

1 the manufacturers.

2 DR. WHALEN: Ms. Dubler.

3 MS. DUBLER: Is there any way to get
4 comparative information on the different manufactured
5 products in any of these publications, handouts,
6 whatever? In other words, if there were a real
7 difference in what the data showed about complication
8 rate for one of these manufacturers versus the other,
9 is there any way to bring that information to the
10 attention of women?

11 DR. RHODES: Well, in the labeling I don't
12 know that that would be our preference to have
13 comparative data but there are venues for information
14 like our handbook where we could have information
15 about all the products.

16 MS. DUBLER: I would agree. I don't think
17 it belongs in the individual sponsors labeling but if
18 that comparative information could be included some
19 place, I think it would be helpful.

20 DR. WITTEN: Well, I would just mention that
21 since each sponsor -- this is true in general for PMA
22 products or any other product that we regulate -- the

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1 sponsor studies are all different. They were
2 performed differently.

3 The protocols may be different. The
4 populations may be different. In general in terms of
5 doing direct comparison of one product versus another,
6 if the study was performed in a way to be able to
7 evaluate that comparison, it's really hard to draw
8 those types of conclusions.

9 MS. DUBLER: Well, maybe you could just
10 print both studies on opposite pages. I just think
11 that there are some differences in the data and I know
12 there are differences in protocol so it's not a one-
13 to-one comparison. If they could be placed in ways
14 that women could at least read them contiguously I
15 think it would be helpful.

16 DR. WHALEN: Dr. Blumenstein.

17 DR. BLUMENSTEIN: This is a thought that
18 I've had before and I don't know why I didn't think of
19 it before now but the web is just an absolutely
20 marvelous revolutionary tool for us. I've always
21 wondered are package inserts on the web? Should they
22 be on the web? I mean, just the raw package insert.

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1 Often times you go to a drug store and you get a drug,
2 you ask the pharmacist for it and they say, "We don't
3 have it. Come back later."

4 DR. BURKHARDT: I hear murmuring here that
5 says they are on the web.

6 DR. BLUMENSTEIN: They are? All package
7 inserts for all products?

8 DR. WHALEN: I doubt they all are.

9 DR. WITTEN: I think that would be up to a
10 sponsor in terms of putting it on the web. We put
11 summary of safety and effectiveness of each product on
12 the web and we also have this handbook available on
13 the web also. The FDA information is available on the
14 web.

15 DR. BLUMENSTEIN: I wonder if maybe that
16 shouldn't be some kind of a law for Congress to
17 consider or something.

18 DR. WHALEN: That will probably depend upon
19 whether the next President is the one who invented the
20 web or not.

21 Ms. Brinkman. **

22 MS. BRINKMAN: I'm back to the question I

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1 originally asked you about individuals that are
2 involved in putting this together. If someone such as
3 myself said I would like to be involved in helping the
4 FDA put this together, that would be permissible?

5 DR. WHALEN: Dr. Witten.

6 DR. WITTEN: If the "this" that you're
7 talking about is the label, it's really the sponsor's
8 label that we approve and we work with them to make
9 sure that it's in a form and has the content that we
10 would approve. That is really the sponsor's label and
11 we're working with them on it.

12 We do sometimes call on panel members to for
13 assistance with that but it's really more the
14 sponsor's label and our responsibility to work with
15 them to get it into an acceptable form. We are trying
16 to get some general advise right now that we can take
17 back and work with the sponsors and the individual
18 product.

19 Now, that's a different situation. If
20 you're talking about the breast implant handbook, I
21 think we would welcome some comments from that. We
22 can talk to you about that after the meeting.

1 DR. RHODES: In fact, we've solicited
2 comments for the handbook. We've sent out mailings to
3 organizations and professional societies asking them
4 to comment.

5 MS. BRINKMAN: And at this time you are
6 planning to update this?

7 DR. RHODES: It's being updated. It's
8 updated periodically.

9 DR. BURKHARDT: I'd like to ask the consumer
10 representative one question. Do you think it is
11 appropriate in general for companies, in this instance
12 implant companies, to market their product in the
13 usual commercial manner to perspective target
14 populations? In other words, I guess that's called
15 pull marketing instead of push marketing which is what
16 people used to do. Do you think that's appropriate?

17 MS. BRINKMAN: Well, whether it's
18 appropriate or not I think that -- well, I wish we
19 didn't but I think it's a fact of the market place
20 that they know their market and they go after their
21 market. Whether it's even appropriate for physicians
22 to advertise, I think it all comes back to those kinds

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1 of ethical decisions and we have no control over that.
2 If I had my druthers, of course not. Of course I
3 would not see ads for breast protheses or implants put
4 in magazines that were aimed at a young population.

5 I think unfortunately what we have the
6 potential to do which is very frightening is to turn
7 out to be akin to the tobacco manufacturers who have
8 seen a market in a younger population and that's where
9 the money lies so they have aimed products towards
10 that population even though they claim that they
11 don't. I think that's a very sad comment on our
12 society. I don't know if I answered your question.
13 Personally, no. It's a fact of life unfortunately.

14 DR. BURKHARDT: Thank you.

15 DR. WHALEN: Thank you, Mr. Rhodes.

16 We are going to break for lunch. I would
17 ask that we be back to start at 1:05 at which time we
18 will have our second period of public comment to begin
19 the afternoon session. Thank you.

20 (Whereupon, at 12:26 p.m. off the record for
21 lunch to reconvene at 1:05 p.m.)

22

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

1:10 p.m.

1
2
3 DR. WHALEN: Good afternoon and welcome back
4 to the panel discussion. We are going to begin with
5 the open discussion period for which we maximally will
6 have 30 minutes. I understand that one of this
7 morning's speakers will be speaking to us. There will
8 be a slight delay in that because there's a videotape
9 involved. I would ask if anyone else wishes to
10 address the panel and, if so, to raise your hand.
11 Just one individual?

12 Very well, ma'am. If you would care to come
13 to the podium, we can allow you five minutes.

14 DR. MELEZ: My name is Kathleen Melez. I
15 did speak Wednesday morning. The answers are the
16 same. I paid all my expenses. I do not receive any
17 funding from pharmaceutical industries nor from any
18 professional societies. I have a lawsuit against
19 Bristol Myers Squibb.

20 I am a physician from Los Angeles. I do
21 take care of breast implant patients. These patients
22 walk into emergency clinics and urgent care facilities

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1 because these patients have no physician and nobody is
2 following them so I do take care of them together with
3 anybody else who wanders into that clinic.

4 I am being paid on an hourly basis to
5 provide medical services for whoever comes into the
6 clinic. I don't believe that's a conflict of
7 interest. I have no conflict of interest with Mentor
8 or McGhan.

9 I would like to touch upon a couple of
10 things which came up during this last three days. I
11 would like to talk a little bit about advertising.
12 Drug advertising is a pain for us. It is getting to
13 be very, very difficult to take care of patients.
14 Patients come in and they know what they need.

15 Children come in because Citramax told them
16 on the Internet to tell Mommy to ask for Citramax if
17 they have an infection. Teenagers come in for birth
18 control which makes their skin pretty. "Do you need
19 birth control pills." "No, no." "Do you have problem
20 with your skin?" "Well, one zit in the nose."

21 In fact, you have warning if it's a magazine
22 you do have on the other side where they advertise the

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1 birth control pill to make your skin pretty, there is
2 a full printout of the FDA instruction. If you have
3 a magnifying glass, you can read all of the side
4 effects.

5 Now, do I read the PDR, the Physicians Desk
6 Reference? Yes, I consult it from time to time. I
7 don't read it all the time. I don't have time. I
8 don't think it should be necessary for me to do
9 independent research in drugs I use or when I have to
10 refill a medication which has been given to the
11 patient.

12 I believe the FDA did and should take care
13 of me anything which is in my hands to take care of
14 patients. Whether it's a drug or a device it should
15 be tested. I should not be getting into trouble and
16 causing harm to the patients because I did not do
17 independent research. Everything on the market for a
18 physician should be properly tested and should be
19 reliably manufactured.

20 Now I would like to talk and answer the
21 questions which a little bit which was raised to one
22 of the other speakers. What kind of a study would you

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1 want? Well, you want a life-long study. If you have
2 a patient with a foreign implant you need to know
3 about it. In fact, any other implant patients they
4 knew, they carry around their medical records.

5 That patient, whether this is now a joint
6 implant or a heart valve, gets special attention even
7 if they come in for a cold or a fever or the flu
8 because you know if you have an infection, for
9 instance a gram negative infection of a device, then
10 that patient looks okay one day and a couple of hours
11 later can die from a gram negative sepsis.

12 I ask patients, "Do you have any device in
13 your body?" If they do, then I do a much bigger
14 follow-up even though they most of the time don't need
15 it. That is, blood cultures and blood tests and an x-
16 ray around whatever this foreign body is.

17 Now, the body is forever fighting a foreign
18 body. It doesn't want to give up and won't give up.
19 You see, when you remove breast implants, 15, 20, and
20 30 years still have those cells, the foreign body
21 cells around. If those cells are not from 15 years
22 before, they continuously try to get rid of it if

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1 possible. You see this in the clinic.

2 There are a lot of reported incidents. You
3 know there are even a lot of things that don't get
4 reported. For instance, cat gut which is absorbable,
5 suture material, they sometimes come out years later
6 and you pick them out from an abominable wound little
7 by little by little.

8 Screws, bone screws. Who knows why 10 years
9 later the body will reject that bone screw. Yes, as
10 long as we have an implant in place, we have to be
11 very vigilant from a medical point of view.

12 Now, from the experimental point of view as
13 I believe that this autoimmune problem is related to
14 a foreign body reaction similar to what the
15 experimental animals had. You know, you varied the
16 critical picture by varying the small particle, by
17 varying the bacteria. That explains why sometimes you
18 have a very late reaction.

19 Now, I also have a very small sample
20 observation of one, myself as a physician, and I did
21 not have any problems for 10 years. Apparently I got
22 loss after five years. Georgetown University sent me

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1 all these questionnaires and I always answered I had
2 no problems.

3 Since then I am probably one of those people
4 forever who have no problems on all of those lists.
5 I tried to do something about it and I wrote a letter
6 to the Institute of Medicine when I had problems 10
7 years later and I never received an acknowledgement of
8 that letter.

9 Very, very quickly I would like to touch
10 upon the insurance issues. Now, I was diagnosed with
11 breast cancer when I was a NIH fellow in 1985. The
12 NIH radiology diagnosed me. The NIH plastic surgeon
13 did the biopsy. The NIH pathologists, two of them,
14 reviewed the slide talk to me. Of course, the
15 insurance provided by NIH covered for my surgery at
16 Georgetown University.

17 About a year later after numerous other
18 problems with little lymph nodes and this and that and
19 mammograms, they said that I have fibrocystic disease
20 which probably was just foreign body reaction. I had
21 a second mastectomy on the other side and all of this
22 was paid not like 10 years later when I had problems

1 and finally I realized that this may be related to the
2 implants in 1996. In California the law provides for
3 reconstructive surgery after cancer surgery so --

4 DR. WHALEN: Doctor, please come to a
5 conclusion.

6 DR. MELEZ: I'll finish this. The insurance
7 company paid partially for one breast and refused to
8 pay for the other breast. Now, do you want to remove
9 one breast implant and leave the other one in place?

10 DR. WHALEN: Are there any questions? Thank
11 you.

12 Next we will hear from Ms. Jama K. Russano
13 from Children Afflicted by Toxic Substances and this
14 will be for 10 minutes, please.

15 MS. RUSSANO: Thank you. I'm sorry for the
16 delay. New York planes can always be troublesome. I
17 took a wonderful taxi cab ride around the Washington,
18 D.C. area trying to find it so at least I arrived but
19 a little frazzled so bear with me.

20 I basically had a breast implant at the age
21 of 14, the silicone gel implant, one on the right
22 side, due to a birth defect called a hemageoma tumor

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1 that was removed and the breast bud was removed along
2 with it. When I was 14 I hadn't developed fully on
3 both sides. I went to a plastic surgeon and they said
4 that it would be perfectly fine to have a breast
5 implant. This was in 1971, SILASTIC I implant, gel.

6 DR. WHALEN: Forgive my interruption but
7 since you weren't hear this morning, I don't expect
8 you to be acquainted with this. There are four
9 questions.

10 MS. RUSSANO: Yes, I'm going to get to the
11 saline one.

12 DR. WHALEN: If you could answer the
13 questions first, that would be great.

14 MS. RUSSANO: Oh, sure. I'm sorry. I am
15 the Director of a children's nonprofit foundation,
16 CATS, Children Afflicted by Toxic Substances. It is
17 not affiliated with any attorneys. I paid my own way.
18 I am going to talk about the affect of saline implants
19 on children. The other question was litigation. I
20 have filed suit in the Dow Corning bankruptcy for
21 silicone breast implants. I do have two children that
22 I breast feed and gave birth to while I had my

1 silicone implant.

2 The reason I'm here today based on saline
3 implants is over the last eight years I started
4 gathering information concerned about children born to
5 mothers with breast implants on nursing and pregnancy.
6 I was at an FDA hearing in 1992 or 1991 and I was
7 basically surprised that there was no data showing
8 research that had been compiled over the number of
9 years identifying the safety of breast feeding and
10 pregnancy. Also of young women implanted with breast
11 implants like I had.

12 In that data of collecting over the last
13 eight years, and more so in the last past few years,
14 more women have had saline implants and more and more
15 women have contacted us. Many women have contacted us
16 asking if it is okay to have implants and can they
17 breast feed and get pregnant. Or they have had saline
18 implants and their doctor has told them that it's
19 perfectly safe to get pregnant and to breast feed.

20 I think that it is very upsetting to find or
21 hear when doctors just haphazardly state with no basis
22 behind it that it is perfectly okay. I know earlier

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1 this week that there was a mother here with her two
2 daughters that she had breast fed and this young girl
3 had seen the Oprah show and I would like to show you
4 this little segment of the Oprah show concerning
5 plastic surgery and young girls.

6 (Whereupon, video shown.)

7 MS. RUSSANO: The plastic surgeon stated
8 that if a young girl understands the reason she wants
9 implants and has underdeveloped breasts she can have
10 surgery. This is not like having braces. This is not
11 like getting your ears pierced.

12 To date there is no scientific data that has
13 followed young girls having breast implants or any
14 cosmetic surgery and long-term health effects. They
15 do not know if implants can do more emotional harm
16 from being teased for bigger breasts or will she
17 become promiscuous having sex at an earlier age. ~~What~~
18 kind of emotional scars will she have when her
19 implants rupture? Or when she wants to feed a baby
20 and finds out that she can't because her nerve endings
21 have been cut and she was*never told that? Or the
22 doctor says it's perfectly safe with absolutely no

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1 data to back that statement up?

2 Does a young girl understand the importance
3 also of losing sensation in her breasts at such an
4 early age? Does she play sports or is she active
5 placing her at greater risk or rupture? The mother of
6 the girl with implants stated she met with four
7 doctors and asked many questions. Clearly she was
8 told it was safe to get pregnant and breast feed. The
9 young 19-year-old girl asked the doctor directly is it
10 safe to breast feed with breast implants and the
11 doctor replied yes, it is perfectly safe to breast
12 feed.

13 Where does he get this information? There
14 are no studies that state the safety of breast feeding
15 with saline-filled silicone breast implants. When we
16 contacted the FDA about this doctor's behavior, we
17 were told that the FDA has no jurisdiction. It is
18 clear that the doctors and manufacturers of saline
19 implants work off of one another.

20 The package insert of Mentor states, "It is
21 not known if it is safe to breast feed." I don't
22 understand how a doctor can turn around and say that

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1 it is perfectly safe. Manufacturers are playing and
2 the doctors seem to be playing off of each other.

3 If they can put the slides up.

4 DR. WHALEN: You're going to need to come to
5 a conclusion, Ms. Russano. It has been the full 10
6 minutes.

7 MS. RUSSANO: Oh, it has? All right. The
8 point is that breast feeding today and young girl's
9 health has not been established in the safety of
10 pregnancy and breast feeding. It has not been
11 established over long periods of time with hormones
12 changing. There is not one single study out there
13 that identifies these issues.

14 There is an Executive Order by President
15 Clinton that was written in April of 1997 stating that
16 all federal agencies must put the health and safety of
17 children first. The health and safety of these
18 children that are going to be over probably close to
19 500,000 children in the next five years -- I'll be
20 happy to provide the panel with my speech and the
21 documentation that I have showing the number of
22 children -- are going to be out there basically

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1 floundering through the system.

2 Doctors don't know how to treat them. They
3 don't know how to identify them. If a child goes in
4 for a fungus or a headache or toxic shock syndrome,
5 they don't even know -- they don't even think to
6 identify that this problem could be related to their
7 breast implants.

8 I ask the panel that if they do allow saline
9 silicone-filled breast implants on the market that
10 they make a clear statement that breast feeding and
11 pregnancy, there is no research and the risks are
12 unknown. And that they also put a very clear
13 statement that women of young age in their teens, that
14 there is no data showing safety. Also there is no
15 data showing safety of women of childbearing age.
16 Thank you.

17 DR. WHALEN: Are there any questions?

18 DR. BURKHARDT: I have a question. Is it
19 your position that women in their teens or of
20 childbearing age should not be allowed to have these
21 procedures?

22 MS. RUSSANO: Yes, it is. Actually, they

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1 are being targeted by the plastic surgeons in various
2 ads. I have copies of those ads. I think that not
3 only this show but Britney Spears is 17 and she had
4 saline implants put in. There has been a number of
5 news articles or news shows saying how perfectly safe
6 and they are cute and bouncy.

7 DR. BURKHARDT: Just to make is clear to me,
8 it's your recommendation that they should not be
9 allowed to do this?

10 MS. RUSSANO: They should not be allowed to
11 do it and there is no scientific data that proves that
12 it is safe for them to do it.

13 DR. WHALEN: Just to clarify the "they,"
14 once again, I want to make sure you heard what Dr.
15 Burkhardt asked. He said teens and women of
16 childbearing age.

17 MS. RUSSANO: Yes. Teens --

18 DR. WHALEN: Just to be inclusive then, that
19 would mean the only population we haven't talked about
20 are zero to 10 and postmenopausal women.

21 MS. RUSSANO: I guess so.

22 DR. WHALEN: Is it your recommendation that

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1 no women should ever have a breast implant?

2 MS. RUSSANO: Until they are absolutely
3 proven safe and long-term studies identify that I
4 think --

5 DR. WHALEN: I just wanted to clarify.

6 MS. RUSSANO: That's what it should be.

7 DR. WHALEN: Thank you.

8 MS. RUSSANO: Thank you.

9 DR. WHALEN: Are there other questions?
10 Very well.

11 I would like to ask Mr. Rhodes if he can
12 plug his computer in to start projecting the questions
13 and we will indeed begin doing that.

14 DR. BURKHARDT: Mr. Chairman, at this point
15 I am not really clear about what our charge is. I
16 understood what our charge as a committee was up
17 through the PMA process yesterday. Could you or the
18 FDA clearly define what charge this committee carries?

19 DR. WHALEN: Dr. Witten is excited and
20 anxious to do just that at this very moment.

21 DR. WITTEN: Yes. I appreciate your asking
22 the question because we want to make sure that it is

1 clear. As I mentioned this morning, at the time that
2 a PMA is approved all the labeling that the sponsor
3 has, and that is generally interpreted as not just the
4 actual package insert but the package insert for
5 physicians, any kind of patient information that
6 accompanies it, any kind of promotional material, all
7 that material would need to be approved by us.

8 What we want to know is in particular for
9 the patient information that is going to be
10 accompanying these products, what kind of information
11 should go into the patient information in particular,
12 but more generally also what kind of information would
13 be helpful to have go along with these products so
14 that information would most clearly explain the risks
15 and the benefits of the product.

16 For example, the first question which says,
17 "Provide specific suggestions on important information
18 to include in each element to the Patient Informed
19 Decision-Making Outline, in particular, important
20 information regarding adverse experiences."

21 The decision-making outline, which was on
22 the web site and has been passed around to you, has

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1 what we have considered at the FDA in thinking about
2 it and thinking about what we've heard from patients
3 and physicians and sponsors over the last several
4 years that we have been considering this question. It
5 contains what we think are elements that ought to go
6 into patient information that accompanies a breast
7 implant.

8 It's really just sort of a list of the kinds
9 of information that we want in there. The way in
10 which the information is presented, some of the
11 questions, for example, that have related to the fact
12 that there have been a lot of numbers presented in the
13 PMAs but how would you present that in a clearer way
14 so that someone could understand what those numbers
15 meant. That kind of recommendation would be helpful
16 from you. Is that clear? Is that clearer I should
17 say?

18 While we are on the first question, can I
19 add something? As I've been listening there is
20 actually two other things. As you answered this first
21 question there are two other things that would be
22 helpful to address that I think fits in this question.

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Based on the things that we've heard both from the patients today and from the physicians, the numbers -- although originally when we wrote this question I think we were thinking about how to frame the numbers maybe so that they would explain things.

One point that has been brought out several times is that the numbers alone perhaps don't exactly tell the full story. There was both a patient and a physician who said when one of these adverse events happens to you, it's 100 percent. Unless the patient has an idea of what that adverse event might mean, it's a little bit hard to interpret the numbers alone.

So it's specific for this question not just in terms of describing the data but if you have any suggestions about how to present the adverse events, both the ones that have cosmetic consequences that are thought to be fairly minor as well as cosmetic consequences, for example, of removal I think would be helpful to us.

I'll just say after you answer this question about adverse events, I'm going to ask a follow-on

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1 question about how to describe the cosmetic benefits
2 of these products also, how they should be most
3 accurately presented in labels.

4 DR. WHALEN: Thank you, Dr. Witten.

5 So we are presented with the first question
6 as projects which is, in my opinion, the most far
7 reaching of the five questions. I think it's probably
8 appropriate that we begin the discussion of this with
9 Ms. Brinkman if you would.

10 MS. BRINKMAN: If it's okay with you, I
11 would like to go home and spend several days working
12 on this.

13 Obviously I think some adverse effects that
14 need to be looked at are those that we need to again
15 talk about, what is product specific, what's procedure
16 specific such as capsular contracture maybe or
17 procedure deflation, infection, the kinds of things
18 that we brought up in the past for adverse effects and
19 then appropriate data to go with those to talk about
20 incidence.

21 DR. WHALEN: Let me just interject if this
22 is acceptable to you, Dr. Witten. Rather than our

1 usual PMA type questions where I try to do a synopsis
2 and ask for your blessing, I think this is more
3 cataloging of the panel's opinions and impressions so
4 we'll just flow with all of our answers as long as it
5 takes. I will ask if you have been satisfied with
6 what we've said but I will not attempt to encapsulate
7 it.

8 DR. WITTEN: I think that will be fine.

9 DR. WHALEN: Thank you.

10 MS. BRINKMAN: Actually, I have a long
11 laundry list of comments from consumers and other
12 groups that I would like the opportunity to rewrite
13 and give to the panel but not right this second.

14 DR. WHALEN: Ms. Domecus.

15 MS. DOMECUS: I think the adverse experience
16 information needs to be written in a way that tells
17 the story for the patient and isn't just tables with
18 numbers, although I think that is important, too. I
19 was just trying to understand even the Kaplan-Meier
20 numbers represented as part of the presentations
21 yesterday and the percentages look alarmingly high.

22 When you see 33 percent of patients had

1 breast pain by four years, does that mean one in three
2 patients had excruciating pain for four years or was
3 99 percent of that one week postoperatively? I think
4 things need to be explained in more paragraph form.

5 For instance, x percent of patients
6 experienced breast pain. This majority of them has
7 gone by one week or one month and x percentage of them
8 the pain is so bad they need to go on and have
9 surgery. If they have that surgery, you know, that a
10 second surgery can be more risky than the first,
11 etcetera, etcetera.

12 My other thought is I think that the
13 labeling should clarify that the studies had a high
14 loss to follow-up rate and that may not appropriately
15 reflect the risks.

16 I was concerned by all of the public
17 testimony about patients being told by their doctors
18 that their symptoms aren't related to the implants and
19 so it was very frightening to hear in light of the
20 lost to follow-up rates.

21 DR. WHALEN: Dr. Morykwas.

22 DR. MORYKVAS: One thing that I think a

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1 little care needs to be taken with is actually in the
2 1995 announcement in the Federal Register is as far as
3 other reconstruction options to me I think is
4 misleading the way that it's written that it implies
5 that -- it doesn't state that there is flap surgery
6 available. It just states really that there is fat
7 transplantation that is available for reconstruction.

8 I just think that any references back to
9 that shouldn't use that particular wording and really
10 should make other surgical alternatives explicit in
11 that there are other surgical procedures such as flap
12 surgery available.

13 DR. WHALEN: Thank you.

14 Dr. Chang.

15 DR. CHANG: I believe that on a practical
16 level very few patients receive package inserts before
17 surgery. For myself it's not sure if someone will
18 receive a 280 or 290 or 300 cc implant so the specific
19 package will not be opened before the patient is in
20 the OR. I believe on a practical level any
21 information that is provided to the physician that is
22 provided for information as a package insert be

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1 available for the patient before they are arriving in
2 the OR.

3 I believe that it would be helpful to
4 someone considering surgery to have some numbers based
5 on the product specific to the sponsor of what the
6 experience has been for deflation rates. To me that
7 would be the most important device related outcome
8 that could be provided to the patient.

9 Then finally, again it will be dependant on
10 the communication and listening skills, both physician
11 and patient, in terms of what is actually communicated
12 and what is received. There are going to be those
13 complications not entirely related to the device but
14 rather to the surgical technique. Again, the more
15 information the public has in terms of asking about
16 the qualifications of their physician who is going to
17 be implanting this device is important.

18 DR. WHALEN: I would like to comment myself
19 for a change and just mention a few things in terms of
20 informed patient decision making. The issue of
21 insurance has been brought up several times. I don't
22 know that FDA has either the authority nor the

1 resources to investigate those sorts of issues across
2 the multitude of insurers that there are across the
3 country. I would further add that I don't think that
4 even should be done because, quite honestly, I
5 wouldn't believe anything that the insurance companies
6 were to tell you. Even if they told you, they would
7 probably change it a week later.

8 I do think that since we have heard
9 testimony today that insurance companies are indeed
10 denying coverage to patients and potentially even
11 denying life insurance based upon having these
12 implants, that is an extremely important element for
13 a woman to know at any age if she were to try to make
14 a decision in this regard.

15 I think that is the type of element that
16 should be in bold print. The phraseology obviously
17 has to be carefully worded and I'm sure that the
18 Health Insurance Association will have some comments
19 upon your trying to do that.

20 The issue of children, which is teenagers,
21 is closer to my heart as a pediatric surgeon. Since
22 there is within FDA's purview oversight of the

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1 advertisements that are done, I think the most
2 stringent views should be taken on any advertisements
3 even considering the venue of those advertisements if
4 even the appearance or illusion is created that there
5 is trying to be an attraction on the sponsor's or
6 manufacturer's part towards inducing teenagers with
7 all the hype that was just well articulated in terms
8 of their body image taking place in those critical
9 years.

10 We heard many tragic stories about women
11 with connective tissue disorders. Everyone on the
12 panel, I think, is well aware of the evidence.
13 Everyone on the panel is well trained in scientific
14 methods. Nevertheless, one of the things I often tell
15 my surgical residents who just can't understand why
16 they are regarded as arrogant, believe it or not, is
17 that perceptions are 99 percent of reality.

18 While we can't chase every perception, these
19 are very heart-felt issues. Indeed, if we're talking
20 about a complication that occurs rarely being 100
21 percent to the person who it occurs to, then I think
22 there should at least be allusion to the fact that

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1 there are multitudes of women who are convinced that
2 their CTDs are attributable to these devices and that
3 should be considered in the decision-making process.

4 Finally, it is difficult, if not impossible,
5 if not even illegal, that the FDA tries to clamp down
6 on the physician element of this critical exercise
7 which is making a breast implant. The manufacturer is
8 probably the smaller part of the equation.

9 While there are inherent difficulties in
10 that, I would strongly urge that FDA and other
11 appropriate Government agencies work with leading
12 national surgical organizations and other medical
13 organizations on trying to refine the consent process,
14 not the consent documents and the consent information
15 nearly as much, and to encourage perhaps through other
16 federal agencies that there be outcome analyses of
17 exactly what that consent process is.

18 Dr. Burkhardt.

19 DR. BURKHARDT: I have a number of comments.
20 The question of insurance is devastating, as you say,
21 if the information we have received today is true.
22 I'm not sure that it is. Until I came to this -- and

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1 I'm not suggesting that anybody is being untruthful,
2 but perceptions differ.

3 Until I came here today I had never heard of
4 a patient who was denied health insurance or life
5 insurance on the basis of their breast augmentation
6 procedure. If that is indeed the case, I think it
7 certainly needs to be looked at.

8 If that is becoming something in the
9 industry that we need to worry about, I agree that
10 should go in the consent forms. I question whether
11 that is indeed the case. Most insurance people I've
12 talked to would be happy to sell you insurance
13 regardless of what kind of shape you're in.

14 The patient information issue with all the
15 comments today there's been an overriding concern from
16 people that they were not warned about things by their
17 doctor or by the company. The things that they were
18 not warned about fell into two classes. The first
19 class was problems that were probably related to the
20 implant. Secondary surgery, deflation of the implant,
21 firmness of the breast, and so forth.

22 There is a large group of problems that they

1 were not warned about which they weren't warned about
2 because we don't think they are related to implants.
3 I think that the FDA has to take into consideration
4 the fact that it is inappropriate to warn people about
5 illnesses that they may think are caused by implants
6 but there is really no scientific evidence of any sort
7 for that.

8 The presentation of numbers is a particular
9 problem. Mainly because for a lot of the
10 complications and numbers we're talking about there is
11 no easily defined end point. Now, when a saline
12 implant deflates, there's not much question about the
13 end point. It is clearly diagnosable and discernable
14 at that time.

15 The other major complication that we're
16 dealing with is called capsular contracture which
17 appears to be hardening of the implant. We have to
18 realize that even with the so-called Baker formula
19 which classifies this into four different degrees of
20 severity, the classification is entirely subjective on
21 the part of the examining physician.

22 Our literature shows that patients who are

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1 examined by the operating surgeon are much less likely
2 to have this problem than the same patients who are
3 examined by an independent authority. This is a
4 normal bias that is built into our studies and I just
5 don't know how you could avoid it.

6 In addition, in my own studies which have
7 not been introduced in evidence here but in controlled
8 studies that I did the incidence of significant
9 capsular contracture, significance hardness of the
10 breast at three and four years in a controlled study
11 varied from zero to 40 percent depending on the
12 particular type of implant and the particular type of
13 surgical technique that was used. I'm not talking
14 about good technique versus bad technique. I'm
15 talking about options in surgery.

16 How on earth the agency can try to get a
17 handle on this kind of problem in terms of rather
18 simplistic number presentation, I don't know. I would
19 be happy to help with it but I just don't know how you
20 could do it.

21 It seems to me that one of the biggest
22 problems that I keep hearing from the public in these

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1 things is the spin that is being put on breast
2 implants. It's the encouragement of the population to
3 undergo unnecessary surgery for cosmetic purposes and
4 the surgery does have a significant incidence of
5 complications. I think we all believe that.

6 Doctors do that. Some are qualified and
7 some are not qualified. By the grace of the Justice
8 Department we now advertise. We have very little
9 control over advertising except for ordinary
10 commercial standards which are applied to us like they
11 are applied to other people.

12 I don't think the FDA can do very much about
13 advertising that physicians do. I am greatly
14 concerned about the tendency at the present time in
15 direct marketing to patients. I don't think there is
16 any way that an implant company can go to an
17 advertising agency and say, "We want to sell implants.
18 You work out our advertising for us," without putting
19 a very positive spin on that advertising.

20 I think it's very difficult to ensure what
21 the agency has previously referred to in these
22 hearings as a fair balance. How do you ensure that

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1 marketing, which is designed to sell a product, is
2 done with a fair balance in this kind of situation.
3 I don't know.

4 I do know that the brochures that were
5 passed around today from both implant companies showed
6 some beautiful pictures. They showed pictures of the
7 way people would want to look. They did not show
8 pictures of disasters, of implant cripples. I'm not
9 sure that if you put -- I've got some pictures that I
10 could show you that are awful from my own practice.

11 If those pictures are put in there, does
12 that inappropriately discourage people from having an
13 operation that is generally quite satisfactory for the
14 great majority of individuals who undergo it. I don't
15 know what the answer is to that. I think it's a
16 reasonable regulatory decision and I just can't deal
17 with it.

18 In regard to whether marketing should be
19 directed at all to teenagers, I would just suggest to
20 the Chairman with great difference on my part that we
21 might use the word minors because 19-year-olds in many
22 places feel that they are able to make this decision.

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1 They are in the majority. They have reached majority.

2 DR. WHALEN: Thanks, Dr. Burkhardt. If we
3 could interject for a moment, I understand there is
4 some information that may be able to be provided to us
5 on the issue of insurance with a little bit more than
6 the suppositions either one way or the other that we
7 have just experienced. We would reinvite Dr. Leroy
8 Young from the Plastic Surgery Educational Foundation
9 who has investigated this issue back to the podium.

10 Dr. Young.

11 DR. YOUNG: I don't think any of my conflict
12 of interest have changed since the other day. I had
13 my secretary contact Blue Cross/Blue Shield and United
14 Health Care in Missouri, who are the two largest
15 providers in that area, and asked the question of how
16 breast implants affect your ability to both get
17 insurance either for reconstruction or having had it
18 for aesthetic reasons in general and both related to
19 your breasts.

20 The answers that we received is that United
21 Health Care, first of all, does not ask applicants if
22 they have had either cosmetic or reconstructive

1 surgery with implants and they do not exclude
2 applicants that have had implants for either of those
3 reasons.

4 Now, they are able to put a rider onto that
5 to say that they will not cover complications of
6 cosmetic surgery but they tend to cover things such as
7 rupture of implants to have the implant removed but
8 not pay to replace it.

9 In the case of Blue Cross/Blue Shield, again
10 they won't exclude you from having insurance. They
11 may put a rider on your policy about your breasts.
12 Usually there is a time limit on that that says if you
13 don't have a problem within some time of a year to
14 five years, then they will drop that requirement.
15 They are prevented by law from excluding people from
16 having insurance.

17 I have the names of the attorneys
18 from the two companies that I'll be glad to give you
19 if you want further information with regard to that.
20 I'm sure they can provide additional detail. That is
21 sort of a capsule summary of the situation. People
22 are not excluded from having insurance. Thank you.

1 DR. WHALEN: Thank you.

2 MS. BRINKMAN: That's limited to Missouri
3 and to those two companies that he talked to.

4 DR. WITTEN: Excuse me. I'll just say that
5 it might be helpful to focus on some of the other
6 issues because I think we've talked about the
7 insurance enough that we recognize there's an issue
8 and I'm not sure that there is anything more that
9 could be said right now that would really help us.

10 DR. WHALEN: Very well.

11 Dr. Bandeen-Roche.

12 DR. BANDEEN-ROCHE: Thank you. A couple of
13 general comments first. I strongly support each of
14 Dr. Dubler's recommendations that were so eloquently
15 stated. That would certainly include being sure to
16 include information sources -- I'm sorry, independent
17 sources of information, preferably right along with
18 the packet of information the patients receive.
19 Perhaps FDA's information would be one good example.

20 I would also very, very strongly recommend
21 that formal evaluation is needed to determine whether
22 there is a reasonable assurance that patients are both

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1 receiving and reasonably comprehending the information
2 that they receive.

3 Let me see. Now, in terms of a couple of
4 general comments on the overall types of data that
5 should be included, I strongly agree with the comments
6 to the effect that wherever there is a lack of solid
7 scientific knowledge, that this should be made
8 explicit.

9 I think that the IOM report serves at least
10 a reasonable template for doing that so that women do
11 not get the impression that, for instance, the rate
12 and severity of long-term complications have solid
13 coverage in the epidemiologic literature and,
14 therefore, they must rely on their physicians and
15 whatever other data sources as that sort of
16 information accrues.

17 In terms of a couple of specific comments on
18 the applications that we saw, my impression was that
19 the Mentor application had a pretty good narrative
20 summary in terms of the comprehensibility of
21 describing it's data, but very little actual data, at
22 least in the version that I saw, whereas McGhan was

1 sort of the opposite. They had extensive data tables
2 that looked like they were straight out of the PMA.
3 Yet, the test was so dense that I worry that many
4 would not be able to follow it.

5 I think that the extensive data should
6 appear but should be accompanied by clear bulleted
7 text describing major rates in way that patients can
8 understand. This is a simple suggestion but, you
9 know, you look in one of the applications and it says
10 that there is something like 8.9 percent rate of
11 reoperation within the first three years. I don't
12 know if that would mean more if one were to say that
13 the estimate is that approximately one out of every 10
14 women will have a reoperation within however many
15 years. Something like that might be helpful.

16 I strongly feel that there should be some
17 overall summary of adverse experience. Now, I'm not
18 the one to define what counts as an adverse
19 experience. Certainly if Dr. Burkhardt doesn't know
20 how to do it, I don't know how to do it. I do think
21 that it can be wrestled with and that an appropriate
22 summary measure can be defined and given.

1 Specific to both of the applications, there
2 is a list of most common risks including deflation and
3 capsular contracture and that sort of thing. Then
4 there is a section that's called other risks and sort
5 of in the middle of that reoperation appears. I would
6 strongly recommend that other surgery is not sort of
7 an other risk. It occurs at the same rate as the most
8 common risks and needs to be identified as such.

9 Then the final thing would be the issue of
10 -- I thinking about the younger women. How do you
11 make them pay attention and take the material
12 seriously. You probably need some sort of a hook.
13 Here is why you should pay attention. Be it that
14 while there are many women who experience very good
15 outcomes, remember that this is a permanent thing that
16 you are going to do. I don't know exactly how to do
17 it but it does seem to me that some sort of
18 consideration about that is needed.

19 DR. WHALEN: Thank you.

20 Dr. Boykin.

21 DR. BOYKIN: 'Since I do a lot of
22 reconstructive breast surgery, I can't say enough

1 about how important I think this whole process is. I
2 envisioned this as a three-sided relationship between
3 the experience and maturity of the surgeon which we
4 have little control over, the limitations of the
5 device which I think we've tried to understand with
6 some great degree in the last couple of days in which
7 we intend to expose to its fullest degree as clearly
8 as we can.

9 The third side, of course, is given the
10 situation of values, choices, and education of the
11 patient. I think that what we can do is provide
12 patient education, at least in the limited forms, and
13 try to control those other avenues of education that
14 may falsely imply security when it isn't there.

15 One of the things that I have to say if you
16 want to talk about graphic details or trying to really
17 get to the meat of the subject, patients that get
18 involved with breast implants need to understand that
19 this is a life-long road. Once you put these implants
20 in, whatever you decide to do with them is going to
21 irreversibly change the shape of your native breast
22 tissue.

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1 I've had to take many of these out over the
2 years and I can tell you that the ladies that have had
3 them removed have not been happy and they look
4 deformed. They are not happy about this and it
5 doesn't get any better at all. Somewhere in this
6 message we need to let these young ladies understand
7 that this is not a short-term relationship.

8 I believe the studies show that the
9 integration of this with the body image takes about
10 six weeks. I actually had a patient who lives out of
11 the country who came back after having implant surgery
12 extremely happy with herself. After a couple of years
13 she said, "I want my implants taken out." I looked at
14 her and I said, "Do you really understand what you're
15 saying?" She said, "Sure. I'm doing fine and the
16 kids are healthy and everything. I just want you to
17 take them out. I just don't want to have to worry
18 about them anymore."

19 I tried to really spend about an hour
20 explaining to her what a different situation this
21 would be and how dramatic it would be. Of course,
22 she's a very intelligent lady, very strong willed. We

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1 proceeded and I took them out.

2 Within 24 hours I got a frantic phone call,
3 a very depressed woman and her husband showed up at my
4 office the next day and we had to reimplant her.
5 She's done quite well but the reality of having the
6 change in her breast parenchyma because of the
7 implants was more than she could handle.

8 This is the road that we get on with
9 patients. This is why there is so much of an outcry
10 of betrayal because they don't understand that this is
11 not a real two-way street. The objectivity of all of
12 this data is lost. When I see patients for this
13 operation, I say, "You can read the statistics but as
14 far as we're concerned, it's either zero or 100. You
15 either don't have a problem or you've got a problem
16 and it's the worse thing in your life because these
17 breasts are important to you." And they are.

18 So given that, perhaps consideration should
19 be given to some illustration of these complications.
20 I don't know how we can do this in a tasteful way and
21 not offend the patients and certainly do something
22 that will be meaningful even to the manufacturers.

1 I also have to say that in terms of
2 insurance, in Virginia we have problems. We have
3 patients who may get insurance but they move out of
4 the category of healthy American down to a lower level
5 because they've got the implants and their premiums go
6 up. I have had one patient that I've had to assist in
7 trying to regain health insurance because she was
8 denied.

9 The complications should be outlined as we
10 have mentioned and, as Karen has brought up, it's not
11 just mentioning the complication but I think it's
12 important to tell them what happens after you have
13 this complication. If you have a capsular
14 contracture, this is how a capsular contracture is
15 handled. You may require another operation.

16 You will have an incision made on the
17 breast. The implant will be removed and at that time
18 a series of events will take place to put you in a
19 different category. I think the complications need to
20 be spelled out but the way that they are handled
21 surgically need to be explained so that the patient
22 will have the education up front about how these

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1 things will move along.

2 A recommendation was made for reoperative
3 mammography and I don't think that's a bad idea. I
4 the adult female patient who is below the range for
5 routine surveillance for cancer, it might not be a bad
6 idea to have a good mammogram before you commit to
7 this operation.

8 There is a very low likelihood of showing
9 anything, at least from our statistics, but at least
10 the next person to do the study will have something to
11 feel more comfortable about when they look at the scar
12 patterns within the breast parenchyma. That's just an
13 idea.

14 Having said all of that, I really think that
15 the idea of the registry is an important one. I think
16 that we need to carefully consider how we can create
17 a secure registry for the data on all patients
18 receiving these implants.

19 After they have gone through this extensive
20 informed consent process and finally decided they are
21 willing to take all of these risks that they can rest
22 assured that if they have a problem, they can

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1 communicate with an agency whether it's the FDA, some
2 educational foundation, or maybe both that will not
3 only respond to them but ensure that this information
4 will be shared in a meaningful way.

5 DR. WHALEN: Thank you.

6 Dr. Blumenstein.

7 DR. BLUMENSTEIN: I just want to say one
8 more thing about insurance. I feel like we're kind of
9 in a data freezone here. We have fragments of
10 information but I don't think we have a definitive
11 answer yet. The main thing I wanted to say about
12 insurance is that it really is kind of a risk and
13 perhaps should be characterized as a risk in the
14 package insert. It is a risk that has the same
15 magnitude and possibility of affecting life as some
16 the other things we've talked about.

17 As I've thought about this, there is a
18 couple of other things, general things. It seems to
19 me that as we've talked here that risk versus benefit
20 has a lot less distinction here than it does in some
21 other kinds of mileus. **

22 As an example, asymmetry has been

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1 characterized as a risk but really is a thing of
2 efficacy. I think that perhaps as the thing is
3 written that there could be a little bit more of an
4 effort to try to identify things, less as risk versus
5 benefit and more as events.

6 I think in terms of the events that do
7 happen, I think there could be better identification
8 of the course or the attribution of the event whether
9 it's due to the device or due to the surgeon and so
10 forth. I think that would help potential recipients
11 of implants because it would show them the things for
12 which they might want to take more care with respect
13 to surgeon selection versus device selection.

14 I think there needs to be a better
15 distinction between what I call bad things and events.
16 In other words, the things that are truly bad should
17 be identified as such -- clearly identified as such.
18 The things that are just events like maybe a revision
19 for sizing and things of that nature should be
20 identified in that fashion.

21 Going on to some more technical details, I
22 think that always we should be using actual estimates

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1 and that these actual estimates should be accompanied
2 with the various caveats that we've heard throughout
3 all of this. That is things like informative
4 censoring, lack of independence between censoring and
5 events and stuff like that.

6 I believe that the most useful statistic to
7 feature is the overall risk of a bad thing. There may
8 be several ways of doing that. For example, you may
9 want to talk about the bad thing being a permanent
10 explanation without replacement is one bad things,
11 whereas another bad thing might be any kind of surgery
12 and so forth. I think that needs some careful thought
13 and especially with respect to the classification of
14 various items.

15 A third technical item that I would like to
16 mention is that I believe it is much better to
17 represent the individual risks as cumulative incidents
18 even though those they still suffer from the same
19 caveats that we've talked about before.

20 Finally, two more points. I have been aware
21 of some research in nursing where they've studied the
22 process by which patients record the dialogue, either

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1 video or audio or both, with the healthcare provider
2 as they are making a decision as to whether to proceed
3 with the particular procedure. I think we could
4 encourage patients to do that. That would be
5 something that the patient could take home with them
6 and review later, even review 10 years later.

7 Then finally the National Cancer Institute,
8 the Office for the Protection of Research Risks and
9 the FDA have put out some very wonderful guidelines
10 that we and Cancer Research used to create informed
11 consent documents specifying all the way from the font
12 size that should be used, the level of language, and
13 headings that should appear, and so forth. I think
14 that document should be consulted and used whenever
15 possible because I think a lot of people put an awful
16 lot of work into that and it's a very wonderful piece
17 of work.

18 DR. WHALEN: Thank you.

19 Dr. Witten, as regards to the first question
20 as to the discussion, has it come to a satisfactory
21 conclusion? *

22 DR. WITTEN: Yes. Thank you. Before you go

1 on to the second question, I would like to ask my
2 follow-on question to the first question which is I
3 would like to ask the panel, there has been some
4 discussion about how to characterize the benefits and
5 about how they have been characterized in the
6 promotional material of the product, as well as over
7 the past couple of days how they have been
8 characterized in terms of how the sponsors spread
9 their quality of life data. I'm wondering whether
10 anyone on the panel can help us out with how to
11 describe the benefits in a informed consent type of
12 document or promotional material.

13 DR. WHALEN: Thank you. We'll go around the
14 table and begin with Ms. Domecus.

15 MS. DOMECUS: I guess the first thing is
16 that the benefits we need to stick to. There is also
17 the studies done to date, again making any notations
18 regarding loss to follow-up. I agree with the earlier
19 suggestion that risks like asymmetry probably should
20 be reflected in effectiveness discussions as
21 well.

22 And that risk of removal and potential

1 permanent disfigurement later also becomes an efficacy
2 issue. I think those things need to be tied into the
3 benefits discussion and probably a reference in the
4 benefits discussion to the section on risks so that
5 patients don't just go to that section.

6 DR. WHALEN: Dr. Morykwas.

7 DR. MORYKWAS: I think it also has to be
8 divided up between augmentation patients and
9 reconstruction patients because the data we were
10 presented on increased in bra cup size is obvious for
11 a reconstruction patient. If they go from no breasts
12 to a breast mound, there is obviously going to be an
13 increase which then is different from augmentation
14 patients.

15 I think that care should also be taken with
16 the quality of life presentations that were given
17 because they already were higher than the general
18 population before implantation and the augmentation
19 patients. I think that should be deemphasized. As I
20 said, they were already higher than the general
21 population anyway so that's kind of a separate
22 population of patients that we're dealing with.

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1 DR. WHALEN: Dr. Chang.

2 DR. CHANG: I think as a general guideline
3 some of the psychosocial terminology used specifically
4 in the studies performed by the sponsors would be
5 appropriate to include as a description of potential
6 benefits in talking about change in contour as all of
7 this is so very subjective. There are specific
8 terminologies, patient satisfaction, that were listed
9 in quality of life studies. I think those would be
10 appropriate since they were included in their surveys.

11 DR. WHALEN: Dr. Burkhardt.

12 DR. BURKHARDT: I'm not sure that the
13 question of asymmetry, which was brought up, should be
14 related to the products. Asymmetry is not always but
15 almost always a result of surgical placement which is
16 not identical on both sides. There is kind of a sense
17 going here that asymmetry is because the implants
18 weren't adjustable or couldn't be made the right size.
19 That's not the problem. The problem almost always is
20 the placement of the devices and that is really
21 nothing the manufacturer has any control over.

22 I would like to make one more comment about

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1 spin and this is perhaps a personal statement. I
2 always bothers me when I read a statement or hear a
3 statement that the sponsors can't prove or the
4 Government can't prove or the doctors can't prove that
5 the implants don't cause some disease because to the
6 lay people that sounds like a terrible deficiency.

7 When we say there is no scientifically
8 acceptable evidence to show that it causes the
9 disease, we're saying exactly the same thing and
10 sending an entirely different message. I think that
11 any information that comes from the Government has to
12 be particularly sensitive to those nuances in
13 description.

14 DR. WHALEN: Dr. Bandeen-Roche.

15 DR. BANDEEN-ROCHE: The first comment I
16 would make is to be sure that any statements that are
17 made are backed up by data. As an example reading out
18 of the Mentor packet talking about augmentation, "For
19 many women it has afforded a state of great personal
20 satisfaction and well being." Has afforded sort of
21 rings of causality to me and definitely not shown by
22 data in this study. Just be careful. Be vigilant

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1 about the wording of statements such as that in terms
2 of, you know, causal sort of statements.

3 In terms of the data presentation itself, in
4 my opinion it's appropriate to present data on bra
5 size change, bust size change, the body esteem
6 satisfaction sort of with your body. I felt that
7 those data were fairly solid provided that they are
8 conditioned on a clear statement. However, at three
9 years this doesn't reflect 25 percent of women.
10 That's got to put the informative censoring problem
11 into clear language.

12 However, the quality of life statements that
13 I see currently I feel are not well supported. One of
14 the studies did not even evaluate quality of life as
15 it is usually defined. This is particularly true for
16 the reconstruction patients. I struggle over whether
17 the quality of life data for the reconstruction
18 patients should even be in there because it's so
19 totally impossible to disentangle whether improvement
20 was due to having implantation or whether improvement
21 was just due to recovering from cancer and I worry it
22 could be very misleading.

1 DR. WHALEN: Dr. Boykin.

2 DR. BOYKIN: In terms of benefits just
3 continuing what Dr. Bandeen-Roche has just mentioned,
4 we have to be careful about these quality of life
5 measures. If I recall, the patients, the young adults
6 who came forward for augmentation had a very high
7 level of self-esteem, self-assurance. As a matter of
8 fact, highest before the operation.

9 That changed somewhat. I don't know if
10 there was any statistical significance. Satisfaction
11 may be already achieved for the most part. These may
12 be very highly successful, highly motivated people.
13 I think the thing I would just limit it to is the fact
14 that from all indications there would be a moderate to
15 significant increase in the breast size assuming the
16 operation is successful without complication.

17 DR. WHALEN: Dr. Blumenstein.

18 DR. BLUMENSTEIN: I find it hard to comment
19 on statements of efficacy because it isn't nearly as
20 important to me. That's all I have to say.

21 DR. WHALEN: Ms. Brinkman.

22 MS. BRINKMAN: I have nothing else to add.

1 DR. WHALEN: Is that a satisfactory
2 discussion, Dr. Witten?

3 DR. WITTEN: Yes. Thank you.

4 DR. WHALEN: Thank you. We now go on to
5 question No. 2 which is to provide comments regarding
6 a suggested waiting period prior to surgery in order
7 to give a patient adequate time to make an informed
8 decision.

9 Dr. Morykwas.

10 DR. MORYKWAS: Well, again, I'd like to
11 divide this, I think by necessity, into the two
12 populations of reconstruction versus the augmentation
13 patients. I think for the reconstruction patients,
14 and we heard Dr. Willey this morning state that it can
15 be in her experience as sort as two days from
16 diagnosis to a mastectomy with the option of immediate
17 reconstruction.

18 I know at our hospital there have been
19 instances where it's been the next day which is a very
20 short time. In that state of mind dealing with the
21 cancer, I don't know if the woman could probably give
22 informed consent as to getting an implant at that

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1 time.

2 At a later time going back in I don't think
3 it would be a problem or just due to vagaries in the
4 surgery schedule if there was a several week interval
5 between diagnosis and the time when they would do the
6 mastectomy and reconstruction. I think that would be
7 long enough to adjust and actually have fair time to
8 evaluate the option. That's very difficult. I don't
9 know what to say about that or recommendation to make
10 about that.

11 For the augmentation patients since that is
12 an elective procedure, I think just built into the way
13 it happens there is a waiting period. You don't go in
14 for the initial consultation to see a plastic surgeon
15 or other surgeon who puts in implants and then
16 immediately go into the operating room and have them
17 put in.

18 There is a waiting period and I don't know
19 if it's an over simplification to say that the busier
20 surgeons are probably the more experienced surgeons so
21 there would be a longer interval between the initial
22 office consult and when you could do the surgery. In

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1 that way I guess a delay would be better because you
2 potentially would get a more experienced surgeon.

3 I think at that time for the initial consult
4 the patient could be given all the documents as far as
5 informed consent, all of the options, the FDA
6 brochure. They could take that home with them and
7 that would give them a fair time. Actually a specific
8 number of days there's no way I could give a number to
9 that.

10 DR. WHALEN: Dr. Chang.

11 DR. CHANG: I have been asked on rare
12 occasions to treat a patient who is having immediate
13 -- who requires immediate reconstruction. I think
14 that it would be much too onerous to impose a time
15 limitation or waiting period.

16 DR. WHALEN: Dr. Burkhardt.

17 DR. BURKHARDT: If I were a woman, I think
18 I would be deeply offended by a federal paternalism
19 that told me that I would be unable to make a proper
20 decision regarding elective surgery in less than, say,
21 five days.

22 DR. WHALEN: Dr. Bandeen-Roche.

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1 DR. BANDEEN-ROCHE: I support some kind of
2 a waiting period just because of the issue of
3 carefully evaluating material and thinking about it
4 hard with some strong effort to make people think
5 about things realistically. I would further hope that
6 the waiting period would be before surgery is
7 scheduled.

8 I have some -- not breast implant related --
9 I have direct experience with this and I can tell you
10 once the surgery is scheduled, there is a momentum
11 that is very hard to stop. I can't say that, you
12 know, I would have changed my ultimate decision but I
13 probably would have tried a few other options and
14 would have enjoyed the extra time.

15 DR. WHALEN: Dr. Boykin.

16 DR. BOYKIN: I'm not really sure if I could
17 decide how much time would be necessary for something
18 this significant. I understand what Dr. Bandeen-Roche
19 is alluding to but I really don't think I would make
20 it a mandatory issue.

21 DR. WHALEN: Dr. Blumenstein, could you at
22 least tell us what is the standard deviation of the

1 interval should be?

2 DR. BLUMENSTEIN: Actually, I was thinking
3 that there should be a waiting period. It would
4 depend inversely on age.

5 DR. WHALEN: Ms. Brinkman.

6 MS. BRINKMAN: All I think you can do is
7 encourage that there be a waiting time for the very
8 reasons cited. There is really no way to enforce any
9 kind of waiting time except to give evidence on why
10 it's appropriate to have some waiting time before one
11 actually is scheduled for surgery.

12 In the case of reconstruction, frequently
13 those patients have had a consult maybe prior to
14 surgery and it's all done in the same procedure.

15 DR. WHALEN: Ms. Domecus.

16 MS. DOMECUS: I don't think there should be
17 any waiting period for reconstruction patients. I
18 think arbitrarily that a week is probably a good
19 amount of time for the augmentation patients. Having
20 said that, though, I don't know how the FDA is going
21 to get its hands on this one because the waiting
22 period really happens between the physician and the

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1 patient unless FDA is just asking if we think it's a
2 good idea to make a suggestion in the labeling.

3 I think at most it would be a suggestion
4 because I don't think it could be a requirement
5 because I don't know how manufacturers would go about
6 policing the physician/patient waiting period
7 requirement if they were to put that in the labeling.
8 I think a week is a good amount of time.

9 DR. WHALEN: Dr. Witten, does that satisfy?

10 DR. WITTEN: Yes. Thank you.

11 DR. WHALEN: Thank you. We move then to
12 question No. 3 which is to comment upon the
13 postoperative symptoms that should cause patients to
14 seek advice from their doctor.

15 Dr. Chang.

16 DR. CHANG: Read it again.

17 DR. WHALEN: Comment upon the postoperative
18 symptoms that should cause patients to seek advice
19 from their doctor.

20 DR. CHANG: I definitely think this is in
21 the purview of information that a physician should
22 give to the patient in terms of warning signs of

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1 inordinate swelling, redness, drainage, signs of
2 infection. Those would be items that I would tell my
3 patient so in terms of warning or advice, caution,
4 those would be the items to convey to a patient.

5 DR. WHALEN: Dr. Burkhardt, if you were a
6 woman, what symptoms would you -- no, I'm sorry.
7 Harkening back to the last question. What symptoms
8 should cause patients to seek advice from their
9 doctor?

10 DR. BURKHARDT: I think patients are smart
11 enough to know that. I don't think there is any
12 hidden diseases here. I realize that people in the
13 audience disagree with me but I don't think there is
14 any hidden diseases we're worried about. If a woman
15 has an infection in her breast or around her implant,
16 she's going to know it. She's going to come in. If
17 she has pain, she's going to come in. I don't think
18 that needs to be listed by a Governmental agency.

19 DR. WHALEN: Dr. Bandeen-Roche.

20 DR. BANDEEN-ROCHE: I'm not qualified to
21 comment on exactly which symptoms but I do hope that
22 women undergoing -- choosing breast implants will see

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1 themselves as data providers. Absolutely they should
2 report whatever is of concern to them. More so I
3 think it would be very worthwhile to try to set up a
4 reporting repository to track implants, to set up a
5 registry, anything that facilitates women providing
6 data to our knowledge.

7 DR. WHALEN: Dr. Boykin.

8 DR. BOYKIN: I'm going to disagree with Dr.
9 Burkhardt a little bit on this. I think that part of
10 this process is to give the patient a database from
11 which to derive some level of comfort. Having said
12 that, I have patients that I will intentionally not
13 give them a list of complications because I guarantee
14 they'll have all of them before the next morning or
15 they will call me about something that is totally
16 unrelated.

17 I think that for this process we should list
18 -- make a list of complications that are of relative
19 importance to the early postop patient; bleeding,
20 swelling, fever, chills, paresthesia. I think that
21 would be very beneficial. **

22 DR. WHALEN: Dr. Blumenstein.

1 DR. BLUMENSTEIN: No comment.

2 DR. WHALEN: Ms. Brinkman.

3 MS. BRINKMAN: We do this anyhow. I mean,
4 we always give patients a list of the kinds of things
5 that they need to know postoperatively that would not
6 be expected, the reasons to call the physician. That
7 is standard practice, I believe, in most
8 organizations. Whatever the surgeons feel are
9 untoward effects with this particular surgery is
10 acceptable; pain, bleeding, infection, those kinds of
11 things.

12 DR. WHALEN: Ms. Domecus.

13 MS. DOMECUS: I have nothing to add.

14 DR. WHALEN: Dr. Morykwas.

15 DR. MORYKWAS: I'll just add some minor
16 things. It seems that this is -- everybody is talking
17 about immediate postoperative complications instead of
18 long-term complications so I'll just say, again, the
19 standard list of symptoms that can occur
20 postsurgically. I also think this is a good time to
21 put in a national registry.* It would be good to track
22 infection rates and some of the other rates. I think

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1 this would be a good place that that data should also
2 be.

3 DR. WHALEN: Thank you. Dr. Witten, is that
4 discussion satisfactory?

5 DR. WITTEN: Yes. Thank you.

6 DR. WHALEN: Thank you. Proceed to the
7 question No. 4 where we are asked to discuss the types
8 of information that patients should be given regarding
9 differences in surgical procedures and postoperative
10 care. Starting with Dr. Burkhardt.

11 DR. BURKHARDT: That's particularly
12 difficult because I think it's very hard to get
13 agreement among surgeons as to which are the best
14 procedures and what procedures have what effect. I
15 mean, we all have some agreement now that certain
16 procedures are probably better than other procedures
17 in particular types of patients. But there is also
18 disagreement even about that.

19 Furthermore, it changes almost month to
20 month. I don't know how this agency could get in the
21 business of giving direct medical advice to patients
22 who have decided that they want to have implants or

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1 reconstruction. This would become a very cumbersome
2 process coming from this level. I really think that
3 has to be left up to the patient and the patient's
4 physician.

5 DR. WHALEN: Dr. Bandeen-Roche.

6 DR. BANDEEN-ROCHE: No comment.

7 DR. WHALEN: Dr. Boykin.

8 DR. BOYKIN: We have through several
9 professional agencies -- organizations, excuse me,
10 which have been represented here, educational
11 materials that are normally provided to patients that
12 discuss the different surgical procedures and
13 postoperative care and I think very nicely. Sometimes
14 these have become outdated over the years.

15 But if you're looking for some guidelines on
16 developing such information, I will certainly confer
17 with the American Society of Plastic Surgeons or the
18 Aesthetic Society considering that. We might be
19 duplicating some things but assuming this might be the
20 initial source of contact for information, it might
21 not be a bad idea.

22 DR. WHALEN: Dr. Blumenstein.

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1 DR. BLUMENSTEIN: No comment.

2 DR. WHALEN: Ms. Brinkman.

3 MS. BRINKMAN: Although it may be difficult
4 to do, I agree that we have to make some attempt to at
5 least do something and not just ignore the issue. As
6 you were saying, conferring with the American Society
7 of Plastic Surgeons. There has to be something that
8 we can include in this information.

9 DR. WHALEN: Ms. Domecus.

10 MS. DOMECUS: I agree with the concept that
11 this information should be provided to patients but I
12 don't think it should be the burden of the
13 manufacturer. I think that's the only thing we're
14 talking about here again. I think it would be
15 difficult unless it was something that specifically
16 came out of the manufacturer's study such as the
17 Betadine issue.

18 I think it would be unduly burdensome to ask
19 the manufacturer to stay on top of and provide some
20 kind of consensus where there is difference of opinion
21 in the medical community* echoing Dr. Burkhardt's
22 comments. I think it would put the manufacturer in

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1 the position of practicing medicine. I think that
2 information should come from the physician.

3 DR. WHALEN: Dr. Morykwas.

4 DR. MORYKWAS: I don't really have anything
5 more to add to this conversation.

6 DR. WHALEN: Dr. Chang.

7 DR. CHANG: I saw two examples by both of
8 the sponsors, "Options in Breast Reconstruction" and
9 "Options in Breast Augmentation." I thought they were
10 very appropriate. Any additional information, as Dr.
11 Boykin mentioned, could be put together with materials
12 already provided by ASPS and the Aesthetic Society.

13 DR. WHALEN: Thank you. Dr. Witten, does
14 that discussion satisfy?

15 DR. WITTEN: Yes. Thank you.

16 DR. WHALEN: The fifth question asked what
17 other elements should be added to the patient informed
18 decision information. Dr. Bandeen-Roche.

19 DR. BANDEEN-ROCHE: I wonder whether any of
20 the chemical, mechanical, biological testing would be
21 described and summarized. I don't know whether it can
22 be made understandable. Just it is an element that we

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1 consider in evaluating safety.

2 DR. WHALEN: Perhaps, with an asterisk, Dr.
3 Li's 1-800 number would be of major assistance.

4 Dr. Boykin.

5 DR. BOYKIN: I believe a description of the
6 chemical composition of the implant should be provided
7 like putting the ingredients of something on a box so
8 people can understand what is there. I believe that's
9 my only comment right now.

10 DR. WHALEN: Dr. Blumenstein.

11 DR. BLUMENSTEIN: Nothing to add.

12 DR. WHALEN: Ms. Brinkman.

13 MS. BRINKMAN: If we haven't done it any
14 place else, I think we certainly have to talk about
15 getting mammograms and what kind of requirements a
16 mammographer should have. Issues of lactation, again
17 what those issues might be.

18 DR. WHALEN: Ms. Domecus.

19 MS. DOMECUS: I guess one thing I'll go back
20 to on this question is my earlier comment about my
21 extreme discomfort of the combination of the loss to
22 follow-up rates in the study and all the testimony

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1 we've heard over the last few days of patients
2 describing situations in which they had complications
3 postimplant, went to their physician and they were
4 told by their physician that it wasn't related and,
5 therefore, they sought medical care elsewhere. I'm
6 really worry about how to capture that.

7 I think it would be helpful at least to put
8 in the patient brochure some information about how to
9 report adverse events to the FDA if there are any
10 ongoing studies. You heard today about a couple of
11 retrospective studies that are going on right now.
12 I'm not sure what those are but ways to contact them.
13 If there is a registry, remind them about that.

14 I'm just really worried about this loss of
15 data and if we added that 20 percent lost to follow-up
16 to the complication rates, what would be really have
17 and would we have voted differently.

18 DR. WHALEN: Dr. Morykwas.

19 DR. MORYKWAS: This is a fairly specific
20 point but it seems like most of the discussion of
21 changes in nipple and breast sensitivity has been
22 hyposensitivity and hypersensitivity occurs. It seems

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1 to me -- not being a woman but it seems to me like
2 just wearing clothes and walking in that instance
3 would be very uncomfortable so I think somewhere the
4 delineation needs to be made between both excessive
5 and suppressive changes in sensitivity.

6 DR. WHALEN: Dr. Chang.

7 DR. CHANG: No other additional information
8 to add, although I would second what Ms. Domecus. We
9 encourage reporting of adverse events so that long-
10 term follow-up and accurate information can be gained.

11 DR. WHALEN: Dr. Burkhardt.

12 DR. BURKHARDT: I think this needs to be
13 included in the informed consent environment. Once
14 again, the incidence of these problems is highly
15 debated and is very much procedure dependent on
16 whether the implant is put behind the muscle or behind
17 the breast or what approach is used. I just don't
18 know how this can be made available in a relatively
19 simply straight-forward manner.

20 This is not the kind of thing I think you
21 can get a Consumer's Report^{**} comparative testing done
22 on. What women want to know is what is the very best

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1 implant and what is the very best surgeon and what is
2 the very best procedure that I can have done. I don't
3 know any way that that information can be made
4 available.

5 DR. WHALEN: Dr. Witten, is that discussion
6 satisfactory?

7 DR. WITTEN: Yes. Thanks.

8 DR. WHALEN: Does any other member of the
9 panel have further comments or recommendations in
10 regard to labeling or patient informed consent?

11 Ms. Brinkman.

12 MS. BRINKMAN: At one time I brought up the
13 comment or suggestion about physician education. I
14 don't know how appropriate that is or if it's within
15 our ability to do that but is it possible to ask
16 physicians to receive some sort of education on breast
17 implants prior to their ability to purchase the
18 product?

19 DR. WHALEN: I would start an answer to that
20 and welcome anyone else to join in. While certainly
21 many individual plastic surgeons have their own
22 ambulatory ORs and they would then be the purchaser of

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1 the product in many instances, it is not the surgeon
2 who is purchasing the products so we get into the
3 whole realm of institutional credential rather than
4 purchasing of the product. It obscures that issue
5 somewhat, not to diminish its importance in any way,
6 shape, or form.

7 Dr. Witten.

8 DR. WITTEN: If you're asking about the FDA
9 role in that, in general we can ask manufacturers to
10 have training programs available but in terms of
11 restricting availability of the product to somebody
12 who has been trained isn't something that we would
13 generally do.

14 MS. BRINKMAN: And I'm not necessarily
15 addressing a large training program. I guess my
16 concern is that it's not board certified plastic or
17 aesthetic surgeons that I'm concerned about. It's the
18 number of physicians doing these procedures without
19 any particular formal training. Even a brief type of
20 review or a two-hour type of information course, none
21 of that. We can't do that or require that.

22 DR. BURKHARDT: May I comment on that? Even

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1 if you could do it, it's a double-edged sword. If you
2 set up a program like that that assumes people are
3 qualified to do the surgery, how are you going to feel
4 if your neighborhood family internist takes a short
5 course on inserting breast implants and then goes
6 ahead and says, "Well, I'm qualified and I can buy
7 implants and do the procedure." That's the problem
8 that you get into here.

9 MS. BRINKMAN: I don't think it's a
10 qualifier. I mean, I don't think it's a certification
11 process by any means.

12 DR. WHALEN: The problem becomes, to follow
13 on what Dr. Burkhardt has just suggested, anything
14 that's even in the most benign and well-intentioned of
15 educational fora that are provided will end up on some
16 osteopath or allopath's wall as a certificate and then
17 can be used. It's a very valid issue that is an
18 entire can of worms that goes into collective
19 bargaining issues.

20 It goes into professional association
21 issues. It goes into credential and it goes into
22 specialty against specialty emphasizing that I'm

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1 saying all this as the one nonplastic surgeon on the
2 panel. I think that perhaps it needs to be addressed.
3 As it is beyond FDA's purview, I don't know that we
4 can even begin to grapple with it today.

5 MS. BRINKMAN: The example given by this
6 surgeon was the fact that evidently there's some sort
7 of very powerful high-speed drill that is available to
8 plastic surgeons and they could not purchase it unless
9 they had taken a particular training course in order
10 to use this particular drill. He said that was an FDA
11 requirement in order to purchase the drill.

12 DR. WHALEN: Any comment, Dr. Witten?

13 DR. WITTEN: Only what I said before, just
14 that we can require that they have a training course.

15 DR. BURKHARDT: I'm familiar with that
16 situation, that piece of equipment, and I think there
17 are two differences. It's my understanding that the
18 company requires training before they will sell you
19 the thing. I don't think it has much to do with the
20 FDA. The other major difference is you don't find an
21 awful lot of unqualified people clamoring to use that
22 drill.

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1 DR. WHALEN: Dr. Witten, are you satisfied
2 with the panel's recommendations and is there any
3 further specific question that you feel we should
4 comment upon?

5 DR. WITTEN: No, I'm satisfied with the
6 recommendations and I would like to thank you for your
7 hard work over the last three days.

8 DR. WHALEN: I would like to make a few
9 brief closing remarks. Usually for people who have
10 been to any meeting I've been at, you know I sort of
11 blaze out the door without remarks. This is an
12 exception.

13 I would like to first and foremost thank my
14 fellow panel members. It's been a delight working
15 with you. I applaud and admire your expertise, your
16 professionalism. I singularly enjoy the enlightenment
17 of these meetings in so many different ways. Thank
18 you to all of you.

19 I would like to thank everyone who took the
20 time to comment both as individual consumers and as
21 representing organizations. There were many
22 singularly tragic stories told to us in the past few

1 days. One comment was made, and I'm sure it wasn't
2 meant necessarily the way I'm phrasing it, but that
3 the panel had disregarded such information. Believe
4 me, we did not disregard that information. It was
5 heard, it was conveyed, it was understood.

6 Finally, I would like to thank everyone from
7 the FDA for the extraordinary job that they always do
8 from AnnMarie guarding that door so zealously. Thank
9 you very much and all the rest of the staff.
10 Everybody in the FDA professional staff but just to
11 make a few named thank yous.

12 I would like to, of course, thank our
13 Executive Secretary Dr. David Krause for sending us
14 enough information in advance to get hernias. To Mr.
15 Stephen Rhodes and the always professional job that he
16 has done with us and the curtesy he has extended to
17 us. To Ms. Nancy Pluhowski who as the mom of all
18 these panels makes sure we try to dot our Is and cross
19 our Ts and we appreciate that very much. To our true
20 boss, Dr. Celia Witten, for enduring this on the panel
21 with us and keeping the ship on a straight course.

22 Finally, a strong note of thanks not just

1 for this meeting but for several meetings to someone
2 we are unfortunately going to lose from this panel,
3 and that is Mr. Jim Dillard. He's exceptionally
4 professional, a joy to work with, and we congratulate
5 him on his promotion.

6 Thank you very much and the meeting is
7 adjourned.

8 DR. BLUMENSTEIN: I'd like to say thank you
9 to our Chair for a very good meeting.

10 (Whereupon, the meeting was adjourned at
11 2:44 p.m.)

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CERTIFICATE

This is to certify that the foregoing transcript in the
matter of: MEETING

Before: GENERAL AND PLASTIC SURGERY
 DEVICES PANEL

Date: MARCH 3, 2000

Place: GAITHERSBURG, MARYLAND

represents the full and complete proceedings of the
aforementioned matter, as reported and reduced to
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Rebecca Davis

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