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DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH ADMINISTRATION
FOOD AND DRUG ADMINISTRATION

GENERAL HOSPITAL & PERSONAL USE DEVICES PANEL

OPEN SESSION

Monday, August 2, 1999

8:43 a.m.

Food and Drug Administration
9200 Corporate Boulevard, Room 020B
Rockville, Maryland

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

2 WELCOME AND INTRODUCTORY REMARKS

3 MS. O'LONE: Good morning. Welcome to the General
4 Hospital and Personal Use Devices Panel for the open
5 session. Thank you for coming. If you have not signed in
6 for this meeting, please do so.

7 I am Martha O'Lone, the executive secretary of the
8 General Hospital and Personal Use Devices Advisory Panel.
9 And before we have panel introductions and turn this portion
10 of the meeting over to the panel, I have two items of
11 business that I have to read into the record.

12 The first is a conflict of interest statement. It
13 goes like this. The following announcement addresses
14 conflict of interest issues associated with this meeting and
15 is made part of the record, to preclude even the appearance
16 of any impropriety. To determine if any conflict existed,
17 the agency reviewed the submitted agenda and all financial
18 interests were reported by the panel participants.

19 The conflict of interest statutes prohibit special
20 government employees from participating in matters that
21 could affect their or their employer's financial interests.
22 However, the agency has determined that participation of
23 certain members and consultants, the need for whose services
24 out-weighs the potential conflict of interest involved, is
25 in the best interest of the government.

1 Full waivers have been granted for Dr. William
2 Rutala and Ms. Marcia Ryder for their interest in firms that
3 could potentially be affected by the panel's decisions. The
4 waivers permit them to participate in all matters before the
5 panel. Copies of these waivers may be obtained from the
6 agency's Freedom of Information Office, Room 12A-15 of the
7 Parklawn Building.

8 In the event that the discussions involve any
9 other products or firms not already on the agenda for which
10 an FDA participant has a financial interest, the participant
11 should excuse him or herself from such involvement and their
12 exclusion will be noted for the record.

13 With respect to all other participants, we ask, in
14 the interest of fairness, that all persons making statements
15 or presentations disclose any current or previous financial
16 involvement with any firm whose products they may wish to
17 comment upon.

18 And the second item of business is appointment to
19 temporary voting status. Pursuant to the authority granted
20 under the Medical Devices Advisory Committee Charter dated
21 October 27, 1990, as amended on April 20, 1995 and October
22 10, 1997, I appoint the following person as a voting member
23 of the General Hospital and Personal Uses Devices Panel for
24 the duration of the panel meeting on August 2, 1999. In
25 addition, the following person will act as panel chair for

1 August 2, 1999, and that's Charles E. Edmiston, Ph.D.

2 For the record, this person is a special
3 government employee and is either a consultant to this panel
4 or consultant or voting member of another panel under the
5 Medical Devices Advisory Committee. He has undergone the
6 customary conflict of interest review. He has reviewed the
7 material to be considered at this meeting. And it's signed
8 David W. Feigal, Jr., M.D., director, Center for Devices and
9 Radiological Health on the 21st of July 1999.

10 And the only other piece of business is that the
11 future tentative date of this panel would be potentially
12 November 16 for this year. We don't have any other dates
13 set aside at this time as tentative dates. And to find out
14 if we're having upcoming meetings, the phone number of the
15 hotline is 800/741-8138 and the code is 12520. That helps
16 to get right to the General Hospital Panel to determine if
17 there are any new messages on that line.

18 I'll now turn the meeting over to Dr. Edmiston and
19 we will begin the open session of the 34th General Hospital
20 and Personal Use Devices Panel meeting at this time. I'll
21 introduce him. He is an associate professor of surgery at
22 the Medical College of Wisconsin and has been a consultant
23 to our panel for quite some time and thank you very much for
24 acting as chair today.

25 DR. EDMISTON: Thank you very much.

1 At this time I'd like the rest of the panel
2 members to introduce themselves, starting with my colleague
3 on my right.

4 DR. FOWLER: Dr. Joe Fowler, a dermatologist at
5 the University of Louisville, Louisville, Kentucky.

6 MS. RYDER: Marcia Ryder. I'm a nurse consultant
7 in vascular access and a doctoral candidate at the
8 University of California at San Francisco in the Department
9 of Physiological Nursing.

10 DR. RUTALA: Bill Rutala. I'm director of
11 hospital epidemiology, occupational health and safety at the
12 University of North Carolina Hospitals and professor in the
13 School of Medicine.

14 MR. PALOMARES: Salvadore Palomares, manager of
15 regulatory affairs at ICU Medical.

16 MR. DACEY: Robert Dacey, consumer representative
17 from Boulder and Longmont, Colorado.

18 MR. ULATOWSKI: Tim Ulatowski, director of
19 Division of Dental, Infection Control and General Hospital
20 Devices, FDA.

21 DR. EDMISTON: Thank you very much.

22 Now at this time I'd like to invite Mr. Larry
23 Kessler from the FDA to give us an update in postmarketing
24 surveillance.

25 POST MARKET SURVEILLANCE

1 MR. KESSLER: Good morning. I want to thank Dr.
2 Edmiston and Martha O'Lone for having me here. Let me tell
3 you how this little presentation happened.

4 About two years ago Dr. Alper asked me, as the
5 director of the Office of Surveillance and Biometrics in the
6 Center for Devices and Radiological Health, to talk a little
7 about postmarket surveillance in front of a meeting of the
8 entire panel chairs in this very room. At the end of that
9 meeting, the panel chairs asked that we give such
10 presentations to all the panels, to give you our perspective
11 on postmarket surveillance, because you will see postmarket
12 surveillance issues from time to time, even in your
13 premarket review.

14 I'm going to give you our perspective on how these
15 relate to some of the work that we think you can play a very
16 important role in helping us with the FDA mission.

17 In the next 10 to 15 minutes I'll describe a few
18 methods of device postmarket evaluation at the Center,
19 present challenges in accomplishing postmarket evaluation,
20 and describe the pivotal role that advisory panels can play
21 in postmarket evaluation of medical products.

22 This schematic is a fairly brief overview of the
23 way in which we generally perceive our overall role at FDA.
24 From the left-hand side of the chart here--this is a time
25 chart basically--design modification happened basically at

1 industry and with the clinical community and patients
2 telling industry what new products they need, what clinical
3 needs need to be met.

4 FDA gets more and more involved as we travel from
5 design modification through testing and clinical testing to
6 review. On the right-hand side of the chart you'll see,
7 under the postmarket evaluation part of this, at least five
8 different mechanisms we have at our disposal to help
9 evaluate and monitor products as they live and breathe on
10 the market. We have the Medical Device Reporting Program
11 and two postmarket surveillance authorities--Section 522 in
12 the postapproval or PMA authority. I'll talk about these
13 three in some detail.

14 I won't today, because of time, talk about our
15 epidemiology program or the large field inspection force we
16 have running out of ORA with our contacts through the Office
17 of Compliance, but they are a very critical part of
18 postmarket evaluation. I just won't get to talk about them
19 today.

20 While we're doing review and after we do
21 postmarket evaluation, the FDA should have constant contact
22 with the clinical community to find out what's going on and
23 to communicate our findings and problems, something we need
24 to improve on. One of the ways in which we do contact the
25 clinical community is our contact with advisory panels, and

1 I'll say a little bit about how postmarket evaluation and
2 advisory panel work should meet.

3 Well, why bother with any of this at all? Well,
4 because there are a series of questions that we find often
5 need to be asked in the postmarket period. First and most
6 obvious is long-term safety. A number of products that
7 reach the market do so on the basis of fairly modest or
8 short-term studies. Rather than wait for long-term studies
9 to prove complete safety or effectiveness, some products
10 will make it to the market where we will not have complete
11 long-term data.

12 This may be particularly true in terms of
13 long-term implantables, where we would hesitate to wait,
14 say, 10 years, which is what we might want to see for
15 certain kinds of implantable performance, and we don't want
16 to do clinical trials that last for 10 years, so we'll let
17 something on the market based on a shorter period of time
18 data and then look at it later.

19 Other important questions come up often in the
20 postmarket period. For example, performance of device in
21 community practice. Often you will see products for review
22 that are done in carefully designed clinical trials but
23 products then move to community practice and we won't see
24 the same effects and we will often see different patterns of
25 adverse events that you will see in the premarket review.

1 Sometimes effects of changes in user setting are
2 important in product evaluation. For example, a larger
3 number of products than ever before are leaving the hospital
4 doors and winding up in out-patient clinics and at the
5 bedside at home. Some of those products need professional
6 training to be used properly and we get adverse events on a
7 daily basis that show serious injuries, illness and death
8 from products that went from the hospital to home either
9 without adequate training or labeling or other kinds of
10 problems that can be sometimes avoided.

11 I'll talk for just a minute about the Medical
12 Device Reporting Program because a number of people who know
13 a bit about FDA and postmarket evaluation think MDR is where
14 our postmarket evaluation begins and ends, and that's not
15 the case at all but it is one of our most important
16 programs.

17 Since 1984, manufacturers must by law report
18 deaths and serious injuries as well as malfunctions or near
19 incidents to FDA. Since 1990 with the Safe Medical Devices
20 Act, all user facilities--every hospital, nursing home,
21 ambulance, surgi-center--must report deaths to the FDA and
22 serious injuries to manufacturers.

23 Unfortunately, the User Facility Reporting Program
24 in the country does not work nearly as well as it should.
25 The number of reports we get per year from manufacturers is

1 roughly in the 80,000 to 100,000 range and only 5 percent of
2 those reports of our total MDR system come from user
3 facilities.

4 Beginning about 1992 we were receiving over
5 100,000 reports of adverse events each year. Information
6 should include device specifics--the event description,
7 event date, patient characteristics--with which we could see
8 if there's a potential problem that needs rectifying in the
9 postmarket period. Unfortunately, reporting in the MDR
10 program is often very limited--limited information. It
11 sometimes provides critical signals to FDA but sometimes we
12 miss things because the information is poor.

13 Part of this comes from the unfortunate litigious
14 environment that we all practice in. Often we'll hear
15 manufacturers around this room tell you the reason our data
16 are limited is when they call a hospital after a hospital
17 has told them that their device may be involved in a death
18 or serious injury, the hospital will say, "That's all I can
19 tell you. My lawyers tell me to give you no other
20 information."

21 Part of this has to do with the vast number of
22 reports which are associated with use error, and hospitals
23 are nervous about reporting out of their facility problems
24 where their users may not have read the instructions, may
25 not have followed the instructions so carefully or chosen to

1 use products in ways that the manufacturer did not initially
2 intend.

3 But we do get a lot of mileage out of the 100,000
4 reports we get per year and here are some examples of things
5 that reflect adverse event reports and actions taken
6 prompted by the MDR program, related to products that
7 involve this panel.

8 For example, we get directed inspections of a
9 manufacturer this year for blood leukocyte filters and
10 hypotension and released a public health advisory related to
11 leukocyte filtration.

12 We've done product recalls in the past few years.
13 In fact, one explosion of an infusion pump puzzled one of
14 our analysts. We had outstanding collaboration from our
15 Office of Science and Technology staff, who looked into the
16 problem with us, and eventually convinced the manufacturer
17 to do massive, 15,000 pump recall and reservicing.

18 In the recent past infusion pumps have presented a
19 lot of problems with free flow and we put out patient
20 notifications about this problem. This problem continues
21 with a lot of pumps and we do all we can to try to minimize
22 the problems that we see in free flow with infusion pumps,
23 but it's a constant problem.

24 I want to talk for just a couple of minutes about
25 these two authorities because this is where you as panel

1 members can be most influential and helpful to the FDA.

2 Postmarket study authorities--there are two of
3 them that we can invoke. One is postmarket surveillance
4 Section 522 and the other is the Postapproval authority.
5 Section 522 was originally mandated in SMDA '90 and changed
6 in FDAMA '97. And the changes were to reduce some of the
7 scope of the original 522 act.

8 Postapproval refers to PMA products only and is
9 also sometimes called condition of approval studies.
10 Section 522 covers only Class II or III products whose
11 failure may present a public health problem. The language
12 in the statute is more specific but this is the basic
13 essence of that language.

14 We see both authorities as a complement to the
15 premarket role of the FDA and the role that you play.

16 The criteria that we use for postmarket
17 surveillance study in the requirements for manufacturers are
18 whether we can figure out what the critical public health
19 question is, and it can result from for-cause situations,
20 new or expanded conditions of use or other reasons. We have
21 to consider whether other post-market strategies, such as
22 the MDR program, give us enough information without
23 requiring manufacturers to do additional study on their
24 product in the postmarket period. And we have to consider
25 practicality and feasibility of the conduct of studies.

1 We also try to figure out how will the data be
2 used? And I'll come to that in just a minute.

3 Postmarket surveillance studies have a wide
4 variety of approaches. Our early foray into postmarket,
5 earlier in this decade, was heavily weighted toward studies
6 at the bottom end of the more rigorous type--randomized
7 trials or case control studies. However, recent guidance
8 that we've published this year on postmarket surveillance
9 studies suggests that we will be expanding the kind of
10 approach that we would require manufacturers to apply,
11 including detailed review of complaint history or the
12 literature or nonclinical testing of the device, to help us
13 resolve potential postmarket problems.

14 But postmarket studies are challenging. First of
15 all, the rapid evolution of technology makes studies
16 obsolete. It is indeed wonderful that the medical device
17 community revises their products on almost a weekly basis
18 but it makes a postmarket study a particular challenge
19 because by the time a study protocol is approved, fielded,
20 data are collected and analyzed, it is often the case that
21 the product is no longer marketed. So is it still relevant?
22 It makes it a challenge.

23 Second, in truth, there's a lack of incentives for
24 the industry. It is a rare situation where a postmarket
25 study is going to give great good news to a company, so

1 they're not excited about doing these, frankly.

2 There's also a lack of interest in the clinical
3 community. Very few postmarket studies are sexy enough to
4 be publishable, like the premarket stuff with the hot new
5 technologies. So that presents a big challenge.

6 But by far we think the biggest challenge that we
7 have faced, both in postapproval studies and in Section 522,
8 is a lack of a clearly specified public health question.
9 What are we going to do with the data once it arrives? Are
10 you going to suggest a relabeling? Are you going to suggest
11 expanded or restricted indications for use? Would you
12 consider advising us of a product recall?

13 If one of those actions doesn't occur to you and
14 you're just interested in the question, then it probably
15 isn't a good candidate for a postapproval or postmarket
16 study. But if you can help us with a clearly specified
17 public health question and what you think you might do with
18 the answer to that question, it'll help us formulate the
19 appropriate protocol and hold the manufacturer responsible
20 to conduct that protocol and bring results here back to the
21 panel, which we rarely have done.

22 So that's my challenge for you. When considering
23 a postmarket study, whether postapproval or 522, and that's
24 an issue that we can work out at FDA and you needn't be
25 concerned with, please ensure that the question you're

1 asking is of primary importance, help specify that question
2 and note the clinical or regulatory relevance of answering
3 the question. What will we do with the data? That'll help
4 us formulate the question; it'll motivate the company; it'll
5 motivate the clinical community to contribute data,
6 answering the question; it'll help us address potentially
7 important postmarket surveillance problems.

8 The 100,000 events that we get every year
9 represent thousands of deaths and scores of thousands of
10 serious injuries that occur because of medical devices
11 sometimes being used improperly, being handled improperly or
12 sometimes failing. Our job is to try and minimize that and
13 we hope you'll help us in that mission.

14 Thank you very much. I'd be glad to take any
15 questions.

16 DR. EDMISTON: I think in the interest of time,
17 we're going to move on. Thank you very much, Mr. Kessler.

18 Our next presenter will be Mr. Charles Ho, who
19 will give us a presentation on Y2K.

20 Y2K INFORMATION

21 MR. HO: Good morning. I'm Charles Ho. It is my
22 honor to be here to talk before the General Hospital and
23 Personal Use Devices Panel to discuss with you the year 2000
24 problem.

25 Yes, medical devices are subject to the year 2000

1 problem. Susceptible devices can be found in the
2 microprocessor or PC-controlled products, software
3 applications, device interfaces to databases and
4 recordkeeping systems and also in embedded chips for date
5 display or recording.

6 What is the year 2000 problem? It's the failure
7 of a computer system to properly process a display face due
8 to representing the year using only two digits or other
9 date-related problems, such as failure to recognize the leap
10 year. For example, list of confusion between the 2000 and
11 1900.

12 An example of a year 2000 failure. A chemical in
13 a clinical laboratory test has an expiration date in the
14 year 2000. However, the testing device reads this date as a
15 in the year 1900 and did not allow the test to proceed,
16 since the testing device thought the chemical was out of
17 date.

18 So how do we define the year 2000 compliance? For
19 the purpose of a database, year 2000 compliant means, with
20 respect to medical devices and scientific laboratory
21 equipment, that the product accurately processes and stores
22 date/time data, including but not limited to calculating,
23 comparing, displaying, recording and sequencing operations
24 involving date/time data during, from, into and between the
25 20th and 21st centuries and the years 1999 and 2000,

1 including correct processing of leap year data.

2 So what is the FDA requesting of the panel?

3 Please provide us with advice regarding problematic devices
4 from the panel's domain of expertise. Please identify types
5 of devices which because of their use of dates, could
6 present risks to patients if not addressed. Please provide
7 suggestions to CDRH regarding actions to reduce risks from
8 year 2000 problems.

9 What has the FDA done regarding the year 2000
10 problem? Since 1996 we have made internal assessments of
11 potential impact and vulnerable devices. In June 1997 we
12 sent a notification letter to manufacturers to advise them
13 of the problem. FDA will address the year 2000 problem in
14 premarket reviews. New submissions are not required for
15 repairs which are only date-related. Repairs/updates before
16 impact will not be classified as recalls.

17 In addition, we are also participating in the
18 Biomedical Equipment Working Group. This is a group of
19 federal users of devices and scientific equipment. The work
20 group is chaired by the Department of Health and Human
21 Services. We send a consolidated request for information in
22 January 1998. We think that the public and the private
23 health care organizations have the same information needs.

24 We established a website in the spring of 1998.
25 We sent out a guidance on FDA expectations in June of 1998.

1 The address of the FDA product database can be
2 found at www.fda.gov. Please select the year 2000 item.

3 The Biomedical Equipment Database. This is an
4 FDA-operated World Wide Website. The data are provided
5 voluntarily by the manufacturers. It is a certification by
6 the manufacturers. The data are continually updated,
7 searchable and downloadable.

8 What does the project database show us? Well,
9 many companies have not yet reported. Presumably
10 assessments are still in progress. Most noncompliant
11 products involve date display or date recordings. They
12 usually record date-stamping.

13 A limited number of products have significant
14 operational problems, such as the problem of the expiration
15 date that I talked to you about. PC-based problems and
16 PC-type problems, such as recording and date-stamping.

17 Manufacturers are providing a number of solutions,
18 such as software upgrade, patches or complete replacements.

19 Major additional letters to manufacturers. In
20 January 21, 1998 we sent out a letter on the year 2000
21 impact on biomedical equipment. This was followed by the
22 June 29 and September 2, 1998 letters. Then September 21,
23 1998 we sent a letter on manufacturing process concerns.
24 May 26, 1999 we sent a guidance on MDR reporting. June 18,
25 1999 we sent out a year 2000 readiness survey.

1 Major additional communications to health
2 facilities and consumers. December 29, 1998 we sent a
3 letter on computer date problems on medical devices on
4 January 1, 1999. This is about the rollover from 1998 to
5 1999. May 26, 1999 we sent a guidance on MDR reporting.
6 And most recently, on July 16, 1999 we sent out a Y2K
7 planning.

8 The future CDRH/FDA activities. We have already
9 established a Biomedical Equipment Clearinghouse. We are
10 expanding the database to include complaint as well as
11 noncompliant devices. We are continuing to do outreach
12 communications with industry, clinicians and consumers. We
13 are pursuing rigorous action on products which present
14 significant risk. We increased inspectional emphasis on
15 Y2K.

16 Health care facilities. We recommend that health
17 care facilities do the following. Inventory and assess
18 devices used; obtain information on device status; test
19 devices for Y2K compliance; check interconnected or
20 networked devices; check device information system
21 connections; plan for or develop workarounds, upgrades or
22 replacements; and finally, develop contingency plans.

23 If you have any comment, please give your comments
24 to the panel executive secretary or to Dr. Tom Shope at the
25 address listed. You can also send comments to him via

1 e-mail at Tbs@cdrh.fda.gov.

2 DR. EDMISTON: Thank you very much, Mr. Ho.

3 At this time we'll move into the main
4 presentations but before we do that from the FDA I'd like to
5 make a statement.

6 The charges of this panel today are twofold. This
7 morning we're going to discuss guidance for review of
8 needleless systems and this afternoon we're going to discuss
9 and make recommendations to the FDA for guidance in the
10 development of jet injectors. That will be the focus of
11 today's presentations. We will try to keep on task and try
12 and keep on time. These are two extremely important areas
13 that need to be discussed.

14 I also want to point out again that anyone who
15 comes to the podium, please speak directly into the
16 microphone. Identify yourself and your affiliation.

17 For those members in the audience, representatives
18 from industry and from private organizations, we would like
19 you to state not only your name and affiliation but we wish
20 you would also state what, if any, financial interest you
21 may have in the medical device industries.

22 At this time I would like to ask Mr. Tim
23 Ulatowski, the division director for Dental, Infection
24 Control and General Hospital and Personal Use Devices, to
25 provide an overview of this morning's topic.

1 **ISSUE: GUIDANCE FOR REVIEW OF**

2 **PROTECTED SHARPS SYSTEMS**

3 **FDA PRESENTATION**

4 MR. ULATOWSKI: Thank you, Mr. Chairman, and
5 welcome to the panel. Thank you for taking the time out of
6 your busy schedules to come in and have this discussion with
7 us today about these important devices.

8 There's somewhat of a misnomer in the agenda this
9 morning. We're discussing protected sharps devices, not
10 needleless systems per se.

11 But at any rate, today's discussion is a somewhat
12 different panel session for a panel session. Usually we
13 discuss premarket submissions, premarket approval
14 applications, investigational applications in closed session
15 or sometimes premarket notifications, so-called 510(k)s.
16 But today we're having a discussion about guidance
17 documents, either current ones or future ones, and there
18 will be no voting today, as there usually is when we talk
19 about a premarket submission.

20 We are talking about different devices from the
21 morning to the afternoon, somewhat different--protected
22 sharps devices in the morning and jet injectors in the
23 afternoon. Certainly they're somewhat different but they're
24 related in terms of the problems they're trying to address.

25 In the morning session we are revisiting our 1996

1 guidance on protected sharps and what we intend to do is to
2 update the guidance based upon your comments and post it
3 under our new good guidance practice procedure, which came
4 into effect a couple of years ago.

5 Now we're not here to discuss worker safety policy
6 or current events that are driving an interest in protected
7 sharps per se. That's certainly an important issue. We're
8 here to talk about a guidance document and how to update
9 that guidance document to the benefit of the agency.

10 This guidance we're talking about does not address
11 some devices that fall under the aspect of worker
12 protection, sharps containers and some other devices. We
13 are talking about primarily protected syringe devices, but
14 there are many other devices that come under the purview of
15 our guidance that we'll be discussing today.

16 As I was considering having this as a discussion
17 item, I think one of my concerns, my critical concerns was
18 as we move forward with clearing products, as FDA moves
19 forward and people are relying upon our clearances across
20 the country, we want to make our evaluations of these
21 devices certainly up to date and pertinent, relevant to
22 what's going on today in terms of what people think we ought
23 to be doing in terms of product evaluations.

24 I think some people out there think we get
25 products and we're fidgeting with them and testing them on

1 ourselves, trying to stick ourselves and what-not. We don't
2 really do that. We do get samples and we do fiddle with
3 them, as we are engineers and nurses and what-not and
4 physicians, and we love to fiddle with things, but primarily
5 our focus is upon the documentation contained in the
6 documents and the testing that's done by the manufacturers
7 or the people they bring in to evaluate the products or to
8 whom they send products for evaluation.

9 I'm primarily concerned about the clinical survey
10 aspect in our guidance document as we discuss things this
11 morning. I know that there's various organizations and
12 institutions who have their own surveys for their purchasing
13 purposes or whatever, and each has its own scheme of
14 questions and answers and approaches and how many products
15 are tested and what controls are run.

16 I think there's a place for everyone doing their
17 own thing to a certain extent but as far as FDA's purposes,
18 I want to try and reconcile some of those differences in
19 approaches and see where we need to be doing perhaps a more
20 comprehensive job in some cases and where we can leave some
21 other evaluations as people feel it's necessary in their own
22 institutions.

23 So that's my reflections today and Irene Naveau is
24 going to bring us up to date in a little more detail on the
25 guidance document.

1 DR. EDMISTON: While we're waiting let me ask Mr.
2 Ulatowski one question. Do you prefer that in the course of
3 this morning that when we refer to these systems we refer to
4 them as protected sharps systems? Would you prefer that?

5 MR. ULATOWSKI: I think that's more generally the
6 scope. There are some needleless or blunted needle-type
7 systems but more generally it's protected sharps.

8 DR. EDMISTON: Fine. Thank you.

9 MS. NAVEAU: Good morning. The guidance document
10 under discussion this morning is entitled Supplementary
11 Guidance on the Content of Premarket Notification
12 Submissions for Medical Devices with Sharps Injury
13 Prevention Features. The document is intended to assist
14 manufacturers, distributors or importers in preparing 510(k)
15 submissions for medical devices or accessories with sharps
16 injury prevention features, as well as to facilitate the
17 510(k) review in a consistent manner.

18 I plan to include in my discussion today a brief
19 background of the existing guidance document, as well as a
20 review of working definitions of those types of medical
21 devices to which this guidance document pertains. The
22 desirable performance characteristics of these devices will
23 be identified. Elements of the guidance document will be
24 addressed and then a brief summary.

25 Finally, I'd like to present a list of questions

1 that were previously submitted to the panel to review for
2 subsequent discussion and recommendation.

3 The earliest medical device with a sharps injury
4 prevention feature was reviewed in 1984 as an accessory to
5 an IV administration set. In 1985 a shielded syringe was
6 reviewed.

7 Since that time, the General Hospital Devices
8 Branch has reviewed over 225 sharps injury devices with
9 safety protective features, with the largest number of
10 devices reviewed in 1991 and 1992 and in 1996 and 1997.

11 It should be noted here that other divisions in
12 the Office of Device Evaluation also review various medical
13 devices with safety features. Therefore a comprehensive
14 list of these devices is not currently available.

15 In 1994 a supplementary guidance document, the
16 precursor of the guidance for review today, was presented to
17 panel. At the conclusion of that particular panel meeting,
18 we acknowledged the comments and recommendations of the
19 panel, as well as the public, specific to the performance
20 data section and sample size recommendations for studies
21 being conducted. The revised draft supplement guidance in
22 effect today has been used by the agency and industry since
23 March 1995.

24 The guidance document is used in our review for
25 various types of safety devices and include the blunt or

1 blunted needles of stainless steel or a plastic material,
2 the prepierced septum devices of various configurations,
3 reflux valves, which are sometimes referred to as
4 bidirectional valves, vial adapters, those devices that
5 provide needleless access to a drug vial for reconstituting
6 and withdrawing medication, retractable needles, shields and
7 guards associated with syringes, and recessed needles.

8 These devices are integral components of an
9 existing device or may be marketed alone. For example, a
10 reflux valve can be marketed alone for use as a heparin lock
11 type of device used in conjunction with an IV catheter, an
12 IV administration set or a syringe.

13 What are we talking about when we refer to devices
14 with safety features? There are any number of definitions
15 for devices with safety features but for our purposes today
16 I'd like to read two working definitions of these devices.

17 A medical device with a sharps injury prevention
18 feature is a device designed with a component or attachment,
19 either active or passive, that protects the user from a
20 sharps injury.

21 Sharps injury prevention features are found in
22 devices such as but not limited to piston syringes,
23 hypodermic single lumen needles, IV administration sets,
24 intravascular catheters, vacuum tube holders, as well as
25 blood collection devices.

1 These features can be a component of a finished
2 device, such as a sheathed or shielded syringe, while some
3 safety feature products are marketed separately as
4 accessories that are attached to devices by the user at the
5 time of use.

6 For regulatory purposes, accessories to a device
7 are classified in the same class as the devices to which
8 they are assembled.

9 The second definition: a needleless system is one
10 that provides repeated access to a patient's vascular system
11 without the use of sharps. Fluid flow through the system
12 may be unidirectional or bidirectional, with the latter
13 allowing the user to administer or withdraw fluids or
14 medications.

15 An example would be a prepierced septum and blunt
16 canula. With this type of septum, a blunt canula connected
17 to a syringe or secondary IV administration set can be
18 inserted into the prepierced septum on a Y site of an IV
19 administration set, an adaptor or other secondary IV or
20 extension set.

21 Another example is a valve connector, sometimes
22 referred to as a reflux valve. It prevents fluid flow
23 through the device in either direction when not activated.
24 However, when a male or mating lower connector is inserted
25 into the prepierced septum at the end of the valve's

1 housing, the valve is activated in various ways, depending
2 on the valve configuration. This activation opens the fluid
3 flow pathway for the infusion of IV solutions or medications
4 and for the withdrawal of blood samples.

5 In the next two slides I've listed a number of
6 desirable performance characteristics that we believe should
7 be considered by industry in conducting their simulated
8 clinical and actual clinical studies in the evaluation of
9 safety devices. Evaluation of these characteristics may
10 require actual use of the device and by targeting questions
11 to health care workers who may or may not have had any
12 experience with the device.

13 These characteristics can usually be assessed with
14 visual inspection of the device or by simple manipulation of
15 the mechanism and should include: hospital personnel are
16 shielded from the needle before, during and after disposal.
17 The protective mechanism can be used equally well,
18 regardless of hand preference or for hand size, for that
19 matter. If additional steps to the usual procedure are
20 necessary to activate the protective mechanism, they would
21 be few. And they do not interfere with the usual
22 nonprotected procedure.

23 It is not necessary for the user to place either
24 hand near the needle during a procedure and the hands should
25 remain behind the needle at all times.

1 In addition, the protective shield or retracted
2 needle reliably locks securely into place with little
3 effort. The protective mechanism is designed in such a way
4 that the user is always aware of its status; that is,
5 whether or not the device is engaged or locked into place.

6 The design of the protective mechanism allows
7 appropriate visualization during device use. The user is
8 not exposed to the needle during disassembly and the
9 mechanism is compatible with the sharps disposal system used
10 in the facility.

11 In September 1998 OSHA published a request for
12 comments from a number of health care organizations related
13 to occupational exposure to blood-borne pathogens due to
14 percutaneous injury. The FDA responded by submitting the
15 preceding list of desirable performance characteristics that
16 are found in the guidance document.

17 . Five similar performance characteristics were
18 listed in OSHA's recent executive summary as suggestions
19 from researchers for selecting safer medical devices.
20 However, it has not yet been determined how OSHA will
21 incorporate these suggestions in their revised standard.

22 This may be an opportunity for FDA to meet with
23 OSHA and consolidate recommendations regarding the
24 characteristics of devices with injury prevention features.

25 The performance characteristics on the previous

1 two slides are listed in this table. They were compared
2 with those characteristics outlined in the evaluation forms
3 the three other organizations use; that is, the Service
4 Employees International Union, the SEIU, from their guide In
5 Preventing Needle Stick Injuries in 1998; the New York State
6 Department of Health, the NYSDOH, from their study of needle
7 stick prevention devices in March of 1992; and the Training
8 for the Development of Innovative Control Technologies, the
9 TDICT, from their Safety Feature Evaluation Form found on
10 their website.

11 The results of this comparison indicate that
12 similar evaluations are being used by these organizations
13 and in most cases concur with our characteristics. For
14 instance, we all agree that the user should be protected
15 from needle stick injury before, during and after use, that
16 the safety feature may be activated with either hand, and
17 the user be able to visualize the fluid and the fluid level
18 during preparation and use.

19 We have included a statement indicating that the
20 device with safety features should be compatible with the
21 sharps disposal system in the facility. The statement may
22 be included in their evaluations, but it was not evident in
23 the material that I had access to.

24 The guidance document does not include a list of
25 targeted questions, as do these organizations, but it does

1 contain recommendations to industry regarding their report
2 forms that would include this information.

3 Apart from the section that addresses appropriate
4 device description and labeling, much of the guidance is
5 directed to device specification and performance test
6 specific to sharps injury prevention. What it does not
7 address are sharps containers which are addressed in their
8 own guidance document and needle recappers.

9 In essence, the guidance provides overview
10 information to applicants to aid in the analysis of
11 performance characteristics of these devices and contains
12 recommended types of tests that can be performed. Again
13 only recommendations are suggested to industry. Therefore
14 the document does contain a checklist or a to-do list for
15 manufacturers to follow.

16 In this document we refer to five main types of
17 performance testing for devices with sharps injury
18 prevention features. Those include bench testing,
19 biocompatibility data, preclinical, simulated clinical and
20 actual clinical studies.

21 The guidance also contains factors that should be
22 considered before conducting a simulated clinical or actual
23 clinical study; for example, how a device is equivalent to
24 other similar devices, and microbiological issues.

25 Typically, needleless systems present a

1 contamination concern addressed with simulated testing in a
2 microbial challenge test, whereas the sharps devices present
3 a needle stick concern addressed with simulated clinical and
4 actual clinical study data.

5 In summary, we have established that the 1994
6 revised draft guidance document has served as a working
7 document for FDA reviewers and industry alike for the past
8 five years. The document includes recommendations to
9 industry, especially related to design features and
10 performance characteristics that should be included in their
11 studies prior to 510(k) submission.

12 Several types of surveys are in progress by
13 industry during their preparation in introducing their
14 safety devices into the marketplace and by organizations
15 dedicated to the protection of health care workers and
16 others that use devices with protective features.

17 In light of public health issues that have arisen
18 and emerging new technology, we are revisiting our document.
19 We recognize that it may need revision for the following
20 reasons: for consistency in our reviews and to assist the
21 manufacturer in assembling scientific information,
22 especially microbiological and performance data to determine
23 substantial equivalence. There may be other areas in the
24 guidance, as well, which you may offer your suggestions for
25 change.

1 I'd like to read now the following questions that
2 were previously submitted to the panel. I understand that
3 the questions will then be considered separately for
4 discussion and recommendation.

5 Number one, "Our current guidance document allows
6 sponsors to perform either a simulated clinical use study or
7 an actual clinical use study to evaluate the performance of
8 the sharps injury prevention feature. In most cases,
9 sponsors have provided information from simulated clinical
10 studies. When would it be appropriate for FDA to consider
11 data from actual clinical use versus simulated clinical use?

12 "Are there minimum criteria in terms of sample
13 size, independence of the evaluators and number of sites
14 that FDA could consider for both the simulated clinical and
15 actual clinical use studies?

16 "In addition to the survey format, are there any
17 other methods that the FDA should consider when evaluating
18 the performance of these types of devices?

19 "Are the evaluation criteria listed in the
20 guidance document appropriate and inclusive?

21 "How could the results of these evaluations be
22 presented to users? Should the results be included in the
23 labeling?"

24 And two, "Currently sponsors submitting
25 applications for needleless access devices are asked to

1 demonstrate that their device is substantially equivalent by
2 providing nonclinical bench data to demonstrate that their
3 device does not increase the risk of microbial contamination
4 of the fluid pathway, validation of the cleaning method, and
5 instructions for use. What additional types of information
6 should be considered for our premarket review?"

7 Three, "What mechanism does the panel recommend to
8 the FDA to increase user awareness of the safe use of these
9 devices?"

10 And four, "Is there a need for educational
11 programs for the use of sharps injury prevention devices?
12 If so, what content should be included in the educational
13 programs to encourage the safe and effective use of these
14 devices?"

15 And five, "Are there other areas of the guidance
16 document that should be revised?" Thank you.

17 DR. EDMISTON: Thank you very much.

18 Do the members of the panel have any questions for
19 Ms. Naveau?

20 [No response.]

21 DR. EDMISTON: That being the case, I'd like to
22 invite to the podium Dr. Joseph, director of the Office of
23 Health and Industries Program at the FDA.

24 DR. JOSEPH: I'll say good morning while we get
25 ready and we appreciate your being here and thanks to the

1 division for including us today.

2 As was stated, I'm Dr. Joseph, the director of the
3 Office of Health and Industry Program in the Center. The
4 office has several activities in which we engage on behalf
5 of the Center, one of which is outreach and educational
6 activities.

7 What I'm going to talk about today is a little bit
8 about to put our educational activities in a context. I
9 think it's really important to briefly review what our
10 mandate is in terms of the FDA mandate relative to devices.
11 And because there are other sister agencies who also, as
12 Irene said, have an interest in this area, I thought we'd
13 briefly take a little snapshot of what OSHA's mandate is and
14 see how we can blend our activities and then get your advice
15 on that.

16 Okay. The mandate of the FDA in terms of medical
17 devices is to really focus on our regulatory activities on
18 the product features and product aspects, and that's again
19 to ensure the safety and effectiveness of those devices. So
20 we pretty much look at the labeling requirements, the
21 performance test methodology, good manufacturing practices
22 and quality systems.

23 Whereas the Occupational Safety and Health
24 Administration has a deep interest in sharps injury
25 prevention devices, as well, and from their mandate you can

1 see that they're tasked with ensuring that workplace
2 conditions are safe and healthful for employees, and they do
3 this by enforcing their standards developed under their act,
4 as well as collaborating with the states to ensure that
5 those conditions are met and providing research,
6 information, education, training in occupational safety and
7 health.

8 And as Irene said, recently OSHA issued their
9 request for information and comments on a number of items to
10 reassess their blood-borne pathogen standard. They asked
11 specifically for information on 16 items. I've just listed
12 three here, which has sort of some interesting possible
13 overlap with where our interests are, and that's in training
14 and education in the safe use of medical devices and any
15 effect on reducing injury rates and the impact on the
16 delivery of patient care.

17 But we've, as I said, we do have a role and there
18 are things we can do. Irene mentioned we cleared in excess
19 of 200 devices with some sharps injury prevention features.
20 We have cosponsored several meetings with CDC, OSHA, NIOSH,
21 NIH and the most recent one was last August relative to the
22 prevention of transmission of blood-borne pathogens.

23 We have issued three safety alerts or notices, all
24 of which went to the health care community, two of which
25 pertained to recommendations on the safe use of safety

1 prevention technology relative to administration sets, and
2 most recently, the one we issued in February of this year,
3 on capillary tubes. I think that was probably the first
4 alert that we issued that was jointly sponsored by OSHA,
5 NIOSH and ourselves.

6 We've also issued eight guidance documents on
7 injury prevention aspects, of which three were directly
8 related to sharps prevention devices, the primary one being
9 the one that you'll be discussing the morning; the other two
10 are supplementary to it.

11 Irene mentioned we responded to the OSHA request
12 for information by providing them with the human factors
13 desirable performance characteristics that we look for and
14 feel would assist and go a long way in preventing any
15 injuries.

16 And I failed to mention under the safety alerts
17 that we also are currently developing a new notification on
18 use of devices with sharps injury protection features and
19 we're just now trying to determine the direction or if those
20 will be interval notices.

21 But we've also been planning an educational
22 teleconference with several federal agencies on sharps
23 injury prevention activities and devices. We've been
24 communicating with OSHA in trying to determine if they're
25 willing to take the lead in this venture and we certainly

1 are willing to collaborate with them on that.

2 And as Irene read to you, there are three
3 questions that we would appreciate response from you as
4 guidance for the future, since the office has been tasked
5 with doing some additional educational or outreach
6 activities and before moving too much further along, we
7 thought it would be helpful if we could get your guidance on
8 the mechanism that the panel could recommend for us to
9 increase user awareness of the safe use of devices.

10 If indeed there is a need for educational programs
11 for use of sharps injury prevention devices, should you
12 respond in the affirmative to that, then what should the
13 content be included in those programs that would encourage
14 the safe and effective use of those devices?

15 And in the interest of being very brief, that's
16 all I'll say this morning. And I look forward to whatever
17 information or guidance you can provide us. Thank you.

18 DR. EDMISTON: Thank you very much.

19 Are there any questions from the panel members for
20 Dr. Joseph?

21 [No response.]

22 PRESENTATIONS BY USERS OF PROTECTED SHARPS SYSTEMS

23 DR. EDMISTON: That being the case, we're going to
24 move on to our presenters, the users of protective sharps
25 systems.

1 Before I do that, I'd like to reiterate again when
2 you come to the podium, please speak clearly into the
3 microphone. Also it's very important for you to identify
4 the organization you're part of. We need to know what, if
5 any, financial interest you may have in the medical device
6 community.

7 And I should also emphasize that we're trying to
8 run a tight schedule today because we're going to have some
9 significant discussion regarding this particular guidance
10 documentation. I want to encourage our next presenters to
11 limit their comments to 15 minutes.

12 The first person I'd like to call to the podium at
13 this time is Dr. June Fisher, who's a clinical associate
14 professor of medicine at the University of California and is
15 director of training and development for innovative controls
16 and technology. Dr. Fisher.

17 DR. FISHER: I would like to make the comment that
18 I am thankful for the invitation to speak here today and
19 that I really am very excited to see that the FDA is
20 addressing the issue of health care worker health and safety.

21 I know there's a mythology out in the general
22 community that there's an oppositional thing between patient
23 safety and health care worker safety and I know that in
24 institutions these are weighed. I think that this has been
25 proven repeatedly that this is an erroneous approach to

1 patient care.

2 As a clinician, that is my primary concern but I
3 do know that the health care worker who has a safe
4 environment can provide much better care. The most obvious
5 example is if you think about in terms of back injuries. I
6 do not want to be lifted in a hospital but if I had to be
7 there, by somebody who has had a back injury and is not
8 supplied with the appropriate devices to lift people.

9 I think that this certainly goes for the needle
10 stick area and I really welcome this kind of--the FDA is
11 vigorously approaching the issue of health care worker
12 safety in their desire to improve patient safety.

13 I am not going to talk specifically about
14 needleless systems. It'll be a little bit more of an
15 overview, which will be consistent with some of the
16 presentations that went a little earlier.

17 [Pause.]

18 I have a lectureship in engineering but I must say
19 that I'm totally baffled when we have anything like this. I
20 think it's every speaker's nightmare to not have your slides
21 available. Since your time is a little pressed, I will try
22 to speak a little extemporaneously and then hopefully the
23 slides will be projected.

24 The Training for Development of Innovative Control
25 Technology is a program that was started in 1989 and has

1 been funded for almost 10 years by the National Institute of
2 Occupational Safety and Health and it's a program that
3 brings together product designers, industrial hygienists and
4 users. And most of my discussion will be really based on
5 user-driven technology.

6 You're going to have to bear with me. They were
7 organized.

8 This is our logo for our slide. I hope I'll have
9 a few more minutes.

10 DR. EDMISTON: Of course you will.

11 DR. FISHER: As all presentations that I do around
12 this topic, I always use this dedication slide. This is a
13 group of health care workers who--the first group are still
14 alive and the bottom group are people who have died from
15 occupational exposure to blood.

16 I have to make the point that these are all in one
17 city. And when I do speak around the country, I hear from
18 many people that probably the same numbers do exist, so that
19 as important as the CDC numbers have been, most of us feel
20 that these numbers are very, very limited. And I don't have
21 time to discuss that, so we have to remember that there is a
22 real human face and there are serious outcomes for this.

23 I was asked to talk a little bit by people earlier
24 today so I put this slide in. Coming from California, we
25 have a particular circumstance that we now have legislation

1 mandating the use of safer devices, which will change the
2 whole direction in California and will have impact or
3 already has had impact nationally.

4 We have the blood-borne pathogen standard, which
5 is OSHA. We have a Cal/OSHA standard now, which is working
6 under an emergency order, which mandates the use of
7 engineering controls. If this is not passed by the board,
8 the emergency standard will continue so that this will be in
9 effect regardless of what--in California we have a political
10 board. The assumption is that they will pass this.

11 There's legislation in Tennessee, Maryland and I
12 think in 20 other states--somebody may speak for that--and
13 there's federal legislation pending on it. So we have,
14 although we don't want to deal with the political issues, we
15 do have a political driving force.

16 As I said, our project is a project that brings
17 together the industrial hygienists, product designers and
18 health care workers. And, as far as I know, this is unique
19 for any area in health care. And I would certainly
20 recommend that this kind of collaboration exist for many
21 areas in device development.

22 I do know, as an aside, because I have a
23 lectureship in engineering, I have 48 product designers
24 usually a year running around the hospital and there are
25 major, major issues that need to be addressed, not just in

1 these devices, that could be improved by bringing together
2 the user and the product designers.

3 Why bring the health care workers to it? This is
4 from a modification of Warren Estrine from HEMAS because
5 they have a familiarity with new existing devices, the
6 knowledge of the medical device procedure and protocol and
7 an understanding of the environment in which the devices
8 will be used and intimacy with the concerns of the actual
9 user and an advocacy that goes on.

10 The manufacturers do try to have this but in my
11 only experience with them, they really don't fully
12 understand the line user. I suppose the best example is
13 when I was a resident at Stanford. The hospital was built
14 by talking to the chiefs of medicine. The building didn't
15 work, and it was the first instance we made it very clear
16 that you have to go to the person who's doing the job.

17 Our project involves a large group of institutions
18 and this is an old slide and it can be expanded now because
19 we have national involvement with both dental areas and with
20 some of the other hospitals in the country.

21 This slide, and it's upside down and it's supposed
22 to go later--it's showing you when we do simulation studies.
23 I think we'll have to forego that.

24 Our methods developed our review of data on needle
25 stick injuries, an appraisal of the health care workers who

1 are doing the observational studies, failure analysis of
2 devices. And I really want to emphasize that that is very
3 important, to do failure analysis and simulation studies
4 with the devices and joint brain-storming sessions and
5 multi-center health care worker testing.

6 One of our first things we did was to provide a
7 tool for health care workers to assess devices and you got
8 some of that when the chart was presented before. If
9 there's a consistency with the SEIU it's because they
10 adapted their devices from ours, so I wouldn't say that
11 independently this occurred.

12 And we have now 14 devices where we have the
13 tools--I don't know if I can focus this any better--and you
14 can get these tools on our web page, which give guidance to
15 the health care worker in evaluating the device. And I
16 chose the one for needleless systems for IV connectors
17 today.

18 The interesting thing about these devices, I'm not
19 going to go over the specifics within 15 minutes but we can
20 provide you with those, all of them. I don't know Martha,
21 if you were able to get that off the web. We could provide
22 that for the committee. I have a copy here.

23 These were the first written criteria for now 14
24 types of safety devices. They provided a means for
25 involving health care workers and most of these have been

1 validated in multiple institutions. This is an old slide.
2 The 14 are now in the 1999 AHA document.

3 And while they were originally used for a tool for
4 health care worker evaluation and selection, it became the
5 industry benchmarks. So it is very important to develop
6 these criteria that are user-based because it does drive the
7 industry.

8 That was the surprise to us, a picture
9 showing--this is when our team was living down in the
10 emergency room. Here is a product designer actually who is
11 now trying to do laboratory failure analysis of the device.
12 This is a picture--actually the woman in white is a product
13 designer, industrial hygienist and nurse who is guiding
14 another nurse in testing of the devices, using the criteria
15 sheets.

16 One of the things that we did is also we do design
17 evaluation courses for nurses. When you're talking about
18 education, this is one of the things that actually we want
19 to include. We're hoping now to be able to develop a
20 program with the American Nurses Association where we will
21 hope to develop 400 master trainers around the country so
22 that we could emphasize the training.

23 Training is essential. When the question was
24 asked for health care workers, you cannot just coldly go in.
25 This is one of the slides for our course. We're not

1 expecting the nurses to be product designers but we were
2 trying to help them develop a language so they could talk to
3 product designers and manufacturers in a constructive way.

4 The importance of it is that out of this course,
5 not only did they learn something but we learned a lot. And
6 what we got out of that course was a user-based performance
7 standard for design evaluation selection of medical devices.

8 And a performance standard is different than
9 benchmarks and it should not stifle innovation. We were
10 very aware that the manufacturers have to have that kind of
11 freedom where they can develop new devices.

12 We are still in the early stages of development.
13 It should be user patient-based. You give a framework for
14 evaluation. And we need a national task force to develop
15 consensus on performance standards and this is one of the
16 things that I was talking about with Tim for a long time,
17 that if the FDA could take the lead in promoting this kind
18 of census, it may not be something that you can do yourself
19 but if you develop that national consensus, that will be
20 furthering things.

21 And performance standards versus criteria
22 performance are generalized. It's procedure-based and
23 encompasses the product life cycle versus the point of use
24 only. Before, I was talking about the specific criteria.

25 It's a rather extensive document. We can also

1 give you copies of that that can be made, but these are the
2 areas that they cover. Obviously patient care and quality
3 care came first. User safety, user fit and satisfaction, we
4 felt, came before patient fit and satisfaction. And product
5 life cycle, which we're talking about sharps boxes,
6 administrator's fit and satisfaction.

7 One of the other things that came out of there was
8 the issue of scenarios, which you call simulation and we're
9 calling them scenarios. It's the ability of the actual user
10 to test-drive new products and it approximates real-life
11 situations and it draws attention to unforeseen
12 difficulties. It's a very systematic way of doing that.

13 These are the variables that we identified and
14 that impacted on the use. Some of them may sound silly to
15 you. Why lighting? Well, that's labeling and packaging.
16 Noise? Why noise, people ask us, because a lot of the
17 engagement of the devices depends on sound. And crowding,
18 condition of hands, visibility. Some of these, I think, are
19 included in your document, also. So we feel these are the
20 variables to be considered for the sharps devices.

21 And here is the way we rank them. You choose what
22 is applicable to your clinical situation and then develop
23 the device. This chart shows how you put them all together.

24 And, as an aside, I just have to say we tested
25 that at UCSF and I think the system works because a door was

1 open in the room when we were doing the simulation and one
2 of the nurses was acting as a patient who was having some
3 difficulties and the intern ran in and said, "Can I help
4 you?" So I knew that we had a good scenario. We just
5 closed the door.

6 What came out of that is that we needed a
7 user-based design and that users should be involved from the
8 very beginning of need-finding and they should be involved
9 throughout the whole process. Rarely are they. This is
10 really the process that goes on. If you don't believe me
11 you don't have to, but we've gone to manufacturers who've
12 all told us this is, in reality, what happens. And we would
13 push that the user be involved from the beginning.

14 One of the other things I just want to put in,
15 what we really are aiming for is to have the PEST. That is
16 passive, easy, simple and throughout. That's the summary of
17 what we think is desirable in a device.

18 I would like to go over briefly the overheads. I
19 have to apologize for the overheads because they're
20 handwritten. There was a power failure as I was trying to
21 use my computer and I couldn't wait any longer because I had
22 a plane waiting for me. As a physician, my handwriting is
23 not very good but I think you can read that.

24 These are the recommendations for FDA, to
25 participate in the promotion of primary prevention of

1 occupational exposure to blood. I know that there's a lot
2 of emphasis and there should be and people do get stuck but
3 I think we have to think about primary prevention so we
4 don't even have to think about post-exposure treatment.

5 The first thing, some of these are very specific
6 and some are more general. One is labeling of all sharps
7 devices. At present, the only sharps devices that are
8 labeled are those that have the safety feature. We believe
9 that the ones with nonsafety features need to be labeled,
10 also, and they clearly need to be labeled.

11 There are going to be instances where you have to
12 use a standard sharp device but you should be very aware
13 that it is a standard sharp device, so we think that they
14 should all be labeled. They should not be treated
15 differently.

16 I think it's interesting that previous speakers
17 from FDA brought this up, to actively solicit device failure
18 inadequacy from end users. I think you may have to redefine
19 things. I don't want to think about death or serious
20 injury. I think any needle stick, and we have probably
21 900,000, should be analyzed and FDA should be having their
22 handle on. I'm not asking you to look at all 900,000 but
23 that there should be more awareness of what's going on
24 there.

25 There should be promotion of criteria for

1 systematic pilot-testing of market-available devices. I
2 didn't talk about that because of the time but what I
3 presented before, we consider are just screening tests.
4 That pilot testing systematically is a very urgent issue.
5 And from my experience, both in my institutions that I've
6 been in and now I've been in many institutions talking
7 around the country, pilot testing is--at best I could call
8 it a joke.

9 Generally you give the device to people and you
10 come back two months later and ask them, "Did you like it or
11 you didn't like it?" That is not pilot testing. There
12 needs to be a very systematic approach to doing it and to
13 actively collecting the data.

14 And I think if there were criteria for this that
15 you would be getting better pilot testing and actively
16 collect failure inadequacy data obtained from pilot test.
17 If you had good pilot tests, that would really give you
18 postmarket data that is really not available now. So we're
19 recommending that there really be an emphasis on the pilot
20 testing.

21 And there should be expanded requirements for
22 simulation testing. From what I can gather, the simulation
23 testing is left to the manufacturer to define what they are
24 and I think that that causes a great deal of variability.
25 There should be standards. I'm not saying that you

1 specifically say you have to do this and this and this, but
2 put the benchmarks out there, the standards for the
3 variables to be included in that testing.

4 And to require, before you even do the testing, a
5 user-based work task analysis. Define what variables you
6 want in that test. If you're going to go in the emergency
7 room and you're going to use some standards that you devised
8 for the out-patient department, that doesn't give you much
9 detail. Or if you just bring a group of people together
10 that doesn't represent the spectrum of work and say, "Well,
11 try this," and sit in the room, which has no clinical
12 bearing at all, so I think that you should have user-based
13 work task analyses and require testing for failure.

14 That sounds very strange but in our own experience
15 if you just go to a naive health care worker, they know what
16 their problems are but they don't know how to look at it.
17 They're so grateful that you have a new device that they
18 say, "Oh, it's fine." And you look at them and you say,
19 "That is fine?" So they have to understand how to go to
20 failure, to do all those mistakes.

21 Our trained users will throw things on the floor,
22 will do bad practice because they know that's what they have
23 to look at, because that's what you're going to get in
24 reality. And to require the inclusion of trained users in
25 the testing process. This is why we're excited about our

1 collaboration with the ANA, to train these kinds of
2 resources around the country, but I think that should be
3 required by the FDA in your simulation testing, that you've
4 had some trained users who can foresee.

5 And my last slide is that our performance
6 standards and our criteria and some discussion scenarios are
7 all available on our website, which is here. Thank you for
8 allowing me to speak. I think I've covered the 15 minutes.

9 DR. EDMISTON: You're right on time, believe it or
10 not. You're right on time.

11 Are there any questions from the panel for Dr.
12 Fisher?

13 [No response.]

14 DR. EDMISTON: Dr. Fisher, I have one question.
15 When you use the word "pilot," are you referring to bench
16 testing or to simulated clinical testing?

17 DR. FISHER: No, I'm actually--thank you for
18 asking that. I think they should be bench-tested. I think
19 there should be evaluation before you even do a simulation,
20 at least for the evaluation. For the manufacturers, they
21 should then go to simulation.

22 And then the pilot testing is actually postmarket
23 pilot testing by the institutions. And I think most places
24 say they do that. They're going to decide if they're going
25 to buy a device or not and they bring it on the unit and

1 look at it.

2 DR. EDMISTON: So you're defining pilot testing
3 really as product evaluation within the institution.

4 DR. FISHER: Yes. And I think that that's a very
5 valuable area that FDA could use for a postmarket details
6 without having to wait for the death, which may come a year
7 later. So I think that that data could be extremely
8 valuable.

9 DR. EDMISTON: Well, thank you very much.

10 Our next presenter is Ms. Toni Hughes, a
11 perioperative nurse who is representing the Association of
12 Operating Room Nurses.

13 MS. HUGHES: Good morning. Thank you for the
14 opportunity to submit a statement on behalf of AORN to this
15 Federal Drug Administration advisory panel.

16 My name is Toni Hughes. I'm a registered nurse
17 with a bachelors of science degree in nursing and a
18 certification in operating room nursing. I'm a
19 perioperative nurse at Anne Arundel Medical Center in
20 Annapolis, Maryland. I have been a perioperative nurse for
21 19 years and a surgical department manager for the past two,
22 a member of AORN since 1981. I was the chair of the AORN
23 National Practices Committee from 1998 to 1999 and am an
24 active member of the Maryland Nurses Association and the
25 American Nurses Association.

1 Organized in 1949 with a current membership of
2 43,000, AORN, the Association of Perioperative Nurses, is
3 the professional organization of perioperative registered
4 nurses, whose mission is to promote quality patient care for
5 providing its members with education, standards, services
6 and representation.

7 AORN supports the development and use of products,
8 such as safe needle devices, to prevent unnecessary
9 exposures of perioperative personnel to hazardous
10 blood-borne infections. Perioperative nurses are acutely
11 aware of the potential dangers associated with use of
12 needles and other sharps in caring for perioperative
13 patients. Although only 13 percent of the sharp injuries in
14 the operating room are due to hollow bore needles, needle
15 stick injuries are even more significant risks than the
16 preoperative and postoperative patient care arenas.

17 Eighty percent of all blood-borne exposures are
18 the result of needle stick injuries. One study has found
19 that a needle stick injury prevention strategy eliminating
20 100 percent of needle sticks and not costing more than 36
21 percent of the cost of needle devices would not increase
22 overall costs.

23 As participants in product evaluation and
24 purchasing teams, perioperative nurses recognize the complex
25 challenges encountered when trying to identify the most

1 effective and affordable products available.

2 As health care employers begin to acknowledge the
3 hazards and risks associated with direct delivery of health
4 care services and begin to seek safe needle devices for
5 workers, manufacturing standards should be established to
6 ensure that truly safe and effective devices are available
7 in the marketplace. The FDA's role in supporting the
8 development and manufacturing of high quality, safe,
9 affordable and effective devices is critical to achieving a
10 truly safe working evidence. AORN supports the FDA's
11 efforts in collaboration with manufacturers and users to
12 build a safer health care working environment.

13 DR. EDMISTON: Thank you very much.

14 Does the panel have any questions for Ms. Hughes?

15 [No response.]

16 DR. EDMISTON: In that case, thank you very much.

17 Our next presenter will be Ms. Mary Alexander, who
18 is the past president of the Intravenous Nurses Society.

19 MS. ALEXANDER: Good morning. I'd also like to
20 thank the panel for allowing INS to make a statement.

21 My name is Mary Alexander. I'm the chief
22 executive officer of the other INS, with the Intravenous
23 Nurses Society. We're a national nonprofit member
24 organization that was founded in 1973. INS is the largest
25 organization for the IV specialty and exists to promote

1 excellence in intravenous nursing through standards of
2 practice, education, public awareness and research. The
3 organization's ultimate goal is to ensure that patients
4 receive safe, high quality, cost-effective nursing care.

5 The Intravenous Nurses Certification Corporation
6 is also affiliated with INS. However, it is a separate
7 corporation established in 1983 to ensure the clinical
8 competency of intravenous nurses. INCC achieves this goal
9 by administering certification exam and recertification
10 programs.

11 A registered nurse who passes the certification
12 exam and meets the experience criterion receives the
13 certified registered nurse intravenous credential. This
14 credential is maintained by continuing to practice the IV
15 specialty and completing continuing education requirements
16 or retaking the exam.

17 INCC exists to benefit and protect the public
18 through assessment, validation and documentation of the
19 clinical eligibility and continued competency of nurses
20 delivering intravenous therapy in all practice settings.

21 INS understands the inherent dangers involved in
22 administering IV therapy. Vascular access devices, needles
23 and sharps are fundamental to the practice of IV therapy.
24 INS members are the frontline health care workers who
25 provide IV therapy to patients in a variety of practice

1 settings, which are now extending beyond the acute care
2 setting and including but not limited to the home,
3 physicians' offices, skilled nursing facilities, subacute
4 facilities and ambulatory infusion centers. As well as our
5 members, more practitioners are involved and their
6 competency and skill levels differ widely.

7 INS supports engineering and work practice
8 controls that eliminate or minimize exposure of the health
9 care worker to blood-borne pathogens. In 1997 INS wrote a
10 position paper on safety products which appeared in the
11 Journal of Intravenous Nursing.

12 INS supports research and development activities
13 on IV products and medical products and devices to improve
14 patient care and protect the health care worker, education
15 and compliance with commonly accepted principles of
16 infection control and basic practices, choice of products
17 based on engineering design that accomplishes the prevention
18 of transmission of blood-borne pathogens and improvement in
19 patient outcomes, safety and risk management based on
20 professional responsibility and clinical standards of
21 practice, and blood collection design characteristics which
22 result in effective safety device, which include the
23 elimination of the need for the clinician's hands to be
24 placed in front of a sharp needle tip, integration onto the
25 device's design and not an accessory, activation before

1 disassembly in that it remains in effect after disposal, and
2 simplicity in utilization, preferably a passive system.

3 Requiring all health care facilities to use
4 needleless systems and sharps with engineered protections,
5 such as retractable needles, and instituting training and
6 education in the use of safer medical devices provides an
7 effective means of preventing percutaneous exposure
8 incidents and reducing the needle stick injuries each year.

9 INS contends the best way to reduce the risk of
10 accidental needle sticks to health care workers is through
11 ongoing education, training and competency testing, use of
12 vascular access devices that minimize the risk of needle
13 stick injuries, in compliance with OSHA's blood-borne
14 pathogen standards.

15 Frontline health care workers should not have to
16 risk their lives while saving the lives of their patients.
17 INS applauds and supports your efforts to positively impact
18 health care worker safety. Thank you.

19 DR. EDMISTON: Thank you, Ms. Alexander.

20 Are there any questions from the panel members?

21 [No response.]

22 DR. EDMISTON: Thank you.

23 Our final presenter will be Susan Wilburn, the
24 president of the American Nurses Association, who will
25 address the panel.

1 MS. WILBURN: Good morning. Thank you very much.
2 It's a pleasure to be with you here today and thank you for
3 taking a look at this issue that is of critical importance
4 to the American Nurses Association and the two and a half
5 million registered nurses around the country that we
6 represent.

7 My name is Susan Wilburn and I'm the senior
8 specialist for occupational safety and health at the
9 American Nurses Association, so my work is to work with you
10 to protect nurses from needle stick injuries and the
11 subsequent illness and death, as Dr. Fisher described. And
12 I wanted to start today to talk a little bit about our
13 members and the impact in recent years of needle stick
14 injuries on their lives.

15 The American Nurses Association is the
16 professional association representing nurses in the United
17 States with our 200,000 members and as the professional
18 association, we develop the code of ethics for nurses; we
19 establish standards of practice; we develop standards for
20 certification and certification testing of basic nurses and
21 nurses in specialty practice, including advanced registered
22 nurse-practitioners. And as the largest union representing
23 nurses in the country, we also, in 28 states across the
24 country, represent nurses for the purposes of collective
25 bargaining and the advancement of the economic and general

1 welfare of registered nurses. And my role as the
2 occupational safety and health specialist falls in all of
3 those areas.

4 Our members are all too often the victims of
5 needle stick injuries. This nurse, Linda Arnold, that many
6 of you may have had the opportunity to hear from and have
7 known about over the past four years, had a needle stick
8 injury after she finished an IV insertion of a patient with
9 AIDS. Linda is a nurse from Lancaster, Pennsylvania, a
10 small community hospital, and most people in that community
11 not only were unaware that the community had any patients
12 with AIDS but the first time they learned about it was when
13 one of their own, a very young nurse who, at the time of her
14 needle stick was 23 years old and had only just come out of
15 nursing school about three years prior when she had her
16 needle stick injury.

17 As a result of her needle stick injury, she did
18 develop HIV and subsequently AIDS; in fact, in very short
19 order. And as a result of her injury, Linda did a great
20 deal of research on her own, working in collaboration with
21 ANA, with a number of other organizations, including SEIU,
22 and worked with the International Center at Charlottesville,
23 Virginia for Health Care Worker Safety.

24 Linda decided that she wanted to start an
25 organization that would prevent, for all nurses, what had

1 happened to her and the tragedy for her family. She founded
2 in 1996 the National Campaign for Health Care Worker Safety.
3 And part of the goal of her campaign was to get institutions
4 around the country to implement and use safer needle stick
5 devices, as well as to educate nurses and other health care
6 workers about the importance of working together with their
7 employer to evaluate, select and implement these safer
8 devices.

9 But one result or lack of result during the many
10 years of Linda's work, as well as work for many years by a
11 number of us, even following the FDA advisory in 1992 about
12 IV needleless systems, is that this is data from November
13 '98 from the American Hospital Association consultant, Gina
14 Pugliese, that across the country, the percentage of use of
15 safer needle devices is abysmally small. You can see the
16 largest use of safer devices in needleless IV access, and
17 most of us believe that it is not coincidental that this has
18 occurred in the years ensuing since the FDA advisory in
19 1992.

20 But for hypodermic needles and syringes, the most
21 common use of injections, there's less than 10 percent of
22 the hospitals around the country, as of last November, had
23 implemented safer devices. November was immediately
24 following the California legislation and then subsequent to
25 November, last spring there's been a number of other states.

1 So this number will be increasing rapidly and
2 there also with come with it a need from the FDA and the
3 other organizations responsible for worker health and
4 safety, as well as consumer health and safety, to assist
5 these institutions as they implement their new regulations
6 to be able to provide education to employees and to choose
7 the right devices.

8 Another of our members, Karen Daley, who is the
9 president of the Massachusetts Nurses Association, had a
10 sharps injury last summer. And I know that you're not
11 talking about sharps injury containers; however, if the
12 needle that was in the sharps container that stuck
13 Karen--she was working in the emergency room, she was
14 working on the day shift, she had taken care of a patient
15 and had administered a medication, had taken the sharp that
16 she was using, put it in the sharps container and in the top
17 of the sharps container the previous needle that had been
18 dropped had not dropped down into the box. It was a mailbox
19 kind of drop container where the weight of the sharp itself
20 is supposed to drop that sharp down below.

21 It did not do that and even though in the previous
22 five months the nurses in Karen's institution, who are
23 represented by the Mass. Nurses Association for collective
24 bargaining, had repeatedly gone to the employer and
25 labor-management committees and said, "Get rid of this

1 container; it's not safe," well, the day after Karen got her
2 diagnosis of HIV and hepatitis C, all of those sharps
3 containers were removed, but too late for Karen.

4 What happened is as she dropped her sharp in,
5 there was a needle already in the top. She got stuck about
6 a millimeter and a half into her index finger. And nine
7 months later--and most of you know that six months following
8 a needle stick injury, 95 percent of all seroconversion to
9 HIV will occur. With coinfection with hepatitis C, that
10 seroconversion can be extended. And I just heard of another
11 nurse in the last month that it was 11 months before she
12 came back with a positive HIV test.

13 Karen Daley is a tremendous leader within the
14 American Nurses Association and you can barely imagine the
15 devastating effect its had on our entire organization. And
16 the way we all learned about Karen's illness was because the
17 Massachusetts Nurses Association had introduced legislation
18 in the State of Massachusetts to require safer needle stick
19 devices and Karen, on the day they introduced the
20 legislation last spring, spoke on the steps of the State
21 House and her story was featured in the front page of the
22 Boston Globe.

23 Now the issue here is not sharps containers. The
24 issue is that if the device that was used by the nurse or
25 whoever had used the device previous to Karen had a

1 blunting, retractable or sheathed feature, Karen wouldn't
2 have been stuck.

3 And I think what's happened is that even though I
4 live in Seattle, I'm less familiar with Power Point than I
5 am with WordPerfect presentations and I think this is what
6 happened in the translation to Power Point.

7 I wanted to just mention quickly the hazards to
8 health care workers and the kind of situation that nurses
9 and health care workers face on a daily basis in the
10 institution.

11 We are subject to various biological hazards. You
12 can see HIV, hepatitis B, hepatitis C, tuberculosis and many
13 others.

14 Chemical agents, and ANA has had a great privilege
15 to work over the past few years with the FDA on the issue of
16 latex allergy and the teleconference a year and a half ago
17 on that subject. Another chemical hazard to health care
18 workers, glutaraldehyde, ethylene oxide.

19 Ergonomic hazards--back and upper extremities.

20 Physical agents like sound and radiation.

21 And then what has been lumped together in the
22 category of psychosocial hazards are stress, violence, shift
23 work, shift rotation.

24 So it's not just needle stick injuries that we
25 need to worry about.

1 Health care workers, with occupationally acquired
2 HIV, Dr. Fisher mentioned the CDC data for confirmed cases
3 of the HIV virus from a needle stick or other blood-borne
4 exposure. As of December '97 there were 54 documented cases
5 and 132 possible cases that didn't meet all the criteria but
6 are very likely to be occupationally acquired HIV.

7 And as Dr. Fisher mentioned, with the number of
8 cases you saw just from one hospital in California and the
9 fact that in March of this year I learned about two nurses,
10 Karen Daley and one other who I'll mention in a minute, who
11 were notified that they had become infected with both HIV
12 and hepatitis C, two in one month, all of us that are
13 involved in this field of occupational safety and health
14 believe that these estimates are very, very low.

15 And if you take prevalence data from the CDC and
16 from the Hospital Association, who has said that 16,000 of
17 the 800,000 to 1 million needle stick injuries per year,
18 16,000 of those are needle stick injuries from patients with
19 HIV, and then you add onto that the .03 seroconversion rate,
20 that will bring you to a number of between 10 to 35
21 occupationally acquired HIV infections per year. And with
22 only 54 since 1985, we know that this is an underestimation.

23 I also wanted to note that of the 54 documented
24 cases, 87 percent were from percutaneous injuries and 89
25 percent from hollow bore needles, so we can hone down the

1 area of the greatest risk.

2 Then the risk from these needle stick injuries. I
3 mentioned HIV .03 or 1 in 300 risk, but the risk from a
4 needle stick injury sustained from a patient infected with
5 either hepatitis B or hepatitis C is so much greater. And
6 as a result of the blood-borne pathogen standard that was
7 implemented in 1991, we have reduced the death rate from
8 hepatitis B from thousands per year to a negligible, less
9 than 10 per year, as a result of the requirement for
10 immunization.

11 The problem with hepatitis C though, is that there
12 is neither an immunization nor at this point a reliable
13 cure.

14 The data is all across the map in terms of
15 hepatitis C. We at the American Nurses Association believe
16 that we have only begun to see the needle stick injuries
17 that have seroconverted to hepatitis C. We know that there
18 is as long as a 10-year lag time between infection to
19 illness and we know that it was only in the last year, in
20 1998, that the CDC began to recommend that health care
21 workers be tested for hepatitis C following a needle stick
22 injury. So that we don't know how many people have
23 developed hepatitis C and we're going to be seeing this
24 tidal wave over the next number of years.

25 This was a scan that didn't work. I'll go on.

1 Now when we talk about needle stick injuries, of
2 course we need to find out whether there is a way that we
3 can reduce the number of needle stick injuries, and this is
4 a slide that demonstrates the data from the CDC case
5 controlled study from '93 to '95 in Minnesota, New York and
6 California. That's the starred percentages.

7 For butterfly or wing steel needles there was a 23
8 percent reduction in needle stick injuries following the
9 implementation of safety butterflies, a 76 percent reduction
10 with blunt needles, and a 66 percent reduction in needle
11 stick injuries with a hinged recap IV needle. And the last
12 84 percent reduction from IV safety catheters is data from
13 the University of Virginia Charlottesville trial. So we
14 know that there is great benefit from the implementation of
15 safety devices.

16 ANA's recommendations to the FDA and in general to
17 institutions as we look at safer devices are to incorporate
18 user training and in-use testing by users and evaluation by
19 health care workers to implement safer devices.

20 Our main goal is to remove all barriers to
21 implementation. And as many of you know, we've been working
22 in a coalition to pass the Pete Stark legislation which
23 would require the implementation of safer needle stick
24 devices on a federal level, as we've been working state by
25 state.

1 There are some folks that say that there should be
2 no unsafe devices on the market, that every device that is
3 on the market should have a sharps injury prevention
4 feature. We know as nurses that there are uses for what are
5 less safe devices or unsafe devices.

6 And I have a question for you, for the panel, and
7 the question in general is do we need a supplemental
8 premarket review for devices with sharps injury prevention
9 features or should all devices undergo the same kind of
10 testing and that any device that increases the risk of
11 needle stick injury to either the health care worker or, of
12 course, to the family member who is at home taking care of
13 that patient and may be administering diabetes, may be
14 administering some other medication at home, that any device
15 that is being used by any consumer or any health care worker
16 should be a safer device?

17 And as Dr. Fisher mentioned, we have begun a
18 process to develop experts across the country in device
19 evaluation and selection and our first training will be in
20 Massachusetts since, of course, the state is very, very
21 eager for this not to happen to any other nurse, and that
22 will be in November.

23 And last comment, the family at home that's taking
24 care of the patient, I talked to a nurse the other day in
25 Wisconsin about the issues related to needle stick injuries

1 and she said, "Well, you know, the other day I
2 walked"--pediatric nurse--"I walked into a patient's room
3 and there was a baby in the bed that had a needle stuck in
4 its stomach." This was a syringe that had been
5 inadvertently left in the baby's bed and the child had
6 picked it up, as children do, to play with it and when the
7 nurse came in to observe the child, this was a syringe stuck
8 in the baby. And we know that you will join with ANA in
9 wanting that not to happen to any baby but also not to
10 happen to any other health care worker, either. Thank you.

11 DR. EDMISTON: Thank you, Ms. Wilburn.

12 Are there any questions by panel members? Yes,
13 Dr. Rutala.

14 DR. RUTALA: Yes, I have one question. You
15 mentioned some data from Gina Pugliese November 1998 where
16 there was some market data where health care institutions
17 were not implementing various engineering controls.

18 Certain professional organizations have believed
19 that engineering controls should be implemented when there
20 is a demonstration of efficacy; that is, actual clinical
21 efficacy. And certainly we've heard this morning that these
22 devices should be safe and efficacious. How do you feel
23 about the issue of actual clinical efficacy versus simulated
24 efficacy testing?

25 MS. WILBURN: In the questions I noted that most

1 of the manufacturers have been doing simulated testing
2 instead of actual testing and we believe that not only
3 should it be actual testing but it should be actual testing
4 with an educated group of trainers who, like the group that
5 Dr. Fisher has worked with, can really put a device through
6 its paces and not just be thrilled with a new bell and
7 whistle that is much better than what we've had before.

8 I also wanted to add that Dr. Kessler earlier was
9 talking about the use of medical device reporting and we've
10 learned at ANA how unsatisfactory medical device reporting
11 has been for incidents that occur to health care workers.
12 When I've gone around the country to talk to nurses about
13 medical device reporting, specifically about the issue of
14 latex allergy, they say, "Well, we know all about MedWatch.
15 We know that we're supposed to use it when there's a patient
16 incident. We are unaware that it applies to health care
17 workers."

18 So there needs to be an additional education and
19 advisories from the FDA to reinforce to end users that it is
20 not only the consumer or the patient but it's the user of
21 the device that should be reporting an incident.

22 DR. EDMISTON: Thank you very much.

23 I want to thank our four presenters. This ends
24 our formal scheduled presentation portion of the morning.

25 Before we move on to the open public hearing

1 session, Martha O'Lone has a statement she needs to read.

2 OPEN PUBLIC HEARING

3 MS. O'LONE: Actually this is part of the open
4 public hearing. I have two statements that I promised if
5 people were not able to attend that I would read into the
6 record for them.

7 The first is from the Department of Health
8 Services Sharps Injury Control Program at the State of
9 California, from Dr. Cone and Martha Davis. They said,
10 "Since we may not be able to attend the meeting, would you
11 please accept and read into the minutes the following
12 comments?

13 "Recent legislation in California, AB1208, added
14 Labor Code Section 144.7 that required the Division of
15 Occupational Safety and Health, Cal/OSHA, to revise the
16 blood-borne pathogen standard. The revised standard
17 requires California health care workers to use needles with
18 engineered sharps injury protection and needleless systems
19 to reduce the risk of sharps injury and potential
20 transmission of blood-borne diseases.

21 "In addition to the requirement for a revised
22 standard, Labor Code Section 144.7 also directed Cal/OSHA
23 and the California Department of Health Services to jointly
24 compile a list of needleless systems and needle devices with
25 engineered sharps injury protection to assist employers in

1 complying with these new requirements. "Within the
2 California Department of Health Services, the Sharps Injury
3 Control Program has proceeded in the development of this
4 list. We make no claims to evaluating devices placed on
5 this list.

6 "Now that other states have passed similar
7 legislation, the impact and importance of this California
8 safety device list increases. As the FDA is a federal
9 organization which approves medical devices and associated
10 safety claims and labeling, it is our hope that the FDA will
11 take the lead and establish a process which standardizes the
12 product safety claims across all states with similar
13 legislation.

14 "In developing the list, we requested the
15 assistance of the FDA in identifying needles with engineered
16 sharps injury protection and needleless systems. We were
17 told that the FDA could not provide a complete list of
18 FDA-approved needles with engineered sharps injury
19 protection and needleless systems. We could, however, begin
20 to develop our list by searching the Releasable 510(k)
21 database for antistick syringe, which has a product code
22 80meg.

23 Only a small subset of devices making safety
24 claims are available with "meg" codes. As of July 6, 1999,
25 there were only 17 products listed with the product code

1 "meg." We are aware of piston syringes not on the "meg"
2 list that are available on the market that make safety
3 claims. We also understand that there are not similar
4 anti-stick or safety device codes for blood-drawing devices,
5 for needleless intravascular administration set, safety
6 catheters, for safety lancets, for blunted surgical needles
7 or for hemodialysis needles.

8 Please provide a way for us to identify safety
9 products. You may wish to consider providing a way to
10 search the Releasable 510(k) database for engineered safety
11 products in all categories mentioned above or consider new
12 product codes specific to identify needle devices with
13 engineered safety component. Alternatively, once safety
14 claims are approved by FDA, could FDA maintain a list of
15 these safety needle products?

16 "Additionally, we would like to know what are the
17 criteria, if any, for making safety claims, above that of
18 'not significantly different from existing products.'

19 "The following comments refer specifically to the
20 Supplementary Guidance on the Content of Premarket
21 Notification 510(k) Submissions for Medical Devices with
22 Sharps Injury Prevention Features.

23 "Currently a device manufacturer of a piston
24 syringe makes the following safety claim: 'Once sealed,
25 works like a built-in portable sharps container' and

1 provides 'sharps container savings. Can eliminate the need
2 for containers in patient rooms.'

3 "Are these claims reviewed when the FDA reviews a
4 product as a medical device with sharps injury prevention
5 features? The Supplementary Guidance on the Content of
6 Premarket Notification 510(k) Submissions for Medical
7 Devices with Sharps Injury Prevention Features should
8 incorporate specific safety criteria for what constitutes a
9 safe sharps disposal container.

10 "Lastly, to protect the safety of our health care
11 providers, FDA should make readily available results from
12 Medical Device Reporting System that is device-specific. We
13 encourage product users to report to FDA MedWatch on
14 injuries involving device failures with potential for
15 blood-borne pathogen exposure. It is important to know which
16 devices have had failures resulting in injuries and the
17 frequency of occurrence. Users of products need to know the
18 risk associated with each device. We would like to see FDA
19 prescribe specific test methods to assess safety performance
20 of a needle safety device or other medical device product
21 that manufacturer claim will be 'safer' to use than a
22 'standard device.' How safe is safer and what are the risks
23 associated with a 'standard device?'"

24 It ends with "Thank you for allowing us to submit
25 comments."

1 DR. EDMISTON: Thank you very much.

2 MS. O'LONE: And we have one more. The second one
3 that I have is from a manufacturing firm and our purpose is
4 to go over some things to add to the guidance, and this goes
5 through actual line deletions, so it may not make as much
6 sense if I read all this comment on the second page, but
7 I'll begin with their first page and then try to address
8 what they've listed as revisions. Those would be addressed
9 also as written comments in the draft that goes out in the
10 Federal Register in the future.

11 This is from Biomedical Disposal. It was written
12 by Cathryn Cambria, who's the director of regulatory affairs
13 and quality assurance. Its subject is suggested changes to
14 the guidance document.

15 "In developing these comments we were guided by
16 the belief that this guidance document should reflect
17 changes in technology, regulations, and the marketplace
18 since March 1995 when this guidance document was issued;
19 allow and encourage new technology as it becomes available;
20 and include clarifications to avoid potential
21 misconceptions. Separately, making the guidance document
22 for needle destruction units available via the Internet
23 would additionally help reduce confusion."

24 They have on here, "Biomedical Disposal is a
25 private company located in Atlanta, Georgia, which markets

1 products designed to make the health care workplace safer.
2 Specific products for needle safety include the SharpX, a
3 FDA-approved needle destruction unit." And they state that
4 they also recently acquired a patent for safety syringe
5 technology.

6 Their main comment that they made that I'll share
7 now, in the interest of time, is that they felt that the
8 guidance should be amended to say that it's for the review
9 of 510(k)s for devices with built-in sharps injury
10 prevention features, and also to reiterate that there is a
11 separate guidance document for needle destruction units.

12 And that's the end of the comments that they have
13 that are pertinent to read at this time.

14 Well, now that we are in the open public hearing
15 portion of this meeting, let me read a statement. This next
16 half hour or so will be available for members of the public
17 who would like to address the panel. Please raise your hand
18 so we can determine the number of speakers that are present
19 who may be interested in addressing this panel.

20 I am aware at this time that we have a
21 representative from the Service Employees International
22 Union. Could you raise your hand please?

23 Do we have any other individuals who would like to
24 address this panel? Could you please come forward? One
25 more? We have two individuals. Could you come forward,

1 please, state your name, your affiliation?

2 MS. GOODENOUGH: Good morning. My name is Laurie
3 Goodenough. I'm a registered nurse and a member of Local
4 200A, Service Employees International Union, AFL-CIO.
5 Service Employees International Union has 1.3 million
6 members, including 675,000 health care workers. It's the
7 nation's largest organization representing the interests and
8 concerns of our nation's caregivers.

9 SEIU has been a leader in fighting to protect our
10 members from a wide range of workplace hazards they face.
11 In 1986 SEIU originally petitioned OSHA for the blood-borne
12 pathogen standard that was eventually completed in 1991.
13 Understanding the important role of FDA regarding the safety
14 and efficacy of needles and other sharps, in 1991 we
15 petitioned FDA to better regulate conventional needles and
16 other sharps which can occupationally transmit hepatitis and
17 HIV.

18 While FDA largely denied our 1991 petition, the
19 agency has cleared well over 200 safer devices with
20 integrated safety features. Unfortunately, however, fewer
21 than 15 percent of needles and other sharps purchased by
22 health care facilities today use these potentially
23 life-saving devices. Most health care workers have never
24 seen these safer products. In other instances, lack of
25 proper training has led to resistance to adoption of safer

1 products by the health care workers themselves.

2 On behalf of SEIU, I offer our experience on what
3 we have found to be the critical elements necessary to
4 achieve success at the work site level during the conversion
5 from conventional to safer needles and other safer sharps.

6 Education and training must be coordinated with
7 the manufacturer of the device and the education staff of
8 the facility before the device is put into use.

9 Training must be mandatory for all staff using the
10 new device.

11 Training should include a review of the
12 manufacturer's written program, as well as a video program,
13 on the use of the device for the initial training and
14 ongoing training.

15 There must be assurance that the manufacturer's
16 representatives have clinical experience and are available
17 on-site or on-call for 24-hour coverage during the initial
18 implementation and use of the new device.

19 There must be an opportunity for a performance
20 test on the new device, including three return
21 demonstrations; at least one return demonstration conducted
22 with the manufacturer's representative and at least one
23 return demonstration conducted with the facility's
24 educational services coordinator.

25 There must be allowance for extended training for

1 workers who fail initial performance tests or are
2 uncomfortable with the new device.

3 There must be follow-up testing within a 30-day
4 period on the implementation and use of the new device.

5 Education must include a review of the risk of
6 exposures to blood-borne diseases from needle stick injuries
7 and how these injuries can be prevented through the use of
8 control technology.

9 Education must be provided on OSHA blood-borne
10 pathogen standards that require the use of feasible safer
11 devices.

12 Education must be provided and disincentives
13 removed on how to report a needle stick injury.

14 There must be the provision of easy, visual
15 reference material--an example would be a poster--that can
16 be posted throughout a facility that can provide key points
17 on the use of the safer control technology.

18 As a part of any effective program to implement
19 safer devices, there must be an ongoing monitoring of
20 surveillance data regarding needle stick injuries before and
21 after introduction of the new control technology.

22 Thank you for this opportunity to suggest actions
23 by FDA to stem this epidemic of 600,000 to 1 million needle
24 stick injuries which affect our nation's health care workers
25 each year.

1 DR. EDMISTON: Thank you. Before you go, are
2 there any questions from the members of the panel?

3 MS. GOODENOUGH: You mentioned our book as part of
4 this checklist and I didn't know if I can offer you one of
5 these to add to--

6 MS. O'LONE: We have that as a resource already.

7 MS. GOODENOUGH: Okay, thank you.

8 DR. EDMISTON: Thank you very much.

9 Could the second speaker come forward please and
10 identify herself?

11 MS. DUCMAN: Thank you very much. My name is
12 Kathryn Ducman. I'm a registered nurse and the director of
13 clinical services with Retractable Technologies
14 Incorporated. We are the manufacturers of safety medical
15 devices. We have a retractable syringe, Vanish Point
16 syringe that has been on the market since 1997, as well as a
17 blood collection device that has been on the market since
18 September of 1998.

19 I appreciate the opportunity to speak and
20 certainly am in great agreement with the previous speakers.
21 I again would like to reiterate that all devices with the
22 potential for sharps injury and/or blood-borne pathogen
23 exposure undergo the same rigorous testing and standards
24 that safety devices must go through, so that frontline
25 health care workers are protected from those injuries.

1 I also would like to see some type of criteria
2 that assesses the length of exposure that these safety
3 devices do protect health care workers from. I think
4 there's an enormous difference between a device that offers
5 instantaneous or in-patient safety as compared to those that
6 must be activated manually outside the patient, which does
7 create an exposure to that sharps injury. So in-patient
8 versus out-of-patient and the length of exposure is a
9 criteria that certainly needs to be included in that.

10 Also safety post-assembly of any safety product
11 needs to be looked at quite stringently. Blood collection
12 devices pose an enormous risk to health care workers because
13 they are large bore hollow needles filled with blood. Many,
14 many of the safety devices on the market, once disassembled,
15 present a nonsafe contaminated needle on the back end
16 phlebotomy needle that is not addressed in any of the
17 labeling. So once that is disassembled, they are exposed to
18 a risk.

19 Also some criteria for the products that are on
20 the market and have had some history if they are creating
21 sharps injuries because of their design, and looking at that
22 criteria that would go back and assess them accurately.

23 Thank you very much for the opportunity to speak.

24 DR. EDMISTON: Thank you very much.

25 Are there any questions from the panel?

1 [No response.]

2 DR. EDMISTON: Thank you.

3 Is there anyone else in the audience who was not
4 scheduled or is interested in making a presentation to this
5 panel?

6 [No response.]

7 DR. EDMISTON: If not, at this time I'd like to
8 close the open public hearing and take a break. Let's meet
9 back here at the top of the hour, 11:00.

10 [Recess.]

11 PANEL DISCUSSION/RECOMMENDATION

12 DR. EDMISTON: Thank you for coming back promptly.
13 At this time the panel will address the questions that have
14 been presented. We will discuss these questions in detail
15 and make recommendations to the FDA.

16 It is possible during the discussion of these
17 questions that we may ask for assistance from members of the
18 FDA, OSHA or NIOSH, who I suspect are still available in the
19 audience.

20 Could we get the first question up on the screen,
21 please?

22 I should also point up before we get started that
23 we are not voting today, although I may poll the panel
24 members to arrive at a consensus for the recommendations
25 which we will be giving to the FDA.

1 I will read the first question. "Our current
2 guidance document allows sponsors to perform either a
3 simulated clinical use study or an actual clinical use study
4 to evaluate the performance of the sharps injury prevention
5 feature. In most cases, sponsors have provided information
6 from a simulated clinical study."

7 Question one: "When would it be appropriate for
8 FDA to consider data from actual clinical use or simulated
9 clinical use trials?"

10 I'd like to open this up to the panel for
11 discussion. Dr. Rutala.

12 DR. RUTALA: I'll begin by commenting that I
13 believe that the demonstration of actual clinical efficacy
14 should be required for any claim, suggestion or hint that a
15 device will reduce sharp injuries. That is, if a
16 manufacturer claims, suggests or hints that a product or a
17 device will reduce sharp injuries, then I believe that
18 clinical efficacy data should be required.

19 The manufacturer should first perform simulated
20 use studies. If the device fails that, additional testing
21 is unnecessary. However, all devices should be tested under
22 clinical conditions.

23 In all such cases, a comparative group must also
24 be studied in order to determine efficacy; that is, the
25 added benefit from the new device. For example, the

1 frequency of injuries from a blunted suture needle should be
2 compared to similar surgeries using standard sharp needles.
3 The usual guidelines for study design should be followed,
4 such as adequate power, objective outcome measures and
5 randomization.

6 If a manufacturer is going to claim the device
7 will reduce needle stick injuries, then this claim must be
8 verified in actual clinical studies. For example, a
9 self-sheathing IV needle device should be tested using
10 pigskin by an IV technician. However, lack of injury in
11 this simulation may not predict lack of injury when used by
12 ordinary personnel on live, moving patients.

13 So in summary, if there is a hint, claim or
14 suggestion that a device will reduce sharp injuries, I
15 believe that not only should the manufacturer do simulated
16 use tests but also actual clinical use studies.

17 DR. EDMISTON: Marcia, do you have any comments?

18 MS. RYDER: I am in complete agreement with Dr.
19 Rutala's offerings. The only thing I would add in regard to
20 the actual clinical study would be the suggestion that not
21 only would these devices be incorporated into health care
22 worker review but also those devices that are used by
23 patients and nonprofessional people also be included in
24 those trials.

25 DR. EDMISTON: Mr. Palomares?

1 MR. PALOMARES: Personally, seeing how the
2 products are used, I don't think it would be feasible to
3 actually conduct clinical studies. You're talking about
4 very low effect size--not effect size but incident rate
5 here. And to actually conduct a study along this nature to
6 develop the information to determine whether it's beneficial
7 or not, basically like was said earlier, the technology just
8 overrides it. By the time the study is done, there's
9 already new technology available and that product is nearly
10 obsolete.

11 DR. EDMISTON: But for instance, if a claim is
12 made that the device will prevent infection or prevent
13 contamination of a line or device, that really needs to be
14 validated; don't you agree?

15 MR. PALOMARES: I agree with that and what I think
16 needs to be done is that there should be a standardized
17 protocol to follow. Right now manufacturers are left open
18 to determine the protocol, the sample size, the challenge
19 organism for a needleless system on microbial challenges.
20 And at that, the FDA doesn't have an adequate benchmark to
21 say did this product perform as good as its predicate?

22 And really that's what we're here to talk about.
23 Is it as good or better than what was previously on the
24 market, to get it cleared?

25 DR. EDMISTON: Mr. Dacey.

1 MR. DACEY: I have to, from a consumer
2 perspective, agree with Dr. Rutala. I'm especially
3 concerned when a product works down the line to where it's
4 in the hand of the consumer or consumer-patient. I was
5 joking earlier that I've self-administered insulin for 20
6 years and I've stuck myself I can't count the number of
7 times inadvertently, but it's my own needle.

8 But I did a little research with our local
9 hospital--I serve on the ethics committee--just to get their
10 perspective in a generalized way around this subject. Again
11 from a consumer perspective it was a case of I didn't know a
12 problem existed until I started asking questions. And I was
13 very impressed with the hospital's response in that they had
14 been tracking these sharps stick incidents and knew what the
15 costs were and I was very impressed with the problems that
16 they were confronted with in this. Then I tried to project
17 that down into home care and it got to be pretty awesome.
18 So I definitely favor more actual clinical use study.

19 And one of the comments I got from the staff
20 people was that they felt at the mercy of manufacturers,
21 that they didn't have a role in the product design. That
22 resonated over and over again.

23 DR. EDMISTON: Dr. Fowler.

24 DR. FOWLER: I agree entirely with Dr. Rutala. I
25 think we might have to make a distinction of the idea of

1 simulated studies versus clinical use studies, however, in
2 that the type of study that Dr. Fisher described earlier, to
3 me is essentially very close to a clinical use study and
4 that sort of study certainly may well be valuable. A
5 controlled situation using humans rather than artificial
6 limbs or animal testing or what have you, that sort of
7 evaluation I think in some situations certainly would be a
8 valid clinical use study.

9 I also agree and understand the difficulty in
10 performing open-ended long-term studies without proper
11 guidance, so I think there should be criteria developed to
12 specify the types of work that needs to be done on a
13 particular product under those controlled conditions.

14 DR. EDMISTON: I think one of the concerns that I
15 have, and if someone from the FDA could jump in and give me
16 some assistance on this, in terms of the 510(k) submission,
17 a device that's submitted to the FDA, even if it's an
18 invasive device, that device is significantly dissimilar or
19 similar to previously marketed devices. That has a major
20 impact, does it not, on how it's perceived by the FDA?

21 MR. ULATOWSKI: That's true. There's two primary
22 methods of getting to the market and all the devices that
23 have been cleared, I believe, have been cleared through our
24 510(k) process, which is a determination that the product is
25 as safe and effective as a legally marketed product already

1 out there that is also subject to the 510(k) process.

2 That has its benefits and its problems. The
3 benefit is in some cases if the product is sufficiently
4 similar to one that's already legally marketed, in fact
5 identical in some cases, one can rely upon certain what we
6 call descriptive information--dimension specifications,
7 certain bench specifications--to clear the product, and only
8 go to other tests as necessary to evaluate differences.

9 The down side is we've been working with a
10 technology here for 15 years plus, perhaps, where the
11 earlier technology may not be the best thing on the block
12 but yet it remains substantially equivalent and legal. And
13 I think one purpose of the guidance and the discussion today
14 from the public and from the panel is to kind of draw a line
15 in the sand, to say these are the features that are
16 appropriate, these are the ways one should evaluate them.
17 And those that would by some chance get some older
18 technologies that don't meet these expectations really
19 should fall by the wayside now.

20 I'm giving a long answer but the short answer is
21 our process constrains us in some respects.

22 DR. EDMISTON: There's no doubt that failure of a
23 device can, in part, be documented by benchwork that occurs
24 in the laboratory. The issue that Dr. Fisher brought up,
25 postmarket evaluation, we really don't know what's going to

1 happen to these devices once they get out into the public,
2 the public domain. We see that with anti-infectives. We
3 see that with a variety of compounds that within the
4 clinical trial period of numerous patients we find no
5 adverse effects; it's when the compound or the device is out
6 in the hands of the public that we do see these problems.

7 So I think we need to separate this postmarketing
8 and I don't want to forget about it; I want to come back to
9 it. I really think the postmarketing surveillance part of
10 it is extremely important.

11 Going back to Dr. Rutala's statements, I am also
12 in line with his comments concerning these devices,
13 especially these devices representing new technologies. And
14 many of these devices do represent new technologies. And to
15 adequately demonstrate that these devices are safe, there's
16 no doubt that simulated studies can demonstrate that within
17 a very defined environment.

18 What I'd like to do is that as we move through
19 this, let's try and arrive at a consensus on each question
20 rather than going back to them all at the end.

21 Martha, could you read the very first response
22 that Dr. Rutala gave us?

23 MS. O'LONE: Well, I know that you started out
24 with some information about clinical efficacy. I didn't
25 quite get every word. I might ask Dr. Rutala--did you have

1 your remarks prepared?

2 DR. RUTALA: Yes, I do. I can give you a copy of
3 them.

4 MS. O'LONE: If you would like me to read them, I
5 can do that.

6 DR. RUTALA: Or I can just reiterate--

7 DR. EDMISTON: We're particularly interested in
8 the first two sentences.

9 DR. RUTALA: That's exactly what I was going to
10 repeat. My comment was the demonstration of clinical
11 efficacy should be required for any claim, suggestion or
12 hint that a device will reduce sharp injuries. If a product
13 does not make a claim, suggestion or hint, then a clinical
14 use study may not be necessary, but a clinical use efficacy
15 study would be required for any claim, suggestion or hint
16 that a device will reduce sharp injuries.

17 DR. EDMISTON: Is there any comment from the
18 panel? We're talking about claims specifically that are
19 made with these devices that may impact on patient care or
20 health care professional caregiving. Yes?

21 MR. PALOMARES: How would you capture that data?
22 When you talk about--

23 DR. EDMISTON: Actually, Dr. Rutala answered three
24 questions in his commentary. I think the issue that's at
25 hand here is that devices that make specific

1 claims--anti-infectives that make specific claims, they're
2 approved for indications. And while these may not be
3 approved for indications, the broad indication is that
4 they're safe devices, that if a specific claim is made, that
5 needs to be validated for the consumer and for the health
6 care professional.

7 So should the panel be in agreement to enter in
8 Dr. Rutala's first two sentences or two and a half sentences
9 as a response to question number one?

10 MR. PALOMARES: I believe in the guidance document
11 it talks about devices that don't--let's say, for example,
12 don't have a needle in it. It could still say it's for the
13 prevention of needle sticks, since it does not have it; it's
14 passively performing that function.

15 DR. EDMISTON: Well, if you make a specific claim,
16 I think it still falls under that purview.

17 MR. PALOMARES: I would not agree with that. I
18 understand that the panel is trying to make what's best and
19 safe for the general public--

20 DR. EDMISTON: I think you just answered that, in
21 terms of the safety perspective, that it would be prudent if
22 the claim is made with that device, to enter into some type
23 of clinical evaluation.

24 Let me summarize this first question, then, the
25 response to this first question. Clinical use efficacy

1 studies should be required for any specific claim regarding
2 sharps injury protection features. All right?

3 The next question, "Are there minimum criteria in
4 terms of sample size, independence of the evaluators, number
5 of sites, et cetera that the FDA could consider for both the
6 simulated clinical and actual clinical use studies?"

7 Mr. Palomares, I'll let you speak first.

8 MR. PALOMARES: Well, understanding if we are
9 going to go in the direction of having clinical studies, how
10 do you determine--

11 DR. EDMISTON: Correct me if I'm wrong from the
12 FDA. We're just making recommendations.

13 MR. ULATOWSKI: That's right. You're providing
14 recommendations and we'll think about what you said in
15 total.

16 MR. PALOMARES: That's fair.

17 DR. EDMISTON: There will also be an opportunity
18 for written comments, both from the private sector and the
19 public sector.

20 MR. PALOMARES: What are you deeming as an
21 acceptable sample size? As well as what level of
22 improvement in safety are you looking for if we make claims
23 along these lines?

24 DR. EDMISTON: I think if you read the guidance
25 documentation under statistical evaluation, they make a

1 lucid argument for the use of confidence intervals. And I
2 think if you look at the confidence intervals, if you had X
3 number of devices in which you're testing in multi-centers,
4 and multi-centers could be two centers, with independent
5 investigators, because obviously you want to have as many
6 users, as Dr. Fisher indicated, as many users looking at
7 these devices on the front end, that an N, in my
8 perspective, an N of 500 is not reasonable considering the
9 number of these devices that are used, even within a single
10 institution.

11 Marcia, do you have any comments?

12 MS. RYDER: Well, certainly as identified, I would
13 agree in terms of the confidence interval perspective and
14 certainly, again because of the scope of the problem and
15 numbers and spectrum of users, that we certainly, as
16 scientists, should require the scientific rigor that is
17 suggested in the document.

18 DR. EDMISTON: Dr. Rutala?

19 DR. RUTALA: Yes, I'm just going to refer to
20 possibly five minimum criteria that could be used in doing a
21 clinical use efficacy study.

22 One is that the body sites tested should conform
23 to the expected use of the device. For example, a
24 peripheral IV should be used on a patient's arm and hands.

25 Two is that the sample size should be based on a

1 clinically meaningful reduction in needle stick injuries. A
2 reasonable number might be greater than or equal to 10
3 percent reduction, but that is debatable. The exact percent
4 reduction should be reported in the manufacturer's package
5 insert.

6 Three, as with drugs, manufacturers should provide
7 data demonstrating efficacy and the study should be properly
8 performed or performed by impartial outside investigators.
9 When observer bias may influence results, observers should
10 be masked as to the intervention.

11 Four, appropriate populations should be studied.
12 That is, the study should have internal and external
13 validity.

14 And five, the device studied should be the actual
15 device to be sold, not a prototype to the device being sold.

16 DR. EDMISTON: Mr. Palomares, how does that sound?
17 Does that sound reasonable?

18 MR. PALOMARES: I agree that it should be the
19 final device. I know a lot of manufacturers try and use
20 prototypes. It's not the best way to do it. I believe most
21 of them don't do that but I know there are some that have
22 done that.

23 I believe--can you repeat those?

24 DR. RUTALA: The first was the body sites tested
25 should conform to the expected use of the device.

1 MR. PALOMARES: I believe that's true.

2 DR. RUTALA: The second was sample size should be
3 based on clinically meaningful reduction in needle stick
4 injuries. A reasonable number might be greater than or
5 equal to 10 percent reduction.

6 MR. PALOMARES: I'd agree until about the 10
7 percent.

8 DR. RUTALA: That is just a proposal.

9 DR. EDMISTON: Actually that's an interesting
10 argument. What we're talking about is the power, the power
11 of statistical tests.

12 If you're working on a urinary catheter you're
13 going to decrease the urinary infection rate, the nosocomial
14 urinary infection rate from 2 to 1.5 percent, that would
15 involve thousands of patients.

16 However, as you determine what would be an
17 appropriate reduction--5, 10, 15 percent--impacting upon
18 your power actually decreases the number of individuals that
19 you would need in your data pool.

20 I think it's reasonable, from my perspective, that
21 if you're going to manufacture a safe device, it should
22 reduce needle sticks and there should be some documentation
23 of this.

24 Dr. Fowler?

25 DR. FOWLER: I agree. I think the statistical

1 methods, as you say, will require varying numbers of
2 subjects, depending on what you're trying to achieve and
3 that is something I think that might have to be a joint
4 decision between the regulators and the industry or
5 manufacturer wanting to make a particular claim. Obviously,
6 as you say, if you want to claim your product is 10 percent
7 better than what's out there, you have to have a certain
8 number of subjects in order to do that and that certainly
9 can be come up by any statistician.

10 I think the independence of the evaluators is, of
11 course, critical and I would also speak to the use of
12 multiple sites, whether that be at least two, perhaps more.
13 Knowing that products of this nature will be used in many,
14 many different sites, having the testing done at multiple
15 sites. It would somewhat increase the variability of the
16 users and would be a more realistic assessment, I think, of
17 the product in its final environment.

18 DR. EDMISTON: Mr. Palomares and members of the
19 audience, I understand that when you're talking about
20 reduction, especially if you're making a claim for a device
21 that it's equivalent to what's already on the market, you
22 may not be looking to demonstrate that the advantage is
23 there's a tenfold or a 10 percent reduction. You're looking
24 for equivalence because this is what you submitted to the
25 FDA.

1 However, getting back to the earlier statement
2 that Dr. Rutala made, if you're going to make a specific
3 claim, then you're looking at more than likely having to
4 provide a statistical argument for that claim.

5 I don't think the FDA is going to hold us to what
6 we're saying in terms of a number because they realize the
7 subtleties that are involved here.

8 MR. ULATOWSKI: As we approached the guidance
9 document back in the mid-'90s, we understood that claims
10 being made and how one approaches clinical evaluation would
11 be a very difficult situation. And we indicated in our
12 guidance that fundamentally everyone's making a baseline
13 claim that you're trying to provide a safe device that's
14 going to help prevent needle stick injuries.

15 And then beyond that, people may want to, for
16 whatever reason, want to make some other disease prevention
17 claim or something else that might incur additional
18 requirements.

19 I think with the discussion I heard this morning
20 and from your response, although it's not a question, it's
21 kind of the coming together of the need for data and is it
22 pre- or postmarket? And what are the numbers?

23 I think in terms of numbers, if the idea is it's
24 preventing needle stick injuries, well, to be able to show
25 that statistically in a significant manner would, depending

1 on your institution, may require some big numbers. And we
2 realize that, so we went to a survey, rather than calling it
3 a clinical study, with the type of traditional clinical end
4 points that one might see in studies, but rather look at a
5 survey and a user familiarity, user confidence sort of
6 outcome, rather than hard and fast incidence differences.

7 That may not be totally satisfactory and it has
8 not been, I think, for every institution because then they'd
9 move to do their own additional studies and collect more
10 data in their own institution. But I hear the interest in
11 clinical information, in following up on claims being made,
12 and that's very helpful.

13 DR. EDMISTON: Let me tell you where I'm coming
14 from. When a new product comes into my institution, as it
15 does into all of our institutions, before we accept that
16 product as part of our inventory we go through our product
17 evaluation committee and at some step there's evaluation
18 that occurs of that product.

19 I can tell you with the sharps issues that quite
20 often we don't have enough information to make that
21 evaluation. So it's been very difficult to get that
22 information.

23 This is a very, very difficult issue in terms of
24 designing appropriate trials that encompass enough warm
25 bodies so that we can reach levels of significance, even