administration errors. But let's not
13 minimize the complexity of the medication use process
14 and, you know, just put these things on the back burner
15 and forget about them five years from now.

16 MR. HANCOCK: I understand the possibilities
17 are enormous if we expand.

18 Others?

19 DR. COMBES: I think our position, from the
20 American Hospital Association, is pretty clear. I
21 mean, we think we can get a lot out of having the NDC
22 number on it.

1 When you say, you know, does it guarantee the
2 five rights, well, if you're giving an expired drug or
3 a recalled drug to somebody, then you're not giving the
4 right drug any more. So again, you know, nice to have
5 the ability to get that information.

6 Again, off the top of my head, I wonder if
7 there's a way to do that by using the barcode as a
8 pointing device since the lot number and expiration
9 date -- and I may be wrong about this -- but is
10 generally in the shelf-keeping unit.

11 And if there's a way to link the dose that
12 you're delivering back to the shelf-keeping unit in
13 your database, you may be able then to pick up the lot
14 number and expiration date.

15 There are different ways to look at this, and
16 I think we have to explore that. But it is very clear
17 that tomorrow, if we had the will, we could get that
18 NDC number on the unit of use and have it barcoded.

19 MS. ESTHER: I'm Sarah Esther. I'm a pharmacy
20 student from Purdue University.

21 And I was wondering if the panel had any
22 comments on the implication of barcode labeling

1 requirements on pharmacists' jobs, and if this might
2 eventually lead to the elimination of pharmacists in
3 some practice sections and greater responsibilities for
4 technicians who might now have the final check.

5 MR. THOMPSON: Well, I'm the pharmacist on the
6 panel, and I'm fairly confident that this will not
7 eliminate the need for pharmacists as the experts in
8 the medication use process and the use of medications.
9 Very good question.

10 But this is another layer of protection for
11 the patient. And, you know, that's the way we need to
12 look at it. You know, I mean, all of us as healthcare
13 professionals, if we could develop systems that
14 protected patients and provided total failsafes and we
15 were all out of jobs, we all become obsolete and out of
16 a job, then we've done our job.

17 So we're not going to get to that point.
18 Systems are complex, and I think you have a long career
19 ahead of you.

20 (Laughter)

21 DR. COMBES: Also, a little reassurance from
22 the hospitals' perspective. One of the things that's

1 very clear in the patient safety movement, and does
2 ensure safety of the medication system, is use of the
3 clinical pharmacist as part of the care team.

4 The more we can free the pharmacist up from
5 this routine of checking and counter-checking and
6 counting and doing everything else, and getting them
7 involved in the care team, the better off our patients
8 are.

9 The amount and complexity of pharmaceuticals
10 we use in healthcare is amazing, and no physician, no
11 nurse, can do that on their own. And the more we
12 employ clinical pharmacists to round with us, to help
13 us tailor drug regimens, and to work as part of the
14 team, the better off everybody will be. So I wouldn't
15 worry about it, either.

16 MR. MURRAY: Good morning. My name is John
17 Murray. I'm in the Office of Compliance for the Center
18 for Devices.

19 My question is for the industry panel. Do you
20 envision that this barcode regulation will address the
21 validation, the design control, and the overall quality
22 of systems? And if it's not going to be in this

1 regulation, what is your recommendation about how we
2 approach that problem to ensure that these systems
3 actually work to protect public health?

4 (No response.)

5 I have a part B question for the lawyers.

6 (Laughter)

7 My part B question is, how do you envision
8 that this barcode rule will impact on legal liability?
9 Currently now I guess it's, you know, a practice of
10 medicine, that whole legal liability history. Will now
11 we shift the big error blame to the IT system, take the
12 human out of the loop?

13 And then who gets -- who is liable? Is it the
14 hospital? The barcode maker? The label maker? I
15 mean, I'm just wondering how this could shift the scale
16 of justice.

17 MR. THOMPSON: Now, I'm not an attorney, but
18 we're not talking about taking the human out of the
19 loop here. We're talking about providing humans with
20 another layer of protection for patients as part of the
21 process.

22 So, you know, this isn't a way to take the

1 human out of the loop. So we'll let an attorney answer
2 the question related to legal liability, but --

3 MS. CIPRIANO: Let me just add one other
4 issue, though, that hospitals are facing. The more we
5 move to technology, and I'll just use robotics as an
6 example, we are seeing limits on liability from the
7 manufacturers.

8 And so whether it's the repackagers or whether
9 it's the dispensing manufacturers, I think there's
10 growing tug and pull in terms of how contracts are
11 written and where the liability is placed.

12 And so I think it is an issue that we have to
13 pay some serious consideration to because, you know,
14 institutions are willing to buy into technology, and
15 even if we believe that the systems are 98 to
16 99 percent accurate, there is certainly that concern
17 about risk when you are buying a system in order to
18 reduce your liability to begin with for errors.

19 So I think it's an unanswered question and an
20 important one that you raise.

21 DR. COMBES: I think the other challenge for
22 hospitals is that having the barcode on a label will

1 probably create some liability, and probably in a good
2 sense that there'll be an expectation that it's used.
3 And when it's not used and patients suffer from a
4 medication error, it will be pointed out to us quite
5 clearly. You have this capability to do something.
6 Why don't you do it?

7 And I think that's really going to be the
8 pressure to make the industry move forward in using
9 information technology much more judiciously than we
10 have in the past, and for better patient outcomes.

11 MS. DOTZEL: Well, that concludes our morning
12 session. I'd like to thank the panel for getting us
13 off to a good start today. I think the discussion this
14 morning has been very productive, and I think it's
15 gotten everybody thinking about the issues we want to
16 continue to talk about this afternoon.

17 There is a cafeteria upstairs on the main
18 floor. You may have seen it as you came into the
19 building this morning. They're expecting us, so we'll
20 break now. We are going to reconvene at 12:15.

21 (Whereupon, at 11:20 a.m., a luncheon recess
22 was taken.)

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

12:18 p.m.

1
2
3 MS. DOTZEL: We're going to start in a minute.
4 Why don't the members of our next panel come on up and
5 take your seats while everybody else is getting seated.

6 Okay. Why don't we get started. Before I
7 introduce our next panel, I'm going to walk through the
8 government panel again. We've had a few changes for
9 this afternoon's session, and I just want to make sure
10 that everybody is acquainted with who's up here.

11 Starting with Dr. Steven Galson. He's the
12 deputy center director in our Center for Drugs. Seated
13 next to Dr. Galson is Dr. David Feigal, who is the
14 center director in our Center for Devices. Seated next
15 to Dr. Feigal, we have Nancy Gieser, who is the acting
16 director on our economics staff in the Office of the
17 Commissioner.

18 And then Diane Maloney, who is the associate
19 director for policy in the Center for Biologics. And
20 sitting next to Diane, we have Peter Beckerman from our
21 Office of Chief Counsel.

22 And our panel this afternoon is the industry

1 panel. We have representatives from the different
2 trade groups, and I will call you up individually.
3 I'll walk through the panel so that everybody knows
4 who's up here, and also so I can make sure I know
5 everybody who's up here.

6 We have Richard Johnson here representing
7 PhRMA. Steve Bende from the Generic Pharmaceutical
8 Association. We have Bill Soller from the Consumer
9 Healthcare Products Association. Kay Gregory is here
10 on behalf of the American Association of Blood Banks,
11 the American Blood Centers, and the American Red Cross.
12 We have Mary Grealey, here from the Healthcare
13 Leadership Coalition. And Tess Cammack -- am I saying
14 that correctly? -- representing AdvaMed.

15 And with that, we'll get started. We'll start
16 with Dr. Johnson from PhRMA.

17 DR. JOHNSON: Thank you for the opportunity.
18 Can everybody hear me? Okay? Hopefully everybody had
19 a good lunch and has come back energized to hear more
20 about barcodes this afternoon. I'm very pleased to be
21 able to offer the PhRMA statement regarding barcode
22 label requirements for human drug and biologic

1 products.

2 PhRMA continues to be supportive of efforts to
3 utilize standardized barcodes down to the unit of use
4 level on drug and biologic products as part of an
5 initiative to reduce medication errors. Current
6 printing and scanning technology allows for the
7 application and reading of a barcode on the label for
8 all but the smallest primary containers. Here are some
9 examples.

10 PhRMA encourages the use of a standard barcode
11 and data structure for encoding the NDC number in these
12 applications. The NDC number is a unique identifier
13 for the manufacturer or distributor, the drug
14 formulation, and package size and type.

15 In addition to the currently used UPC code and
16 Code 128 symbologies, which you can see here, PhRMA
17 also endorses the reduced space symbology and the 2D
18 code data matrix. And for those of you that may not be
19 so familiar, maybe it's helpful to see what they look
20 like. This is another example. This is a Code 128 on
21 a different type of package.

22 Based upon the current state-of-the-art

1 technology available for incorporating barcodes on
2 small container labels, it may be necessary to amend
3 current FDA text requirements so that certain human-
4 readable information now required to be on all primary
5 drug and biologic container labels be exempted.

6 This would provide sufficient space to print a
7 high-quality machine-readable barcode and more
8 prominent human-readable text to help reduce medication
9 errors. And I thought this was a good illustration of
10 how small some of these container labels that we're
11 dealing with can be.

12 If there were agreement on the above
13 conditions, it would be possible for pharmaceutical
14 manufacturers to extend the use of machine-readable
15 barcodes on container labels where there's available
16 space, and have those barcodes on such container labels
17 within two to three years.

18 For container labels where the necessary space
19 is not readily available, the feasibility of
20 incorporating the NDC number into a machine-readable
21 barcode and the timing for its implementation would
22 require further discussion with the FDA regarding

1 requirements for handling exemptions and supplements
2 for label changes.

3 The present technology is limited in its
4 ability to support the application of machine-readable
5 barcodes incorporating additional information beyond
6 that contained in the NDC number, such as product lot
7 number and expiration date. These are variable
8 information that would have to be applied lot to lot.
9 And you can see some of the wide variety of
10 pharmaceutical packages that we deal with.

11 The material benefit of a barcoded lot number
12 and expiration date to achieve a reduction in
13 medication errors warrants further discussion among
14 stakeholders.

15 As a recent paper from NCCMERP cites, further
16 research is needed to quantify the safety and cost-
17 effectiveness of barcoding in the medication use
18 process, and should be undertaken before their
19 universal incorporation into these processes. The use
20 of barcoding technology as a mechanism to improve
21 medication safety should be implemented incrementally
22 with careful planning, and given thoughtful

1 deliberation for cost, cultural, and implementation
2 issues.

3 PhRMA is prepared to convene a group of
4 interested stakeholders to do this kind of needs
5 assessment, and looks forward to the opportunity to
6 work with the agency and other stakeholders in efforts
7 to improve patient safety. Thank you.

8 MS. DOTZEL: Thank you, Dr. Johnson.

9 Next we have Dr. Steven Bende, who is here on
10 behalf of the Generic Pharmaceutical Association.

11 DR. BENDE: Good afternoon. On behalf of the
12 Generic Pharmaceutical Association, I'd like to thank
13 Secretary Thompson and the FDA for their efforts to
14 reduce medication errors, and for providing an
15 opportunity for industry comment on barcode labeling of
16 human drugs and biologics.

17 GPHA represents 98 percent of the generic drug
18 manufacturers whose drugs are dispensed for 45 percent
19 of all prescriptions written in the United States, and
20 representing less than 10 percent of total drug
21 expenditures.

22 GPHA is now the united voice of the generic

1 drug industry. We are completely committed to patient
2 health and safety, and strongly support any measure in
3 all areas that improve these. Indeed, the foundation
4 of our industry relies on the safety and effectiveness
5 of affordable pharmaceuticals to provide increased
6 access to therapeutically equivalent prescription
7 medications for all patients.

8 Consistent with this commitment to quality and
9 safety, GPHA firmly supports the comprehensive use of
10 standardized barcode labeling on human drugs and
11 biologics. We also support the use of associated
12 standardized data formats to aid in the reduction of
13 medication errors.

14 Now, clearly there are some hurdles to
15 overcome, and we've heard about a lot of those this
16 morning, including space limitations of smaller drug
17 packages, current regulations on label text
18 specifications, and the state of technology to actually
19 apply barcoding to packaging online in high enough
20 quality and high enough speed to insure readability.

21 Other issues include what information we've
22 been hearing a lot about, lots and expiration date

1 numbers, and which of the various technologies we
2 should standardize on.

3 At this time, we will not be making a
4 recommendation for technologies to support or what
5 information should be on there -- should be contained
6 in any code. However, we do support -- from hearing
7 from our health system colleagues this morning, we do
8 support NDC number, lot number, and expiration date.
9 And how many of those and which of those are included
10 immediately needs to be debated.

11 To that end, we recommend formation of a task
12 force to swiftly investigate solutions to these issues
13 to aid the agency in developing new barcode regulations
14 that might result in decreased medication errors. Some
15 of the participants of this task force should include
16 end users of the technology, pharmacists, drug
17 manufacturers, FDA, and especially the technology
18 companies who make the technologies behind barcode
19 labeling and the scanners.

20 We stand ready to participate in such a task
21 force, and we extend an offer to assist in its
22 formation and operation. And thanks for the chance to

1 make these comments.

2 MS. DOTZEL: Thank you, Dr. Bende.

3 Up next we have Dr. William Soller, who is
4 here representing the Consumer Healthcare Products
5 Association.

6 DR. SOLLER: Good afternoon. I'm Dr. Bill
7 Soller. I'm senior vice president and director of
8 science and technology for the Consumer Healthcare
9 Products Association, CHPA. We represent manufacturers
10 and distributors of nonprescription medicines and
11 dietary supplements.

12 CHPA supports efforts to reduce medication
13 errors, including those that encompass errors in
14 information acquisition by consumers, who are the
15 principal end users of self-care products, as well as
16 by those in the professional setting that also might be
17 using OTCs.

18 Potential market-based solutions and the
19 ability to leverage existing systems are critical to
20 our industry, and I have three general areas of
21 comment. First, in the consumer self-care setting,
22 drug facts labeling is a means designed to address

1 medication errors. Barcoding to prevent medication
2 errors would not be of value in the self-care setting.

3 OTC manufacturers and FDA have been mutually
4 concerned about optimizing safe and effective use of
5 OTCs through even better labeling, including ways to
6 minimize medication errors in the self-care setting.

7 Working with other groups, including CHPA, FDA
8 developed the Drug Facts Final Rule for improving the
9 content and format of all OTC labels for outer
10 packaging to make essential information on use and
11 selection easy to access and comprehend.

12 This regulation dictates the format, order,
13 print size, content of wording which the lay consumer
14 will receive when they obtain an OTC drug, and requires
15 the active ingredients section to appear first on all
16 information in a special box entitled "Drug Facts,"
17 which also contains directions of use, warnings,
18 storage information, and lot number and expiration date
19 are required by separate regulation.

20 The new drug facts labeling is an important
21 step to reduce potential medication errors in the self-
22 care setting. And in the development of the drug facts

1 box, consideration was given to how consumers use
2 nonprescription drug products in the OTC setting, which
3 is quite different than OTC utilization in the
4 professional setting.

5 In the self-care setting, this encompasses
6 self-selection by consumers and represents the vast
7 majority of self-use of nonprescription medicines.
8 Access and veterans are key drivers to purchase
9 decisions, and reliance on the consumer reading the OTC
10 label is the principal stratagem for self-care with
11 OTCs. We want and we encourage consumers to read the
12 label, to understand their medication, and to dialogue
13 when necessary with health professionals.

14 It's unlikely that the use of barcodes by
15 consumers in the non-institutional self-care setting is
16 reasonably feasible or preferred over the human-
17 readable printed label to prevent medication errors.
18 Scanners are needed to read barcodes.

19 Consumers do not have handheld scanners linked
20 to their personnel medication records. Further, they
21 most likely don't have the need nor the desire for such
22 access, given their state of health, current

1 medications, and cost and upkeep of what might be
2 envisioned as a futuristic personal scanning system for
3 all consumers.

4 My second general point is that the universal
5 product code, the UPC on OTCs, is an efficient and
6 effective means to track retail distribution and sales.
7 Currently, all OTC products intended for retail sale
8 bear a barcode, the UPC on the outer container.

9 The UPC is a unidimensional barcode that can
10 be read at high speeds at the checkout counter. It is
11 the symbolic representation of a number, like a license
12 plate, which is assigned by the manufacturer for
13 tracking each SKU or shelf-keeping unit through its
14 distribution and sales network.

15 Since the UPC is a number, it is simply a link
16 to a different electronic-based archival system within
17 distribution centers and retail stores. The vast
18 majority of the 750,000 OTC retail locations use the
19 UPC to track some 150,000 individual shelf-keeping
20 units for literally billions of OTC packages.

21 The vast majority of OTC products have more
22 than one SKU. While each SKU has its own NDC number,

1 National Drug Code number, it may have a number of
2 different UPCs, between one and twelve, in order to
3 track different modes of distribution and sales for the
4 SKU of the product. And a UPC has a retail life of
5 about six months to many years.

6 Companies need to track SKUs individually by
7 their UPC in order to assess sales by account,
8 promotion success by package size, inventory
9 management, and package tracking in case of product
10 tampering or for a recall. This system is essential
11 for a robust business environment. It is very
12 efficient and it is very effective.

13 My third general set of points focus on the
14 scope and extent of a possible rule in this area. On
15 scope, given that the major use of OTCs is by the
16 consumer versus in institutions, should a barcode rule
17 apply where it would not be used, the self-care
18 consumer retail setting, but where it would be
19 potentially very disruptive to distribution? We think
20 not.

21 On extent, do you mandate the NDC as the
22 barcode on all OTCs, as the UPC or as a separate

1 barcode in addition to the UPC? Well, if the NDC were
2 mandated as the UPC, this would mean that we would not
3 be able to track all our channels of distribution and
4 sales models, and this would have a major small
5 business and larger business impact, unless -- unless
6 we were to frequently change the NDC, which would
7 increase manyfold the NDC listing and delisting
8 activities by FDA, industry, and institutions. And
9 there would be another source of medication errors.

10 Could you use two unidimensional barcodes, the
11 NDC and the UPC? Well, this wasn't recommended by the
12 panel this morning to have more than one barcode. It's
13 not recommended by the council that administers the
14 barcode. And we have heard of instances of confusion
15 in the retail area in terms of inventory and pricing
16 and other matters.

17 Could you go to different or combined
18 symbologies, reduced size symbology or composite
19 symbology? These are very attractive to us because
20 they record the size of that barcode, potentially
21 giving us more label space for consumer information.

22 But it's fair to say that this is a fast-

1 evolving area. Suppliers are supportive of this, and
2 will be coming out with new adaptable scanners in the
3 near term. Other industries, the fruit industry for
4 individual UPC labeling, want to go to reduced size
5 symbologies, as does the CD industry.

6 But this is in the future, I think the near
7 term future, because at the same time, we have a retail
8 environment that is highly invested in flatbed scanners
9 that don't read RSS easily or at all. And this could
10 lead to pushback from retailers due to consumer
11 dissatisfaction and refusal to stock products.

12 Longer term, and maybe not so far in the
13 longer term, RSS, CS, and maybe other technologies
14 offer a longer term solution, and no regulation should
15 interfere with this kind of technological advance.

16 Again a comment on extent. Do you barcode to
17 the individual OTC dose? We don't think this would be
18 useful to the consumer in the self-care setting, as I
19 outlined earlier. And this raises the general scope of
20 the rule. And it would likely require that if this
21 were done, that we would have to delete the needed
22 opening instructions on the back of the blister pack.

1 Do you require a lot number and expiration
2 date? Well, they are already on the OTC label. And as
3 a practical matter, if you look at a unidimensional
4 barcode, as is currently used, you cannot put the lot
5 number and expiration date into that. You would
6 require some sort of composite symbology, which is not
7 available today in terms of a widespread production
8 form.

9 We simply don't have the validated systems or
10 processes for online application of lot number and
11 expiration date through barcoding technology. This
12 would likely require major retooling, and again, the
13 question of scope vis-a-vis OTCs comes in mind.

14 So as you consider scope and extent, and
15 phased-in implementation, does the immediate answer for
16 the fewer number of OTCs used in the hospital setting
17 reside with the repackager? And/or do you consider a
18 national information database linked to the UPC to be
19 the least disruptive to the overall distribution
20 channels, thereby allowing technology to advance and be
21 implemented at the retail level for even better
22 solutions in the future?

1 As a way of marshaling industry expertise and
2 thinking on how to overcome the significant barriers
3 surrounding this issue, we have formed an industry
4 coalition on barcoding that includes PhRMA, GPHA, CHPA,
5 and HDMA in order to address the stakeholder input from
6 this meeting and provide future suggestions on how we
7 might move forward in a feasible, practical, and cost-
8 efficient way. Thank you.

9 MS. DOTZEL: Thank you, Dr. Soller.

10 Next we have Kay Gregory, who is here on
11 behalf of the American Association of Blood Banks,
12 America's Blood Centers, and the American Red Cross.

13 MS. GREGORY: Good afternoon. I'm pleased to
14 be here today representing the blood banking community.
15 Just by way of explanation, when we originally
16 submitted our statement for the panel, we did not yet
17 have approval from the American Red Cross. We're
18 pleased to say that they have now joined in our
19 statement. So I can truly say I'm here representing
20 the entire blood banking community.

21 The American Association of Blood Banks is the
22 professional society for over 8,000 individuals and

1 2,000 institutional members involved in blood banking
2 and transfusion medicine throughout the world. Our
3 members are responsible for virtually all of the blood
4 collected and more than 80 percent of the blood that is
5 transfused in the United States.

6 America's Blood Centers is an international
7 network of community-based blood centers that collects
8 nearly half of the U.S. blood supply and about 25
9 percent of the Canadian blood supply.

10 The American Red Cross, through its 36 blood
11 services regions, supplies approximately half of the
12 nation's blood for transfusion needs.

13 We welcome the opportunity to work with the
14 Food and Drug Administration and other interested
15 parties in developing regulations on barcode labeling
16 for human drug products, including biologics. Remember
17 that blood is classified both as a drug and as a
18 biologic.

19 The primary problem in transfusion medicine
20 indicates a need to reduce the human error, not the
21 problem you may all think would be most prevalent,
22 which is transmission of infectious diseases through

1 blood transfusion. That's really relatively minor and
2 has been pretty well conquered. Now we're looking for
3 other areas for improvement.

4 The introduction of new technologies such as
5 barcoding aimed at reducing the risk of human error can
6 save patient lives. We suggest that FDA adopt a broad
7 systems approach to the issue of minimizing the need
8 for human interface. Mandating the use of barcodes
9 without also considering how the barcode can be read
10 and how it will be utilized in various hospital systems
11 will not automatically reduce human error.

12 And while barcodes may offer one approach to
13 reducing transfusion errors, the FDA must not codify
14 policy that would limit the use of other equally
15 effective technologies in development, such as radio
16 frequency tagging.

17 The important issue is not to mandate the
18 particular symbology to be used. Rather, FDA and
19 providers should focus on requiring electronic data
20 interchange, and the definition and use of standard
21 data structures.

22 In answer to the questions that were posed in

1 the Federal Register notice, you should be aware that
2 blood and blood components are already barcoded.
3 Codabar has been in use since the 1980s. However, a
4 newer barcode, ISBT-128, has been successfully
5 introduced in other countries, and is currently under
6 consideration in the United States.

7 The FDA endorsed -- note the word "endorsed,"
8 not "mandated" -- ISBT-128 in a guidance document
9 published in June of 2000, "Guidance for Industry:
10 Recognition and Use of a Standard for the Uniform
11 Labeling of Blood and Blood Components."

12 It is also expected that future editions of
13 the AABB standards for blood banks and transfusion
14 services will require ISBT Code 128 if a facility is to
15 remain accredited by the AABB.

16 Since many of the considerations in the design
17 of ISBT-128 are also under consideration at this public
18 meeting, our written statement provides a detailed
19 description of considerations that led to adoption of
20 ISBT-128. I want to quickly highlight just a few of
21 them.

22 First, internationally agreed-upon placement

1 of labeling information. And note the word
2 "international." Internationally unique numbering
3 system. Internationally standardized product codes.
4 Encoding of date and time of collection, production,
5 and expiration.

6 Encoding of special testing results. Encoding
7 of manufacturer, catalog number, and lot numbers of
8 blood. And finally, most importantly, a mechanism for
9 continued maintenance and growth of the standard.

10 This slide shows an example of a labeled unit
11 of blood with all the various pieces of information
12 encoded in the barcode. Starting at the upper left is
13 the identification number, or what for many of you
14 would be considered the lot number. The ABO and Rh
15 type, which is extremely important.

16 The product number or the product code, as we
17 call it. The expiration date and time. Any special
18 testing results. And finally, although it's not
19 identified here, the barcode at the bottom left is the
20 product name. In this instance, it's red blood cells
21 with adenine saline added.

22 Now let me move to the other side of the

1 people that we represent, and that is the transfusion
2 medicine side, and talk about additional technologies
3 needed to prevent mistransfusion of the wrong unit of
4 blood.

5 Transfusion of incompatible blood, or
6 mistransfusion of blood, is the most common cause of
7 morbidity and mortality related to transfusion.
8 Serious errors are made at the time of sample
9 collection within the laboratory, at the moment of
10 blood issue from the laboratory, and at the bedside
11 when transfusion occurs.

12 ADO-incompatible transfusions due to
13 misidentification of recipients at the time of
14 transformation are the reported cause for as many as
15 two dozen patient deaths a year in the United States,
16 and such instances we know are under-reported.

17 The blood banking community encourages
18 research, development, and widespread application of
19 new technologies aimed at ensuring that the right
20 patient gets the right unit of blood. Some such
21 technologies, including methods of computerized
22 barcoding and patient wristbands, are already being

1 introduced in some individual hospitals.

2 Unfortunately, there has been only limited application
3 of existing technology to reduce mistransfusion.

4 Here are our recommendations, in conclusion.
5 The entire transfusion medicine community, both the
6 government and private agencies, must move forward to
7 encourage the use of promising technologies designed to
8 avoid patient harm. In this light, these are our
9 recommendations.

10 First of all, FDA should require the blood
11 bank community to adopt ISBT-128 or a comparable system
12 for labeling of blood or blood components. One of the
13 reasons for saying comparable is that we wanted to hear
14 what the outcome of this particular meeting would be,
15 although our preference right now would certainly be
16 for ISBT-128.

17 However, FDA should also recognize that this
18 cannot be done overnight. If it were mandated today,
19 it would require three to four years for
20 implementation. It will require significant resources
21 on the part of both industry and the agency. Because
22 blood bank systems are classified as medical devices,

1 they undergo 510(k) review. The agency must be
2 prepared to do such reviews in a timely manner.

3 Finally, we encourage the development and use
4 of patient and product identification systems for blood
5 products that will be compatible with whatever is
6 developed for drugs, pharmacy use, et cetera. Thank
7 you.

8 MS. DOTZEL: Thank you, Kay.

9 Next I'd like to invite Mary Grealey, who is
10 here on behalf of the Healthcare Leadership Coalition.

11 MS. GREALEY: Good afternoon, and thank you
12 for the opportunity to be here today and to share the
13 Healthcare Leadership Council's views on this vitally
14 important subject. Before I discuss our specific
15 recommendations, let me say a word about the Healthcare
16 Leadership Council and our approach to this issue of
17 barcoding.

18 The HLC is unique in that it represents all
19 sectors of the healthcare industry that would be
20 affected by the FDA's barcoding regulation. We are a
21 coalition of chief executives of hospitals and health
22 systems, pharmacies, pharmaceutical companies,

1 pharmaceutical and medical/surgical companies and
2 distributors, and medical device manufacturers. We
3 also represent pharmaceutical benefit managers as well
4 as health plans. As you can see, a pretty diverse
5 group, but all would be affected by this regulation.

6 Two years ago, the HLC members created a CEO-
7 level task force on patient safety, a task force that
8 has focused on measurable, evidence-based, and
9 achievable solutions to the patient safety challenges
10 our nations face.

11 This task force has determined that electronic
12 verification of drugs at the point of administration
13 should be a high priority initiative. We believe
14 strongly that automated drug identification has the
15 potential to greatly limit medication errors.

16 The remainder of my statement will be divided
17 into two sections. First, I will offer our broad
18 guidelines on automated identification of medical
19 products that have been developed by our HLC members,
20 and then I'll share with you some of our specific
21 recommendations.

22 I cannot stress strongly enough a critical

1 element in the recommendations I'm about to offer for
2 your consideration. They reflect a consensus of our
3 membership. In other words, we have reached common
4 understanding between the healthcare providers, product
5 distributors, and manufacturers, who will each play a
6 critical role in the success of using barcoding to
7 auto-identify medical products.

8 And it goes without saying that the success of
9 an FDA regulatory standard hinges strongly upon the
10 cooperation of numerous parties along the drug supply
11 chain, from the creators of the barcode printing
12 equipment to the nurse that administers that dose at
13 the bedside. We believe the following suggestions and
14 suggested guidelines will lead to a harmonious and
15 effective system.

16 First, we must be pragmatic. Auto-
17 identification standards should support the highest
18 attainable level of safety through the most feasible
19 and cost-efficient approach that can be implemented in
20 the shortest period of time.

21 Second, the regulatory standards should build
22 upon and not disrupt current market forces. Many

1 pharmaceutical companies have already initiated the
2 printing of barcodes wherever possible on their unit of
3 use packages. An increasing number of hospitals are
4 adding auto-identification systems to their hospitals.
5 We should not discourage this progress, and we
6 certainly should not discourage unit of dose packaging
7 by pursuing requirements that are overly expensive and
8 highly difficult to implement.

9 Third, an FDA barcode labeling regulation
10 should, over the long term, result in reducing or at
11 least not increasing the workforce needs of the
12 healthcare system. Many healthcare providers, as many
13 of us know, are already trying to deal with workforce
14 shortages, and their personnel are stretched very
15 thinly at this point. A new regulation should not
16 exacerbate this problem.

17 And finally, the FDA should construct a
18 regulation flexible enough to accommodate new and more
19 effective technologies as they become available.
20 Barcoding may be the auto-identification choice of
21 technology today, but radio frequency, data matrix, or
22 other technologies may prove to be more effective and

1 less costly in the future. We must not preclude
2 technological advances.

3 These four guidelines, we believe, should
4 comprise the foundation of any FDA barcoding regulation
5 that can expect wide acceptance and successful
6 implementation throughout the healthcare system.

7 Now, having laid that foundation, let me move
8 on to eight specific recommendations the HLC offers in
9 response to the FDA's notice.

10 Number one, if the FDA requires barcoding,
11 then this requirement should be limited to unit of dose
12 drug and biologic packaging used only in the
13 institutional environment. This should include both
14 prescription and over-the-counter medications.

15 Number two, initially barcode data element
16 requirements should be limited to the National Drug
17 Code number, the NDC that we've heard so much about
18 today. The NDC contains all of the necessary
19 information to ensure that the patient is given the
20 right drug in the right dosage.

21 Lot number and expiration date should only be
22 considered when the technology for printing dense

1 barcodes is more widely available, and when we have
2 research showing that patient safety is enhanced to a
3 degree that warrants the difficulty and cost of
4 implementing this additional information. The FDA
5 already requires lot number and expiration date to be
6 in human-readable form on the drug package, and at this
7 time this should be sufficient.

8 Number three, in the near term the FDA should
9 not require the application of barcodes beyond the
10 currently widely used linear, one-dimensional barcode
11 symbology. Requiring the immediate use of reduced-
12 space symbology or two-dimensional barcodes would
13 substantially increase manufacturing and packaging cost
14 and could also reduce printing and verification
15 productivity by up to 40 percent, according to our
16 technical experts. Also, existing hospital barcode
17 scanning equipment would have to be reprogrammed to
18 read newly configured codes.

19 Let me be clear: We do not advocate
20 prohibiting the use of more advanced technologies or
21 symbologies. However, we do believe that the FDA
22 should conduct research and convene the appropriate

1 stakeholders to determine an appropriate timeline for
2 introducing specific standards for the newer developing
3 auto-identification technologies.

4 Number four, we ask that the FDA not limit
5 flexibility by mandating the specific location of the
6 barcode on a package. This kind of specificity is not
7 needed to protect patient safety and could perhaps
8 unduly increase costs.

9 Number five, barcode requirements should apply
10 to containers that are the most critical to medication
11 safety. This includes unit of dose containers. An
12 additional consideration for the FDA is that unit of
13 use containers come in various shapes and sizes, from
14 oral solids and topical creams to prepackaged syringes
15 and vials and ampules.

16 Unit of use containers that are small or
17 irregularly shaped are more difficult to print with
18 barcodes, especially using automated printing systems.
19 Consideration should be given to this particular but
20 very important difficulty.

21 Number six, we believe that the FDA should
22 reevaluate the annual label review process with respect

1 to label changes that may be necessary to accommodate
2 barcodes. Creating a fast track process and
3 eliminating certain element size and data requirements
4 would help accommodate the placement of the barcodes.

5 Number seven, careful thought must be given to
6 the phase-in schedule of any regulation. Consideration
7 must be given to the time and expense involved, and
8 retooling packaging operations, purchasing new printing
9 and verification equipment, redesigning packaging
10 artwork, and refiling for label approvals. The last
11 thing we want to do is to discourage unit of use drug
12 packaging with an unfeasible phase-in schedule.

13 Let's also keep in mind that less than
14 5 percent of the hospitals in this country have the
15 hardware, software, and training programs in place to
16 conduct bedside barcoding at this time. In determining
17 the effective date of this regulation, we need to
18 assure hospitals that sustainable barcoding equipment
19 and software compatible with their existing information
20 technology will be available.

21 And finally, number eight, the FDA or other
22 agencies within Health and Human Services should

1 consider including a grant program to assist hospitals
2 in acquiring the technology necessary to implement
3 bedside auto-identification of medications.

4 Let me close by saying that I can't emphasize
5 strongly enough the commitment on the part of all
6 sectors of the healthcare industry to take the steps
7 necessary to enhance safety and to reduce the
8 possibility of medical errors.

9 Significant progress is taking place. Earlier
10 this week, for example, one of our HLC members, Abbott
11 Laboratories, announced that it will have barcodes on
12 all of its hospital-dispensed drugs by early next year.
13 This is but one example of the advancement in the
14 marketplace that is occurring across the spectrum of
15 American healthcare, and it is essential that any
16 regulation facilitate and not inhibit this progress.

17 The FDA needs to take great care that
18 regulations aren't so costly or so difficult to
19 implement that they result in unintended consequences,
20 such as hindering the production of unit dose
21 packaging. And if we are to realize the broad
22 nationwide gains in patient safety through barcoding,

1 then we need to ensure that hospitals have access to
2 the technologies essential to make it happen at the
3 patient's bedside.

4 On behalf of the members of the Healthcare
5 Leadership Council, I'd like to thank you for the
6 opportunity to address this issue, and we stand ready
7 to assist you in any way possible for the safety of all
8 patients. Thank you.

9 MS. DOTZEL: Thank you, Mary.

10 The last speaker on our panel this afternoon
11 is Tess Cammack, who's here on behalf of AdvaMed.

12 MS. CAMMACK: Good afternoon. Thank you for
13 this opportunity to present AdvaMed's views on this
14 important issue. I am Tess Cammack, associate vice
15 president of technology and regulatory affairs for the
16 Advanced Medical Technology Association, or AdvaMed.

17 AdvaMed is the largest medical technology
18 association in the world, representing more than 1100
19 manufacturers of medical devices, diagnostic products,
20 and health information systems, a diverse range of
21 hundreds of thousands of distinct products.

22 AdvaMed and its members are committed to the

1 voluntary use of industry-approved automatic
2 identification for medical devices where it is
3 economically and technically feasible, and where it is
4 clinically practical.

5 My use of the term "automatic identification"
6 is carefully chosen. We all recognize traditional
7 barcodes used on retail packages, but there are other
8 configurations, including radio frequency technology,
9 that uses an embedded chip.

10 All these technologies can use various data
11 structures under the universal product numbering
12 system, and most modern scanning technology can read
13 them all. Because these technologies will continue to
14 evolve, we refer to automatic identification rather
15 than barcoding, which could inappropriately lock
16 industry into one standard, one coding language, or one
17 technology.

18 AdvaMed is concerned that the request for FDA
19 to require barcoding on all medical devices falls short
20 of the needs of a heterogeneous industry. Devices come
21 in all sizes. They are packaged individually or by the
22 hundreds. They are made from a wide range of materials

1 requiring various sterilization and storage needs.
2 They may be designed for single use or multiple use.
3 Their clinical applications vary greatly.

4 I am here today to challenge us all to see the
5 unique design characteristics and usages of devices as
6 significantly different from drugs and biologics,
7 particularly in light of the agency's interest in
8 exploring whether UPNs on devices can improve patient
9 safety.

10 For this reason, AdvaMed recommends that FDA
11 not include devices in its forthcoming rule on
12 barcoding for drugs and biologics, and that any
13 consideration of auto-identification for devices be
14 addressed separately.

15 Industry surveys indicate that from 1995 to
16 1997, there was approximately 30 percent more UPNs on
17 devices at the unit of use level, and nearly 17 percent
18 more on the shelf-pack level. Unfortunately, this
19 older data are soft and there is a need for updated,
20 unbiased surveys that look at not only the number of
21 UPNs on devices, but also the extent to which
22 healthcare professionals utilize the products that are

1 coded and why they do so. Even so, the data we do have
2 confirm that manufacturers, without regulation,
3 increasingly are auto-identifying medical devices.

4 Decisions are best made when manufacturers
5 work with healthcare professionals to clearly identify
6 the goals and practical limitations of auto-
7 identification. They may ask how a device is used, how
8 often it's used, how it's packaged. The manufacturer
9 will consider lot size, device and packaging size, and
10 surface material.

11 They should consider how hospital protocols
12 might be changed by the use of UPNs, which format might
13 be appropriate, and at what level of packaging UPNs
14 should be used. All this is a process to determine
15 whether the expected benefits warrant the additional
16 burden to the healthcare system.

17 Manufacturers use UPNs on devices for various
18 reasons. Most temporary and permanent orthopedic
19 implants, for example, are auto-ID'd to provide
20 traceability. Other products are auto-ID'd to assist
21 in inventory control. And while some devices may be
22 auto-ID'd to reduce medical errors, there is a notable

1 lack of statistically significant data to indicate that
2 UPNs on all medical devices would reduce medical
3 errors.

4 There are, unfortunately, significant
5 obstacles to auto-identifying medical devices. The
6 packaging material may inhibit the use of printable
7 codes. Small devices with limited packaging may need
8 to rely on two-dimensional symbols or RF technology
9 instead of a linear barcode, or they may require
10 larger, costlier packages.

11 Because a UPN may be applied at different
12 levels of packaging, the UPN may not be present at the
13 point of use, especially for multiple use devices that
14 have been sterilized in-house.

15 Most device companies are small firms for
16 whom, in particular, auto-ID reflects significant
17 investments. The costs to hire technology experts and
18 purchase printers, scanners, and software must be
19 weighed against the expected benefits of auto-ID.
20 Identifying each and every throat swab at the unit of
21 use level, for example, would not be practical or
22 beneficial.

1 On the other end of the spectrum is capital
2 equipment, for which auto-identification at the unit of
3 use may not be appropriate. What would the patient
4 safety benefit be in requiring UPNs on these products?

5
6 These examples tell us several things about
7 industry working with its customers to voluntarily
8 apply UPNs to certain devices. There is no one-size-
9 fits-all approach because medical devices come in too
10 many shapes and sizes.

11 They are packaged differently and in different
12 quantities. They may be used singly or multiple times.
13 They are manufactured in lot sizes that vary from firm
14 to firm. Requiring auto-identification on all devices
15 could unnecessarily increase healthcare costs without
16 improving patient safety.

17 This brings us to the heart of my discussion,
18 whether FDA should require auto-identification on
19 devices to reduce medical errors. A 1999 Institutes of
20 Medicine Report suggests that medication errors,
21 transcription errors, user errors, staffing shortages,
22 and lack of training are the prevailing root causes of

1 medical errors.

2 Those attributed to medical technology are
3 notably absent from this list. You could argue,
4 therefore, that a mandate to auto-ID all devices would
5 have only proportional success and would impose a
6 significant cost burden on the healthcare system.

7 Secondly, it's unclear how healthcare
8 professionals are expected to use auto-IDs on devices
9 to improve patient safety. For drugs, the application
10 is certainly clearer. A patient's list of drugs,
11 dosages, administration times, can be benchmarked
12 against actual usage to minimize the risk of errors.

13 But a similar expectation to benchmark device
14 usage is far more vague. A UPN is but one piece of a
15 system that requires a commitment to scan products,
16 identify patients, update code information, and analyze
17 data if benefits are to be realized. Increased patient
18 safety may be attainable for only a subset of medical
19 devices, depending on the nature of the device and its
20 use in a clinical setting.

21 A UPN identifies a product. It provides
22 traceability, not patient safety. For instances where

1 FDA has determined that traceability is necessary,
2 device tracking has already been ordered. Effective
3 systems to track devices have been in place for years,
4 and applying a UPN to a device will not necessarily
5 improve this process.

6 Clearly, auto-identification is not a silver
7 bullet to resolve medical device-related errors. Firms
8 have already auto-ID'd thousands of devices, and they
9 will continue to work with customers to decide which
10 other products should be auto-ID'd. It is a dynamic
11 process that moves forward, albeit deliberately, in a
12 way that is responsive to customer needs and is cost-
13 effective, employing UPNs selectively where benefits
14 can be realized.

15 To summarize, AdvaMed encourages greater
16 communications between healthcare stakeholders to
17 ensure that automatic identification is voluntarily
18 applied to devices where it is economically and
19 technically feasible and where it is clinically
20 practical.

21 AdvaMed strongly encourages providers and
22 purchasers to fully utilize UPNs when they appear on

1 medical devices. Using auto-ID to prevent medical
2 errors requires not only that manufacturers apply a
3 UPN, but also that users commit to its appropriate
4 employment.

5 AdvaMed supports the voluntary use of UPNs on
6 medical devices, which allows for the use of industry-
7 approved UCC/EAN or HBIC standards, a decision that
8 reflects the clinical use of devices, the interests of
9 healthcare professionals, and the challenges faced by
10 manufacturers in auto-identifying medical technology.

11 For all these reasons, AdvaMed strongly
12 encourages FDA to recognize that the unique diversity
13 of medical devices is so significant that they should
14 be excluded from the agency's forthcoming rule on
15 barcoding for drugs and biologics, and addressed
16 separately.

17 We look forward to working with the agency and
18 stakeholders on this, and we appreciate your attention
19 and interest today. Thank you.

20 MS. DOTZEL: Thank you, Tess. Now I'd like to
21 give the FDA panel members an opportunity to ask
22 questions of our second panel.

1 DR. GALSON: I've got a question for
2 Dr. Soller.

3 If we require barcodes on prescription drugs
4 but not over-the-counter drugs, how do you anticipate
5 dealing with the issue of all the over-the-counter
6 drugs used in hospital settings, particularly ones that
7 are used a lot, like analgesics, where the doses may be
8 very important and we really want to make sure to avoid
9 errors?

10 DR. SOLLER: Let me comment on that. That's a
11 good question, and I tried to address our view in my
12 comments. I think in looking at a proposed rule, it's
13 important to consider scope, and as I mentioned, to
14 think about whether requiring a barcode or a new type
15 of barcode or a revision of the current barcode across
16 an entire category where the intent of the rule would
17 not have necessarily a direct benefit, but where that
18 rule might have a benefit in a subset. That scope
19 should be looked at very carefully.

20 And then also, as I put through some of the
21 comments that our group has been concerned with in
22 terms of what might be a change to the UPC, to think

1 about ways where, you know, on the other hand -- just
2 stepping back for a moment, on the other hand you might
3 think about a perfect solution that's totally systems
4 perform and then plunked into operation.

5 And that clearly can't happen, particularly
6 when the machinery is simply not there. And so you can
7 imagine the industry view, being required to do
8 something when you wonder whether it's even going to be
9 used by the end user. And that is balanced by a
10 perspective that it's important to try and find a way
11 to address medication errors, and there's a commitment
12 by the industry to do that.

13 So how do you balance it? And do you go to
14 the perfect solution, or do you look for some sort of
15 phased-in approach? And what I was trying to suggest
16 from our group, a willingness to dialogue on this, but
17 to think about the repackager as a vehicle here where
18 very specific coding symbology could be worked out with
19 institutions interested in moving forward, and I
20 suspect that will be an incremental march among the
21 institutions and not somebody that will occur quickly.

22 And also to think, in that regard, there's --

1 currently ongoing for NDA products, looking at
2 establishing an informational database on labeling.
3 Can that be taken to a next step that might allow
4 linkage of current UPC which is being used and
5 electronic updating, and then access by various
6 institutions that will slowly move forward to do this.

7 So I think the public health solution is not
8 always a perfect one, but is one that may recognize all
9 the different facets and look for the kind of approach,
10 near, mid, and longer term, that would be appropriate.
11 And our group certainly endorses the kind of regulation
12 that would not put a damper on technological advances,
13 whether it's radio frequency or RSS or CS. All of
14 these are very attractive options for the industry to
15 want to explore.

16 DR. GALSON: Just a quick follow-up. Just as
17 a point of information, really, are your products in
18 general packaged separately for institutional users, or
19 is it -- do they get the same --

20 DR. SOLLER: No. We actually have very little
21 control of that. The institutions will go to
22 distributors. We would sell to distributors. And then

1 that stream of distribution is essentially out of our
2 control.

3 And the institution would then go to the
4 distributor or the repackager. You know, the VA goes
5 to a repackager -- or may do it itself; I don't know
6 that system -- and then work out whatever supply they
7 would need.

8 So we don't -- we've looked into that. We do
9 not have a segmented hospital-directed market that
10 represents any kind of significant size of our
11 industry.

12 MS. GREALEY: I'd just like to comment on
13 that. I think Dr. Soller has raised some very
14 important points there, and really has defined well
15 rather than -- and this may be too harsh of a word --
16 overreaching by trying to capture every over-the-
17 counter medication, where what we're really trying to
18 get at is what's used at the patient bedside, that yes,
19 going through distributors, repackagers, may be a way
20 to approach that that would get at what you're trying
21 to get.

22 DR. GALSON: Thanks.

1 Dr. FEIGAL: I had a comment on a device area.
2 I mean, I appreciate the suggestion to change the
3 terminology to auto-identification and not lock us into
4 a specific technology because there are some pretty
5 exciting technology changes in auto-identification,
6 some of which are very small and may be cheaper than
7 even printing, just as now magnetic storage is cheaper
8 than paper, and who would have thought we would be at
9 that point.

10 There are some unique challenges in the device
11 area for hospitals and healthcare facilities. And one
12 of them is tracking products which have been recalled.
13 And this may be a safety issue that is different for
14 devices than it is for drugs, where the issue, the
15 safety issue, may be more focused on getting the right
16 drug to the right patient.

17 Every year there's between 1,000 and 1400
18 medical device recalls, and actually that number has
19 been growing. And that's just the number of recalls.
20 The actual number of products recalled every year is in
21 the millions. In fact, I think one year we topped out
22 at four billion units of products recalled.

1 Just to highlight one example this year, there
2 was a company whose products were recalled who were
3 shipping 10,000 surgical instruments a month which were
4 not sterilized. And one of the difficulties in
5 hospitals finding these is all of the paths of
6 consignees and middlemen and so forth.

7 But it would seem that there would be an
8 interest on the hospital side of being able to rapidly
9 respond and identify inventories and to be able to work
10 with these types of products. Typically, in the
11 recalls, it's not unusual to not even get 5 percent of
12 the products back or have the hospitals even to be able
13 to identify 5 percent of the products which are
14 defective and have been recalled.

15 And it's a little hard to explain why the
16 performance is so difficult in this area. But it seems
17 like this is one of the potential areas. It's more on
18 the inventory control side of things, but a few years
19 back when a manufacturer was shipping iodine that was
20 grossly contaminated with pseudomonas -- in fact, the
21 blood industry picked that up as they cultured the
22 product looking for another product -- there wasn't any

1 way to trace where any of that product had gone. It
2 affected over 140 different device manufacturers. But
3 in terms of patient safety, there was no way to really
4 tell or track where any of that had gone or to identify
5 was it a significant risk or, you know, wasn't it.

6 I realize these things create certain
7 liability concerns. But I'd be interested in your
8 comments on whether or not there are tools that are
9 needed that would help industry meet its
10 responsibilities a little better than it's currently
11 doing in the recall area, where its performance is
12 fairly inadequate.

13 MS. CAMMACK: You raise a very good issue.
14 And I think the diversity of the industry underscores
15 why this needs to be looked at more carefully and why
16 are recalls -- you said that it's difficult to know why
17 they may or may not be working efficiently.

18 Barcoding may or may not be the answer to
19 that. This is one of the reasons why we'd like to be
20 working more closely with the stakeholders to determine
21 if things aren't going correctly as they should, or the
22 information isn't coming from manufacturers as rapidly

1 or as efficiently as it should. Why is that occurring?
2 Can barcoding resolve that? Maybe it can assist it.
3 Maybe other things are needed as well.

4 But to have a blanket approach for such a
5 wide, diverse industry and say, let's put barcoding on
6 everything so we can improve recalls, are you really
7 going to get your expected benefit at the expense of
8 putting that burden on industry?

9 I think many of the questions that we ask
10 about coding devices, we have to go through that
11 balance and see if we're achieving it. And it comes
12 back -- maybe where we need to start is being clear on
13 the starting data on this.

14 I think it's been suggested a couple of times
15 today we need to do a better job of understanding where
16 products are being coded, how those products are being
17 used in the clinical setting, and how has it been
18 effective in improving patient safety, before we know
19 where are the applications it would be appropriate.

20 MS. GIESER: We've heard some discussion this
21 morning, and again this afternoon, about potential
22 implementation periods, anywhere from possibly as soon

1 as one year, two to three years, and maybe four years,
2 I believe I heard.

3 I wonder if the panel would speak to --
4 elaborate more on how you would benefit from longer
5 implementation periods. Is it reduced costs? Are
6 there some products that are more problematic to you so
7 that you need more time? Can you elaborate?

8 DR. JOHNSON: If I can start, anyway, I think
9 a key issue -- the first issue that it would affect
10 cost and implementation is what data elements are going
11 to be required. Speaking for pharmaceuticals, if it's
12 NDC number only, then the implementation time is more
13 of a package design question.

14 And then how long does it take to get the
15 barcode or some auto-identification code placed on the
16 artwork; where necessary, to get that approved; to get
17 it to the printers; to get it phased in; and to get it
18 out into the marketplace.

19 And that is what we believe we can do two to
20 three years. Again, you've got to consider the wide
21 variety of packages. Some of them already have
22 barcodes. I work for a company that has been working

1 very diligently and made commitments to implement
2 barcodes on injectables, but I can tell you there have
3 been literally probably tens of thousands of manhours
4 of work just to put the NDC number on that subset of
5 our total group of pharmaceutical products.

6 So if you say we have to do other data
7 elements, frankly, we're not exactly sure how to even
8 do that. So to give an estimate on how long it would
9 take becomes very problematic.

10 So I think that deciding what data elements
11 are required, and then considering the wide variety of
12 packages, some will be able to be implemented much more
13 quickly than others.

14 MS. GIESER: If we just spoke to the NDC code
15 only, just for ballpark discussions?

16 DR. JOHNSON: Again, in talking with the other
17 member PhRMA companies, we felt like we could achieve
18 that for most of the products within two to three
19 years. And given that there are some products that are
20 very tiny, there would have to be some discussion on
21 whether or not we would have to remove so much text or
22 shrink the text down that that would be defeating the

1 purpose.

2 Because we have to remember, for a long time
3 to come, we have to maintain both human-readable and
4 machine-readable. And if we have unreadable human-
5 readable text, is that going to contribute to
6 medication error reduction or actually make that worse?

7 So there are some that we just don't know of a
8 solution, even with just the NDC number.

9 DR. SOLLER: Just a comment. Again, I would
10 agree. It depends upon scope and extent. And at least
11 as it would relate to OTCs, I don't think it's just a
12 package design question. I think there's a clear
13 distinction between the PhRMA-related products and the
14 CHPA OTC drug-related products in this regard.

15 I think there are issues relating to listing
16 and delisting. We would see a manyfold increase in
17 that activity. And the impact of that on the system
18 and how that is updated and the validation of that
19 system, I think, would be very important if we're truly
20 interested in going that route and thinking that
21 therefore the many different NDC numbers would now
22 represent how we would track our channels of trade.

1 I don't think personally that -- nor does my
2 group think that that's the best approach. And if
3 you're looking at mandating it down to unit dose or lot
4 number or expiration date, I can tell you that that
5 will require major packaging changes on the former and
6 major retooling, if it's going to be online lot number
7 and expiration printing through barcoding. And that is
8 a very long and length process.

9 With the question noted earlier, to what
10 extent does that really add to patient safety? And so
11 I would think there should be an evidence-based
12 approach there particularly.

13 Last comment, just to reiterate what I said to
14 Dr. Galson earlier: Looking at a repackaging and/or an
15 informational database solution on the OTC side is a
16 much nearer-term type of solution.

17 DR. BENDE: Yes. I mean, just to echo some of
18 the things that have been said, I think implementation
19 time comes after planning and agreement of standards
20 time. And I think we're just beginning the debate
21 about -- and the discussion about that, I hope, now and
22 such that we're hearing all these different

1 technologies aside from barcoding, such as, you know,
2 radio transmitters and what have you.

3 Hopefully, there will be a standardized data
4 format that they all read into, or there'll be some
5 goal that we can all agree upon that is best -- you
6 know, that our end user friends can tell us is going to
7 be the best for them to use, actually, and to actually
8 give a benefit.

9 So in terms of giving it a timetable, I think
10 the first order of business is to agree upon some
11 standards that all of the different technologies would
12 read into. So again, I think we're -- we need probably
13 some good time for planning.

14 You know, I've heard from one or more of our
15 member companies that we would hope that this wouldn't
16 turn into a situation as difficult as Part 11 has been.
17 So with that in mind, I think the planning and
18 agreement upon standards throughout the industry -- the
19 PhRMA companies, GPHA, CHPA, et cetera -- and I think
20 you heard from us that at least some of us have already
21 agreed to talk together, to work together, to move
22 toward that. So I think we're really at that stage

1 rather than the implementation stage.

2 MS. GREALEY: I just wanted to reinforce the
3 importance of the data elements that everyone has
4 touched on here. And we discussed it at length with
5 technical experts, again representing all the different
6 sectors of the healthcare industry, that if we can keep
7 it to the NDC, then we can move ahead and we can move
8 ahead a lot more quickly than if we do try to do
9 something that includes lot and expiration number
10 immediately; that right now, that that would so reduce
11 the productivity of the manufacturers because there
12 doesn't really exist equipment that would allow them to
13 verify and to package at a high rate at their current
14 rate of speed if you were to require that additional
15 information.

16 So it's going to be a constant balancing act.
17 How quickly do you want to move ahead? How costly do
18 you want it to be? How easy do we want it to be
19 implemented? And how much can we achieve in terms of
20 improving patient safety by limiting the data elements
21 that would be required?

22 And I don't think we should lose sight of what

1 is already occurring in the marketplace. The
2 marketplace is driving a lot of this as well. I think
3 you can help it along, but manufacturers and others are
4 stepping up because their customers are demanding that
5 they do it.

6 MS. GREGORY: I think from the blood banking
7 industry, we're a little ahead of everybody else.
8 We've clearly already identified all of the information
9 that we need to capture. We've even been capturing
10 some of it under Codabar. The problem is that that's
11 an outdated symbology and we need to move on to
12 something else.

13 I think for us, the real problem is cost, as
14 everybody has alluded to, but also competing
15 priorities, because what we will need to do is to
16 convert all of our software systems that we're
17 currently using so that we can utilize all these
18 elements most effectively.

19 And the issue is, okay, do we do that? Do we
20 do nucleic acid testing? Do we computerize donor
21 screening? Exactly which of the safety initiatives
22 that we're working on -- where does it fall in line?

1 And I think that's really our big issue.

2 And one of the things is because FDA hasn't
3 mandated it, it kind of falls way down here in
4 comparison to those things that FDA maybe has already
5 mandated.

6 MS. CAMMACK: I'd like to echo a number of the
7 comments that were made on the panel, but add to that
8 as well on the device side, for many of our
9 companies -- I think it's 75 percent of the industry
10 are representative of small companies. And they're not
11 going to have the resources that some of the larger
12 companies have. Maybe they haven't even, you know,
13 entered this arena yet.

14 So they're going to have significant startup
15 costs. So what one company is doing versus a larger
16 company, per se, they may be able to move on a faster
17 track. And it's hard to come up with one target date
18 for how implementation would happen.

19 Or even at a large company level, they may
20 have manufacturing production lines in different
21 countries. Technology used in one country may not be
22 the same as used in another to put the code on

1 something. And if they're having to update those or
2 change those, you know, they're going to be doubly
3 challenged to meet the requirements that would be set
4 forth.

5 So I think the voluntary process that we have
6 is moving forward, and it results in some of the best
7 decisions because it allows manufacturers to add coding
8 when it's responsive to customer needs. And often, it
9 can be done at a time when other labeling changes were
10 done as well, since you have to consider how this is
11 all going to fit on a label.

12 MS. MAHONEY: I have a question, Kay, for you.
13 The blood industry, as you said, has been using
14 barcoding for a while. And I wanted to know whether
15 you have a sense of how that had resulted in reduced
16 errors, and what you see if you think ISBT will result
17 in more reduction in errors, and why.

18 MS. GREGORY: I think that ISBT will result in
19 reduction of errors on what we call the manufacturing
20 side or the blood collection side. I'm not sure how it
21 will result in reduction of errors on the transfusion
22 side unless it is tied in to patient identification

1 systems.

2 We clearly want to go that direction, so that
3 you identify the patient. You identify the caregiver.
4 You identify the unit. And you notice, there are a
5 number of elements of information that need to be
6 tracked for a unit of blood that are somewhat different
7 from what you're talking about on your drugs. For
8 instance, I don't think the NDC code would do anything
9 for us because we can't get all of that information in
10 there.

11 I think one of the big issues may have to do
12 with something else that Dr. Feigal has talked about,
13 and that is tracking. Because one of the advantages of
14 ISBT-128 is that there is a unique identifier.

15 The way things work right now, I might have a
16 blood center, and I use identification code 12345 as
17 identification of a particular donor. Someone else may
18 have a collection center, and they're also using 12345.

19
20 So if I'm a hospital, I get 12345, and now I
21 have to make sure that I can track, well, exactly which
22 place sent me this. Well, this is all built into the

1 ISBT code, so that it can all be barcoded. And I think
2 the tracking will be much simpler for that reason.

3 MS. MAHONEY: And then just a question for
4 PhRMA and the generics industry. I think I heard
5 support for the concept of some sort of coding. And I
6 don't think I heard either of you distinguish between
7 the prescription drugs versus the OTC.

8 Do you have a difference of opinion with
9 regard to those products?

10 DR. JOHNSON: I think PhRMA's focus has been
11 on prescription medications and vaccines. There are
12 some questions about clinical supplies that may present
13 some special concerns. And we hadn't come to a
14 conclusion about samples, although we heard some
15 comments earlier today. So we did not focus on OTC
16 products.

17 MR. BENDE: Yes. We didn't really focus on
18 that, either. I mean, we're talking more specifically
19 about prescription drugs. And I would just like to
20 point out that Bill and I have spoken about this issue,
21 and some of our members are member companies that we
22 actually share member companies, a couple of them, you

1 know.

2 So it's an issue that -- but primarily, GPHA
3 is really more -- we're more focused on the
4 prescription drugs. But, you know, we haven't really
5 weighed in specifically on the OTC problem. But
6 clearly it's of interest to some of our members.

7 DR. SOLLER: We were unanimous in our view.

8 MR. BECKERMAN: I've got a question for
9 AdvaMed. Recognizing the diversity of medical device
10 manufacturers and knowing that you represent a very
11 broad range of them, does AdvaMed have a position on
12 combination devices, things that incorporate both drugs
13 and devices?

14 MS. CAMMACK: Well, I think we'd have to
15 follow how those are regulated by the Agency.

16 MR. BECKERMAN: And I guess, sort of to follow
17 up, a related question. There was some discussion this
18 morning about stratifying medical devices dealing with
19 different classes of devices in different ways. I
20 wanted to see if you would address that, whether you
21 view that as a workable solution.

22 MS. CAMMACK: I think that's an excellent

1 place to start when we talk more with stakeholders.
2 And probably the best way to begin stratifying that is
3 to go back to where are most medical errors occurring
4 and what role do medical devices play in those errors
5 then and is there a way then that barcoding could -- or
6 auto-identification could reduce those opportunities.

7 MS. DOTZEL: I just have one last question.
8 This morning we heard a lot, I think, from the health
9 professional panel -- a lot of, hurry up, FDA. We're
10 waiting for you to do this. You should have done this.
11 You know, get moving. Let's get this out there. And
12 this afternoon, I think we're hearing a little bit more
13 of, whoa, slow down. Create a task force. Study this
14 a little bit more.

15 Obviously, in a perfect world, we would be
16 able to, you know, bring in every piece of information
17 that's out there before we made any regulatory
18 decision. Obviously, if we waited for all that, we'd
19 never make a regulatory decision.

20 And so just your comments on how we kind of
21 balance the need for getting as much information as we
22 possibly can before making a decision on where to go on

1 this rule, with the need to actually do something to
2 address the problems that we're trying to address.

3 MS. GREALEY: I was struck by reading the
4 statements and listening this morning: I think there
5 is much more consensus here than perhaps was apparent
6 to you. They weren't saying, try to do everything all
7 at once.

8 I think they recognized a lot of what you
9 heard here this afternoon: NDC. Linear symbology.
10 It's something that is much more widespread. We could
11 do it now. Let's try and accomplish that.

12 And then, yes, you do need to bring in the
13 stakeholders for some of these other issues that I
14 think everyone on both panels sort of admitted: You
15 know, we're not quite sure how we could do it on
16 smaller vials, ampules, those sorts of things. How do
17 we work in lot and expiration number?

18 I think everyone has had more time since the
19 initial notice had been produced to really look into
20 this, bring their technical experts in. But I think
21 there is a lot of consensus around there are some
22 things that we could do in the near time. And then,

1 yes, let's be firm about establishing a timeline for
2 accomplishing the others, not let it go by the wayside.

3 DR. BENDE: I think I would tend to agree with
4 that. But I think it doesn't benefit anyone to move
5 forward too quickly when we hear our friends from the
6 hospital association say, for example, that -- you
7 know, I don't think they want to have to juggle six
8 different kinds of scanners because there are six
9 different kinds of technologies that people could use
10 to code product.

11 So we really have to start there and say, can
12 we standardize in some way? Can we make this as
13 streamlined as possible to benefit the manufacturers as
14 well, so that there's one -- you know, there's one
15 standard data readout, and give the hospitals and the
16 end users ballpark what they have to -- you know,
17 ballpark a little bit better so they can predict what
18 their users are going to need and they'll have to
19 purchase for them.

20 So I would even say that just the NDC number
21 probably isn't just something we could do, you know, in
22 a couple of months or something like that because there

1 is no standard. I mean, what kind of data -- we heard
2 ideas from Dr. Combes, I believe, about how this could
3 read into a -- this is part of a data issue.

4 So what database, what formats is this going
5 to be going into? Can the hospitals and all the
6 providers agree on a format that it reads into, so that
7 we can get this settled at the beginning, and then we
8 don't have manufacturers having to make changes, you
9 know, in six months for NDC numbers and then in two
10 years for everything else, and they wind up having to
11 implement multiple systems.

12 So I think to do this right for patients,
13 even, it needs to be thought out beforehand, before we
14 even say, well, let's do NDC numbers and worry about
15 everything else. I think we need to start from the
16 beginning and really map this out.

17 MS. CAMMACK: I think for the device industry,
18 we see ourselves as being a very distinct position from
19 drugs and biologics, so much so that I think, when you
20 look at how coding can help improve patient safety, it
21 seems to be a lot more obvious on the drugs and
22 biologics side than it is on the device side.

1 And we feel that there could be some
2 inadvertent or unintended consequences if medical
3 devices were at this time hurried up or rushed into a
4 bill that is really more appropriately addressing drugs
5 and biologics.

6 I think the kind of discussion that's happened
7 today, we could have a full day -- a week-long meeting
8 alone just on devices. I think there are some unique
9 issues there that have to be teased out on a product-
10 by-product category basis.

11 And to suggest that this is -- the time is
12 right to include devices in this forthcoming rule with
13 drugs and biologics, we just think that that's a
14 premature decision. And we may not reap the intended
15 benefits if we progress at that pace.

16 DR. SOLLER: From CHPA's standpoint, I think
17 the meeting has been very helpful in terms of enhancing
18 awareness, and certainly in terms of a coalition of
19 expertise within the industry and beginning that
20 process. I think that is a positive outcome of
21 scheduling this meeting, and clearly, the definition of
22 the issues and where the various stakeholders are in

1 terms of their staked-out positions, in a sense.

2 My view is that there is -- you know, in the
3 discussions to date here, that there is a pretty good
4 consensus of what the end game here is. And I like the
5 terminology that Tess brought in here of automated
6 identification because it implies the need for
7 flexibility and it implies the need to be aware of
8 technological advances.

9 So therefore, scope and extent become very
10 important issues. I'm not telling you anything you
11 don't already know. But probably here an incremental
12 advance is probably best. It allows a measured
13 business response. It allows the advance of
14 technology. And it most certainly allows the evolving
15 market forces to push all of that along and push it on
16 a lot faster.

17 MS. GREGORY: I would just like to caution
18 about the dangers of inactivity and not doing anything.
19 I think that that's what happened to the blood bank
20 industry, is that, you know, we've been kind of going
21 along and we've identified this and we've identified
22 that, you know.

1 But we haven't really laid out a clear road
2 map, and particularly FDA hasn't laid out clear road
3 map, of we really want you to do this. So
4 consequently, we just sort of keep on, and everybody
5 says to me, well, maybe there will be something better
6 down the road that we should adopt, so let's wait a
7 little while. And consequently, we're still using a
8 barcode from the 1980s, and you can imagine -- you
9 know, if you were using anything else from the 1980s,
10 you can imagine how things have advanced since then.

11 So I think the idea of planning and figuring
12 out what you want to do is very important. But I think
13 having a road map and some sort of target dates is
14 equally important.

15 DR. SOLLER: Could I make one comment here?
16 And this is with sincere, all due respect to the
17 representative from the blood supply industry. And
18 I've benefitted from that.

19 But we heard of a barcode in the 1980s being
20 applied in this comment just now. And I think that's a
21 perspective here. To look on one industry that has
22 done a great job, worked decades to get a process that

1 is pretty close to being in place is a lesson relative
2 to other industries that might be affected by
3 barcoding, and how fast you move, and whether you move
4 to expect a full system or whether you move
5 incrementally, as I mentioned earlier, to allow market
6 forces in this American industry to do some good as
7 well.

8 DR. JOHNSON: I would certainly repeat many of
9 the things I've heard. I think we would all urge
10 action as quickly as possible. But I hope that we've
11 also expressed that there are things that can be done
12 in the nearer term, and things that there need to be
13 more discussion before a reasonable timeline could be
14 agreed upon.

15 So, you know, that's probably as clear as we
16 can be. We could say we would like to have serial
17 number identification on every unit, but that's not
18 very feasible.

19 MS. GIESER: Have any of your members provided
20 you any information about ballpark cost estimates,
21 assuming the simpler case of some unique identifying
22 number being placed on the product?

1 And I know you've mentioned a couple of
2 conditions where the costs become quite high, such as
3 verification or high-speed production and certain
4 package sizes. If you can elaborate in any way on
5 issues of cost, we'd appreciate it.

6 DR. JOHNSON: Are you talking about situations
7 where it would be NDC number only?

8 MS. GIESER: Just to start with the simple
9 case.

10 DR. JOHNSON: I can tell you, because Abbott
11 Laboratories did make a public announcement about this
12 yesterday, so for injectables, we're actively working
13 on implementing barcodes. And we are absorbing those
14 costs. So we're not changing the cost of any of our
15 products.

16 So again, that also feeds into timing. If you
17 do it as a phase-in, it's going to have less of a cost
18 impact. If you require changing all of your labels in
19 a very short period of time, costs can be quite
20 dramatic.

21 But there are always label changes going on.
22 It's how many more are you trying to do in a certain

1 period of time?

2 DR. SOLLER: My experience in doing economic
3 estimates with our members is that it's probably always
4 best to wait till the comment period. Then you know
5 the numbers are there and not provide numbers that may
6 change over time. So undoubtedly, as you're asking
7 this, various groups will be looking at that particular
8 issue.

9 But just a comment, and that is that as a
10 company might move forward and essentially represent
11 the prototype and be willing to absorb costs, I can
12 tell you from looking at all different size companies
13 that that is not necessarily how the production world
14 works, and that ultimately it is transferred out.

15 We don't have specific figures for that, but I
16 think that would be true as well for an institution
17 that might use a repackager, that the end user and the
18 end benefit of that repackaging process is the patient
19 in the institution as it would relate to an OTC, for
20 example.

21 And if that were passed on in that context for
22 whatever the nominal cost would be, spread out over a

1 large purchase, again, it's targeted towards the end
2 user, the end benefitter, of that particular
3 repackaging, as opposed to across the entire gamut of
4 the industry where a large part of our end user would
5 not benefit necessarily from that.

6 MS. CAMMACK: And none of our members have
7 provided cost estimates to us at this time. I do know
8 that there are some members that are preparing written
9 responses to FDA as a result of the Federal Register
10 questions, and you should be getting those within the
11 time period.

12 But I would caution, too, even those that are
13 able to provide cost estimates, when they do it on a
14 product-category-by-product-category basis, what one
15 company may experience or anticipate for costs may be
16 very different from another company putting codes on
17 those very same products.

18 It has to do with the way their particular
19 production line is run, their volume, and where they're
20 located. So there is extreme diversity, not only
21 throughout the industry because of the diversity of the
22 device products, but also because of the company size.

1 So you'll see it from product to product.

2 MS. GREALEY: And I think it's been made clear
3 that you really need to draw the distinction between a
4 more simple versus a more complex data requirement,
5 especially what it could do in terms of reducing the
6 speed of manufacturing and the production line.

7 So that definitely would be a much more
8 significant cost. And again, I'm not even sure that
9 the technology is available to do it in a high-speed
10 way if you were willing to make the investment to do
11 that.

12 MR. BECKERMAN: Just quickly, I was wondering
13 whether any of the industry groups have data on hand
14 about what percentage of products are currently
15 packaged in individual unit dose packages. Or, I
16 guess, a related question: What percentage of
17 products, in a big macro view, are sent to repackagers?

18 And if you don't have that sort of information
19 readily at hand, I'd encourage you to submit it to the
20 docket.

21 MS. GREALEY: The one statistic we can provide
22 is, I think, right now 35 percent of the pharmaceutical

1 products are at the unit dose level.

2 MS. DOTZEL: Okay. I'm afraid we're not going
3 to have time to take questions from the audience for
4 this panel. What I'd ask the panel members to do is if
5 you could, you know, take seats up front, and then at
6 the end of our next session, if we have additional
7 time, we'll give people the opportunity to ask those
8 questions.

9 We're going to take a break now. People who
10 have registered to speak this afternoon, if you could
11 during the break please see Mary Gross. Mary, if you
12 would stand up so people who could see who you are.
13 And she will try to get things organized so that we can
14 move through this afternoon, the second part of this
15 afternoon, quickly so that everyone will have
16 sufficient time to speak.

17 We'll reconvene in ten minutes.

18 (A brief recess was taken.)

19 MS. DOTZEL: I'd like to ask everyone to start
20 taking their seats so we can get started.

21 Okay. We're going to get started. First I'd
22 like to introduce one new member to the FDA panel.

1 Dr. Galson had to leave, and we're delighted to have
2 Paul Seligman here. He's the director in our Office of
3 Pharmacoepidemiology and Statistical Science in the
4 Center for Drugs.

5 This afternoon, for the second part of the
6 afternoon, we are going to hear from speakers who have
7 registered to present their views. The way we're going
8 to try to work this is we are going to ask -- we are
9 going to have people come up to the stage, six at a
10 time. We think it will be easier for you to hear them
11 if they're sitting up here than standing down at the
12 mikes. And so we're going to work it so that we come
13 up to the stage six at a time.

14 I'm going to ask the speakers to use the
15 microphones that are provided at the table. You'll
16 have to switch out there, probably two per microphone.
17 Clearly state your name so that we have that for the
18 record. And I'll let you go down the line, and then
19 we'll bring up the next panel.

20 We'll hold all questions until the end to see
21 that we have time to do it. And if time permits, we'll
22 provide an opportunity, first, for the FDA panel to ask

1 some questions of this afternoon's speakers, and then
2 if we have even more time than we anticipate, we'll be
3 able to turn to the audience.

4 So with that, I'm going to take a seat, and
5 we'll start -- oh, one other thing is, for the
6 speakers, I've turned the timer here so -- the lights
7 aren't on now, but you should be able to see the
8 lights. And it will give you, again, the yellow -- it
9 will turn yellow when you have a minute left so that
10 you can kind of have a warning that time is running
11 close.

12 And again, I'm going to try to keep things
13 moving so that everyone who is registered to speak will
14 have an opportunity to speak.

15 MR. DUNEHEW: Thank you. My name is Allen
16 Dunehew. I am the vice president of pharmacy at
17 AmeriNet GPOs, located in St. Louis. I'd like to thank
18 the FDA for the opportunity to come and participate in
19 this event.

20 It was an interesting discussion this morning
21 and this afternoon. Obviously, varying opinions
22 between the morning and the afternoon, but you can

1 probably understand where those come from based upon
2 the constituencies that each represents.

3 In terms of GPOs, we represent providers who
4 provide direct care. So I think it's important we have
5 large numbers of members, essentially in all practice
6 settings, whether that be physician offices, other non-
7 acute surgery centers, hospitals, whatever.

8 At AmeriNet specifically, we've just gone
9 through a competitive bid process, so I do have some
10 updated information to provide you in terms of the
11 number of products that are available in a barcode
12 fashion.

13 And we do have that data by NDC number,
14 actually, either available today or will be by the end
15 of next year. And I could share that at a later date.
16 We required manufacturers to respond to our bid with an
17 indication of whether or not those products are
18 barcoded or not.

19 To get into some general comments, I think
20 it's important to understand when we start to consider
21 regulation, and actually this afternoon's discussion
22 with the panel probably explains why we're here at this

1 point in terms of regulation, because we don't have a
2 uniform system yet and wide availability of products
3 yet.

4 There were some discussions about what comes
5 first. It's kind of like the chicken or the egg. If
6 the hospitals are not going to invest money into
7 expensive systems if the products aren't there, and
8 they can't afford to do that themselves, the other side
9 of it is true that there has to be products -- there
10 has to be a market for those.

11 And it's interesting that some of our members
12 even indicated that they would be willing to pay a
13 slight upcharge for that availability because they
14 recognize the significant savings and the improvement
15 in patient care that can come as a result of that.

16 Some of the discussion about device versus
17 medication, NDC versus lot number and expiration date,
18 meds used at the bedside versus those that aren't used
19 at the bedside, I would just encourage you to take into
20 consideration we are here primarily because of patient
21 safety.

22 And so when you think about a long-term