FOOD AND DRUG ADMINISTRATION

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MEDICAL DEVICES ADVISORY COMMITTEE

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GENERAL AND PLASTIC SURGERY DEVICES PANEL

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MEETING

FRIDAY
MARCH 3, 2000

The meeting was held at 8:00 a.m. in the Ballroom of the Gaithersburg Holiday Inn, Two Montgomery Village Avenue, Gaithersburg, Maryland, Dr. Thomas V. Whalen, Panel Chair, presiding.

PRESENT:

THOMAS V. WHALEN, M.D.	Chairman
JOSEPH V. BOYKIN, JR., M.D.	Voting Member
PHYLLIS CHANG, M.D.	Voting Member
KAREN BANDEEN-ROCHE, Ph.D.	Temporary Voting Member
BRENT BLUMENSTEIN, Ph.D.	Temporary Voting Member
BOYD BURKHARDT, M.D.	Temporary Voting Member
NANCY A. DUBLER, L.L.B.	Temporary Voting Member
MICHAEL J. MORYKWAS, PH.D.	Temporary Voting Member
MAXINE F. BRINKMAN, R.N.	Consumer Representative
CINDY DOMECUS	Industry Representative
DAVID KRAUSE, Ph.D.	Executive Secretary

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

2 8:02 a.m.

3 DR. KRAUSE: Can everyone please take their
4 seats so we can begin. A couple of quick general
5 announcements. Accidentally on the agenda I listed an
6 open public comment period right after the call to
7 order. That's not correct. It won't be until a
8 little bit later. Also PIP America will not be
9 presenting during the labeling presentations from the
10 industry representatives.

11 Good morning, everyone. We're ready to
12 begin day 3 of this the 56th meeting of the General
13 Plastic Surgery Devices Panel. My name is David
14 Krause and I'm the Executive Secretary of the panel.
15 I'm also a biologist and reviewer in the plastic and
16 reconstructive surgery devices branch.

17 I would like to remind everyone to please
18 sign in on the attendance sheets on the table
19 immediately outside the door to your left, my right.
20 At that place you may also pick up an agenda, a roster
21 of the panel members, and information about today's
22 meeting, and also information regarding how you can

1 find out about future meetings of this and other
2 panels.
3 Before turning the meeting over to Dr.
4 Whalen, today I am only required to read the conflict
5 of interest statement into the record because there
6 will be no voting.
7 The following announcement addresses
8 conflict of interest issues associated with this
9 meeting and is made a part of the record to preclude
10 even the appearance of an impropriety. To determine
11 if any conflict existed, the agency reviewed the
12 submitted agenda and all financial interest reported
13 by the committee participants.
14 The conflict of interest statutes prohibit
15 special Government employees from participating in
16 matters that could their or their employer's financial
17 interests. However, the agency has determined that
18 participation of certain members and consultants, the
19 need for whose services outweighs potential conflict
20 of interest involved, is in the best interest of the
21 Government.
22 We would like to note for the record that

1 the agency took into consideration certain matters
2 regarding Drs. Burkhardt, Chang and Dr. Morykwas.
3 Drs. Burkhardt, Chang, and Morykwas reported past
4 related involvements with firms at issue. Since these
5 are past involvements and there are no continuing
6 financial interests, the agency has determined that
7 these panelists may participate fully in the
8 deliberations.
9 In the event that the discussions involve
10 any other products or firms not already on the agenda
11 for which an FDA participant has a financial interest,
12 the participant should excuse him or herself from such
13 involvement and the exclusion will be noted for the
14 record.
15 With respect to all other participants, we
16 ask in the interest of fairness that all persons
17 making statements or presentations disclose any
18 current or previous financial involvement with any
19 firm whose products they may wish to comment upon.
20 Thank you.
21 I'd like to turn the meeting over to Dr.
22 Whalen at this time.

1 DR. WHALEN: Thank you, Dr. Krause. Good
2 morning. I'm Dr. Thomas Whalen, Chair of this General
3 and Plastic Surgery Devices Panel. Today the Panel
4 will be making recommendations to the food and drug
5 administration on the content, format, and consistency
6 issues involving the labeling information and informed
7 consent provided to patients considering saline-filled
8 breast protheses. Before we proceed, Dr. Celia Witten
9 from the FDA would like to make some remarks.
10 DR. WITTEN: Yes. I'd like to welcome
11 everyone to this third day of our panel discussions
12 regarding saline breast implants. We are looking
13 forward to the discussion today on labeling.
14 As we've heard over the last couple of days
15 from a number of different people, the informed
16 consent process is very important for these products
17 and their use and we'll be listening very carefully to
18 what we hear today from the public and from the panel
19 regarding this topic.
20 The public has an important role in helping
21 us as we grabble with this question and we would like
22 to thank everyone in advance for their participation

1 here today. Thank you. I'll turn it back over to
2 you.
3 DR. WHALEN: Thank you, Dr. Witten. The
4 first order of business then is for the companies to
5 make brief presentations concerning their labeling.
6 The first company to be presenting will be McGhan
7 Medical and the presentation will be by Dr. Scott
8 Eschbach.
9 DR. ESCHBACH: Mr. Chairman and members of
10 the panel, good morning. My name is Scott Eschbach
11 and I am President and CEO of McGhan Medical. We have
12 a brief presentation on labeling this morning.
13 Like the FDA and physicians alike, McGhan
14 Medical believes that an informed patient is a highly
15 valuable situation. We work diligently and through a
16 variety of media to carry information to the patient
17 and we are anxious to see the kind of information that
18 are the outcomes of our clinical studies shared in an
19 effective manner.
20 Our task today, and for the next several
21 months, and perhaps beyond that, is to identify the
22 most effective way to do that. We've heard testimony

1 from the public regarding the effectiveness of how
2 information gets to them. We are eager to find an
3 effective way to share with them the information we've
4 been discussing in the last few days.
5 I thought it might be helpful if we very
6 briefly covered with you the kind of vehicles we are
7 using today to get information to the patient, to
8 physicians and patients because, as we discussed over
9 the last couple of days, the issue of being sure the
10 information on procedures and the like is available to
11 physicians in an effective manner and then how it
12 takes the route to get to the patient.
13 Dissemination of information at McGhan
14 Medical encompasses all of our labeling in its
15 broadest sense activities. I'm going to share with
16 you in the next few slides the route we use to
17 disseminate information that is targeted primarily to
18 patients and primarily to physicians.
19 Packaged with the device we include an
20 information package. That is targeted primarily at
21 the patient. That information packet includes a
22 brochure entitled "FDA Information For Women

1 Considering Saline-Filled Breast Implants." This
2 information was mandated by the FDA to be included
3 with our packaging and includes a discussion of a
4 range of the effects, outcomes that we have been
5 discussing over the last few days such as discussions
6 on deflation, additional surgeries, infection, and the
7 like. This booklet is with each of our products.
8 In addition, we include an informed consent
9 to be delivered by the physician to the patient also
10 with verbiage as mandated by the FDA. This informed
11 consent is worded to cover many of the issues that we
12 have discussed.
13 Included in that patient information packet
14 is a discussion of our ConfidencePlus program which is
15 a claims processing program concerning the patient's
16 rights and activities to interface back with McGhan
17 Medical in the event of a deflation of their implants
18 and how we will handle the processing of such a
19 situation.
20 Also included in that packet is a patient
21 device identification card. This card allows the
22 patient to record information on the back regarding

1 the style and serial number of their implant. It is
2 designed and intended to be kept with the patient so
3 that they can keep track of which device they've had
4 implanted.
5 Also packaged with the device, targeted now
6 at the physician, of course, is all the information on
7 our box label. This is typically information
8 identifying the product in terms of style, serial
9 number, date, and the like.
10 In the information packet we include,
11 primarily targeted at the physician as well, the
12 directions for use, a booklet briefly describing
13 techniques and adverse reactions and the like.
14 In addition, we continue to include our
15 registry tracking form. Although registry tracking as
16 a mandated situation for breast implants is no longer
17 required, we do include the registry tracking form
18 should a patient wish to fill out this form and become
19 a member of our database.
20 In addition to the device packaging, we
21 disseminate information through a variety of pamphlets
22 and educational materials. We make available at no

1 charge to physicians three pamphlets entitled, "What
2 is Silicone," "Choices in Breast Reconstruction," and
3 "Choosing Augmentation." These pamphlets give
4 information about and briefly describe the techniques
5 and some of the decision-making situations concerning
6 the decisions a patient will be making.
7 In addition to that information, included in
8 each of these booklets is the verbiage from the "FDA
9 Information for Women" pamphlet. It is included in
10 each of these small booklets.
11 Pamphlets and educational material targeted
12 at the physician include our BioDimensional planning
13 kits with a kit like this for augmentation and for
14 reconstruction. Within the kit among other things is
15 an instructional monograph that describes a general
16 surgical technique for these devices, as well as an
17 accompanying instructional video.
18 We have available -- this is a small version
19 of it. We have this little 8½ by 11. We also have a
20 large OR wall chart sized to aid in the dimensional
21 assessment of our products for choice of the product
22 by the physician.

1 We have a consultational planning tablet
2 that physicians may use in consultation with their
3 patients again in determining the appropriate implant
4 for that patient.
5 Our web site includes the information that
6 is contained in the three pamphlets that I have spoken
7 to you earlier that's readily available on the McGhan
8 Medical web site. In addition, that web site contains
9 the verbiage contained in the "FDA Information for
10 Women" pamphlet.
11 Advertising as well carries labeling
12 information and McGhan Medical does advertise in
13 newspapers and magazines in two ways. In the first
14 way we do product promotional advertising and in this
15 product promotional advertising we include fair
16 balance. Fair balance in the advertising jargon is
17 that kind of information again that was contained in
18 "FDA Information for Women," adverse conditions and
19 the like.
20 We also have one reminder ad out there.
21 Reminder ads are those advertising that simply state
22 perhaps the name of the company. Perhaps simply some

1 suggest of cosmetic surgery like, "Have you thought
2 about it?" Perhaps just the name of a product without
3 making product performance or claims with regard to
4 efficacy of the product. Such reminder ads do not
5 necessarily carry the fair balance.
6 We disseminate information through
7 advertising in medical journals and those advertisings
8 are targeted at the physician and tend to be directed
9 toward product technical features.
10 McGhan Medical has not directly been
11 involved in radio and TV advertising. However, there
12 are radio and TV advertising media placements that
13 have been conducted by physicians and those physician
14 ads do lead to the dissemination through telemarketing
15 programs of the pamphlets from McGhan Medical and
16 video tapes from McGhan Medical targeted patients both
17 of which carry fair balance and information from the
18 "FDA Information for Women."
19 In summary, our position I'd like to state
20 here is McGhan Medical is widely disseminating the
21 "FDA Information for Women" which contains a listing
22 of the risks. However, McGhan Medical is proud of

1 what it's been doing in the studies that it's been
2 conducting and will continue to cooperate with the
3 agency to include appropriate information from our
4 clinical studies in our labeling. In addition to
5 defining what information, we need to define also what
6 kinds of vehicles will be most effective of getting
7 that information to the patient.
8 I would ask as the panel deliberates that
9 they consider the following points. First, that our
10 approach to this be consistent across the industry and
11 that actual data cited in labeling be specific to the
12 manufacturers device, and that such labeling would be
13 handled in a phase-in situation involving the
14 replacement of current labeling in a controlled
15 situation. I thank you for your consideration.
16 DR. WHALEN: Thank you. I'm sure you'll
17 entertain some questions from the panel.
18 DR. ESCHBACH: Certainly.
19 DR. WITTEN: Excuse me. Can I just make a
20 request? Although we are not here, of course, to look
21 at any manufacturer's specific labeling and make
22 comments on the actual words in their labeling, I

1 think it would be helpful for you to pass that
2 material around to the panel.
3 DR. ESCHBACH: This material I've got here?
4 DR. WITTEN: Um-hum.
5 DR. ESCHBACH: Certainly.
6 DR. WHALEN: If I could start with a
7 question. The amount of information that you provide
8 is large and laudable. I've been a commissioned
9 officer in either the active or naval reserve for 27
10 years and the amount of information and policies and
11 instructions that are in the military is legendary.
12 Most of it gathers dust on shelves. There's even an
13 instruction on instructions called the 5215 which
14 lists all the instructions.
15 It would be easy, and perhaps even
16 defensible, for a manufacturer to say, "Look, we
17 provide all of this information. If those surgeons
18 don't give to their patients, that's not our problem.
19 What's your corporate policy and view on the role of
20 the manufacturer in ensuring that such information
21 gets to the patient and consumer?
22 DR. ESCHBACH: We certainly are very

1 interested in seeing this information get to the
2 consumer. We encourage that by trying to remove
3 economic barriers so as much as possible this
4 information is available freely to physicians. Over
5 the last few years, actually, McGhan Medical has taken
6 the position of starting to try and get this
7 information to consumers directly.
8 We will respond to inquiries from patients
9 directly to the company in a reactive sense. If we
10 get a phone call, we are happy to provide any of the
11 patient targeted information directly to the patient
12 should they call. that doesn't happen very often. I
13 have to be honest with you on that. We don't very
14 often get that.
15 It's primarily, I believe, because the
16 relationship between a patient and their physician is
17 still a strong one. Patients still look very strongly
18 to their physician for guidance and support and
19 direction. We have no reluctance t all to provide
20 that information directly to patients.
21 We have begun an advertising program to
22 bring some of the information to the public directly.

1 That has to be a fairly careful situation. We need to
2 act responsibly to not get between a patient and their
3 physician. And yet we as well feel the need to get
4 this information directly to the patient. We have no
5 reluctance to try and comply with that, Dr. Whalen.
6 DR. WHALEN: Ms. Dubler.
7 MS. DUBLER: If a patient or a patient's
8 rights group or a consumer group asks for the
9 physician targeted information, will you provide it?
10 DR. ESCHBACH: I see no reason why we
11 wouldn't. I don't believe we have any prohibition
12 against that. There is nothing secret in the
13 information.
14 DR. WHALEN: Thank you, Dr. Eschbach.
15 DR. ESCHBACH: Thank you.
16 DR. WHALEN: Next we are to hear from Ms.
17 Donna Crawford, Director of Corporate Regulatory
18 Affairs at Mentor Corporation.
19 MS. CRAWFORD: Good morning, ladies and
20 gentlemen. Thank you for the opportunity to speak to
21 you today. My name is Donna Crawford. I am Director
22 of Corporate Regulatory Affairs for Mentor

1 Corporation.

2 I would like to discuss with you today the
3 various physician and patient information and
4 communications programs that Mentor has. We feel
5 these are very important programs because we strongly
6 believe that meaningful information leads to an
7 informed choice.

8 I would like to outline my presentation for
9 you. I will be discussing three different areas.
10 First, I would like to describe what our current
11 approach is and philosophy to our existing
12 communication program. Then I would like to describe
13 what existing methods of communication and labeling we
14 have today. I'll describe the various communication
15 channels that we use and the types of information that
16 we provide.

17 Also, lastly, I would like to describe for
18 you our proposals for some future communications to
19 more effectively provide physicians and patients with
20 information. Specifically I'm talking about providing
21 the results of our clinical studies that you heard
22 several days ago and describe how we intend to expand

1 the communication methods that we have currently.

2 Mentor's physician and patient information

3 program is designed to provide patients and physicians

4 information that is accurate, complete, and up to

5 date. We believe the patient information should be

6 understandable to the lay person because obviously

7 they do not have the medical background of the

8 physician. We strongly believe that this information

9 should equip both the patient and physician to make a

10 well-informed decision.

11 I would like to explain to you what

12 communication channels we currently have for providing

13 information to the physician and the patient. First

14 of all, we have a toll free number that a patient can

15 call in to ask questions. It was started about seven

16 years ago. It is staffed by registered nurses and we

17 currently receive about 500 calls for information a

18 month. These can come from both perspective patients

19 and patients that have already received implants.

20 Secondly, we do have educational videos that

21 are available. These are available upon request to

22 Mentor. They are available for the patient to view in

1 the doctor's office or a patient can request them
2 directly from Mentor.
3 Also, we have a web site that has a great
4 deal of information on it. It's designed to be
5 interactive. It's updated. Currently we have
6 approximately 50,000 user visits per month.
7 Lastly, and probably most importantly, we
8 have labeling that is geared for both the patient and
9 the physician. I would like to describe for you what
10 that is and what information these contain. Our
11 patient labeling consist of three parts. We have
12 information for women considering saline-filled breast
13 implant document. We have two brochures, one entitled
14 "Options in Breast Augmentation," and one entitled
15 "Option in Breast Reconstruction."
16 I would like to talk to you a little bit
17 about the "Information for Women Considering Saline-
18 Filled Breast Implants" document. It is enclosed in
19 each breast implant package. In addition to having
20 this document in the package, we also have a voluntary
21 patient registry card and a patient ID label so that
22 the patient will have a record of what implant they

1 have received.

2 The "Information for Women Considering
3 Saline-Filled Breast Implants" can be obtained several
4 ways. As I mentioned, it can be provided in a breast
5 implant package. It can also be provided to the
6 physician upon request to Mentor so they will have
7 extras to give to patients. It also is available
8 directly to patients upon their request. It is
9 available in multiple languages; English, French,
10 German, Spanish, and Italian.

11 The original version was developed in
12 cooperation with FDA as we will hear. We have
13 recently added the complication raised from our saline
14 perspective study. This is the version that is
15 pending approval in the PMA today.

16 This document has a space for the patient to
17 sign indicating that they have read and reviewed this
18 information and understood it. It also has a place
19 for a witness to sign. The physician is instructed to
20 keep the original and to provide a copy to the
21 patient. This document advises women to review the
22 information prior to making a decision whether to have

1 surgery. It mentioned other alternatives for
2 augmentation, reconstruction.
3 It also advises women with their doctor's
4 advice to decide whether they want to accept the
5 possible risk of surgery in order to achieve their
6 desired results. It lets women know that the
7 physician labeling, which I will describe a little bit
8 later on, is available from their doctors and they
9 should request it if they would like to have it.
10 It gives information regarding the rates of
11 occurrence for most of the common risks that have
12 recently been added. Again, this is part of the
13 labeling that is pending approval under the PMA. It
14 also discusses known and unknown long-term risks.
15 Now I would like to talk about our options
16 in breast augmentation brochure. It is provided to
17 the patient via several ways. It is available in the
18 doctor's office and is also available if the patient
19 calls our 800 line or request it over our web site as
20 I described earlier. It provides a great deal of
21 information on the following areas.
22 It provides information on the anatomy of

1 the breast, what factors to consider when choosing
2 breast augmentation. It describes the various types
3 of Mentor saline implants available including the
4 types and shapes and surface characteristics.
5 It gives the patient information regarding
6 the incision choices and placement choices that are
7 available. It discusses the body's reaction to breast
8 implants, specifically the possibility of capsular
9 contracture.
10 Further, it provides information to the
11 patient as to what to expect during the surgical
12 procedure and the recovery period. It provides photos
13 of some sample breast augmentation results. In
14 addition, it gives them information regarding Mentor's
15 product replacement policy and our limited warranty
16 program.
17 It provides the potential risks and
18 complications of breast implants. This is the same
19 information, a duplicate of the information that is
20 provided in the "Information for Women Considering
21 Saline-Filled Breast Implants" that I mentioned
22 earlier. It provides a place for the patient to sign

1 indicating they have received and read the document,
2 and also a place for the witness to sign.
3 The options in the breast reconstruction
4 brochure is providing to the patients considering
5 reconstruction. It is available in a manner similar
6 to the augmentation brochure either through the
7 doctor's office or upon request directly to Mentor.
8 It provides information regarding the anatomy of the
9 breast. It gives some information on the mastectomy
10 procedure and the various options that are open for
11 reconstruction. It describes the types of implants
12 that are available from Mentor, as well as the body's
13 reactions to implants.
14 It also tells the patient what to expect
15 during the surgical procedure and the recovery period.
16 It gives the potential risks and complications.
17 Again, this is the same information as presented in
18 the "Information for Women Considering Saline-Filled
19 Breast Implants." It provides a glossary of medical
20 terms. It also provides a space for the patient and
21 the witness to sign.
22

1 I would like to talk about the physician
2 labeling. This is a product insert data sheet that is
3 enclosed in each breast implant package. Additional
4 copies are also available upon request from Mentor
5 either through our phone line or web site.
6 Since this is geared to the physician it
7 provides more detailed and technical information about
8 the device, what the various options are in terms of
9 valves and texture surface and shapes and so on. It
10 details the indications for use, the
11 contraindications. It also provides the warnings and
12 precautions to assist the physician in the safe use of
13 the device.
14 Further, we have revised this document to
15 include the adverse events that were reported during
16 our saline perspective study. It gives information
17 regarding the possible reactions to silicone. It
18 provides more detailed information about the clinical
19 study results in terms of the study population, the
20 methods used, and the results that were obtained for
21 both the primary safety and effectiveness parameters.
22 In addition, it instructs the physician to

1 counsel the patient prior to surgery to make sure they
2 are fully informed of the risks and to provide them
3 with the patient labeling. It gives the physician
4 detailed instructions for use in terms of choosing an
5 implant, testing the implant prior to surgery, and
6 filling the implant during surgery. It also provides
7 the company contact information so that the physician
8 will know where to report any adverse reactions.
9 Now I would like to describe for you the new
10 initiatives that Mentor is looking into undertaking in
11 order to communicate the new data that we now have
12 from our saline perspective study. Mentor is
13 committed to being responsive to the needs of the
14 patient and the medical community consistent with what
15 we have heard during the last two days from both the
16 public and the panel subject to PMA approval and we
17 will be working very closely with FDA on this.
18 The new detailed clinical results on both
19 the risks and benefits will be communicated to the
20 patient and the physician. In order to do that, we
21 intend to extend our web site by providing full and
22 updated patient and physician labeling on the web site

1 for those who would like to have it.

2 We will make it fully interactive so that
3 doctors and patients can ask questions and get answers
4 to their issues or concerns. We will have links to
5 medical specialty and third-party web sites such as
6 ASPS, FDA, and the Institute of Medicine. We will use
7 the web site to provide real time information updates
8 and communicate our research findings.

9 In order to ensure that these methods of
10 communication have been effective, we will be
11 conducting focus groups to ensure that the information
12 is, in fact, making its way to the patient.

13 In summary what does this all mean? Mentor
14 is committed to providing complete, current, and
15 accurate information to the patient and the physician.
16 We will undertake new initiatives to expand our
17 communications to incorporate the clinical data that
18 we now have. Mentor will continue to work with the
19 FDA to develop appropriate information for the
20 patients to help them make an informed decision. We
21 feel this is very important because we very strongly
22 believe that meaningful information will lead to an

1 informed choice.

2 That concludes my presentation. Thank you

3 very much for your time and attention today.

4 DR. WITTEN: Excuse me. Do you have any

5 material to pass around such as copies of these

6 information brochures?

7 MS. CRAWFORD: I do have some. The printed

8 versions are what we are using today and does not have

9 the race incorporated because that is still pending

10 FDA review and approval, but I do have some samples of

11 that.

12 DR. WITTEN: Any of the information that you

13 mentioned just now if you could pass it around to the

14 panel.

15 MS. CRAWFORD: Sure.

16 MR. PURKAIT: Hi. This is Bobby Purkait

17 from Mentor Corporation. We do have some samples.

18 Who do I give it to?

19 DR. WHALEN: Are there any questions for Ms.

20 Crawford? Dr. Bandeen-Roche.

21 DR. BANDEEN-ROCHE: I have two questions.

22 First, focus groups is a great idea. Just very

1 briefly I know you'll work on FDA with this but who
2 would you propose to include in the focus groups?
3 MS. CRAWFORD: I'd like to have Bobby answer
4 that question.
5 MR. PURKAIT: Hi. This is Bobby Purkait.
6 Good morning. Focus group, we have a very preliminary
7 plan. We have heard and recognized the fact that we
8 need to understand this basic understanding how
9 patient gets this information and what is the best way
10 to get them. Even if they do get it, do they really
11 understand what is the timely fashion.
12 There are a lot of issues that we want to
13 deal with. We really don't have a full picture in the
14 focus group who those folks should be but we will
15 investigate and we'll make some decision. Definitely
16 physicians, the patient group, the advocacy group,
17 some of the very important group where the patients
18 can go to get some information. That kind of group
19 will look into it. We don't have a full answer but
20 we'll look into it.
21 DR. BANDEEN-ROCHE: Okay. My second
22 question is just about the information that appears in

1 the breast implant package including materials for a
2 signature. Does Mentor receive any assurance that the
3 patients have seen the information? For instance,
4 does mentor receive a copy of the signed forms or is
5 that strictly between the patient and the doctor?
6 MR. PURKAIT: It is primarily right now
7 between the patient and the doctor. We do receive
8 sometimes and we don't receive a lot of times. This
9 is not a very well defined procedure.
10 DR. BANDEEN-ROCHE: Thank you.
11 DR. WHALEN: Ms. Brinkman.
12 MS. BRINKMAN: It's my understanding,
13 because I'm familiar with your material, that the
14 signed piece in the patient education information can
15 not be used, can be used to go in patient chart, can
16 go back to you. There is no process for that and
17 there's no real requirement to use it. It's put in
18 there for anybody's use to interpret anyway they want.
19 Right?
20 MR. PURKAIT: No, that's not quite right.
21 The information that is provided both for the patients
22 and physicians, it is between physicians to explain to

1 the patient. If the patient have an information
2 requirement, they can call us and we'll further
3 augment those. As far as the exchange of
4 communication, what we want to establish is really the
5 open communication channel, what we provided to them.
6 If they have any question, they can call us anytime.
7 MS. BRINKMAN: Thank you. I understand
8 that. I was talking about the area for a signature,
9 though.
10 MR. PURKAIT: Yeah, the area for signature
11 we strongly believe that there is a need for that. We
12 provide them. We like to see that we get lot more
13 cooperation. We will look into this with more detail.
14 That's a very important area we're looking into it.
15 MS. BRINKMAN: Good. Thank you.
16 DR. WHALEN: Thank you.
17 We will now proceed to open public testimony
18 before the panel. I would like to ask Dr. Krause to
19 read us the four question instructions.
20 DR. KRAUSE: Okay. I would like to inform
21 everyone that's going to speak of the instructions.
22 We are requesting that all persons making statements

1 during the open public hearing of the meeting disclose
2 whether they have financial interest in any medical
3 device company, or if their trip to the meeting has
4 been paid for by someone else.
5 Before making your presentation to the
6 panel, in addition to stating your name and
7 affiliation, please address the following questions.
8 I would like to read the questions into the record now
9 so that a rereading by all the presenters will not be
10 necessary. These are the four questions.
11 Question 1: Has your travel and/or
12 accommodations been paid for or will they be
13 reimbursed by someone else? If so, please state who.
14 Question 2: Please indicate whether you
15 have financial ties including grants or other
16 compensation with industry or health professional
17 societies.
18 Question 3: Please indicate whether you are
19 a party to or a witness in a pending lawsuit related
20 to breast implants.
21 Question 4: Do you derive a portion of your
22 income from surgical procedures using saline-filled

1 implants or from treating patients with complaints
2 that the patients believe are related to saline-filled
3 implants.
4 All of the individuals who have registered
5 to speak today, you've been given a number. There's
6 a reserved seating area up here. If you have not, see
7 Ann Marie.
8 Would you like to just let everybody see who
9 you are?
10 See Ann Marie and she will help you get
11 organized. When your turn comes, please step up to
12 the podium. When Ann Marie cues you, be ready to go.
13 Thank you.
14 DR. WHALEN: Thank you, Dr. Krause. Just
15 slight further housekeeping. For this morning's
16 public session the only speakers we'll have time for
17 are those who have been previously identified. The
18 time allotments will be 10 minutes for those from
19 professional societies and 10 minutes from those
20 representing consumer groups, but five minutes for
21 individual consumers in view of the number of people
22 who have asked to address us and in view of

1 reasonableness of time for this meeting.

2 If you have not identified yourself, meaning

3 probably that you were late for this meeting, to Ms.

4 Williams, we will attempt to accommodate you later but

5 we will reduce your time by 50 percent and that will

6 only be within the constraints of the time that we

7 have allotted.

8 That being said, we'll go first to three

9 individuals who will speak to us from professional

10 societies, the first of which is Dr. Shawna Willey

11 from the American College of Surgeons.

12 Dr. Willey.

13 DR. WILLEY: Thank you. Good morning. I'll

14 answer the questions first. My travel has not been

15 paid for by any professional society. I came here

16 with my own provisions. I have no financial ties to

17 any industry or health professional societies. I have

18 never been a witness or a party to a pending lawsuit.

19 I do not derive any portion of my income from surgical

20 procedures using breast implants or from treating

21 patients with complaints that are related to breast

22 implants.

1 My name is Shawna Willey and I'm a general
2 surgeon practicing in the northern Virginia and
3 Washington, D.C. area. I'm an assistant professor of
4 surgery at George Washington University Medical Center
5 where I have a practice that focuses on the surgical
6 treatment of breast disease.
7 On behalf of the American College of
8 Surgeons, I would like to thank you for the
9 opportunity to offer a general surgeon's perspective
10 on the issue of labeling information for patients who
11 are considering saline-filled breast implants.
12 I would like to focus my comments on the
13 principles involved in obtaining informed consent and
14 also on the idea of imposing a waiting period on
15 patients who are considering breast implants. I
16 believe you have written statements in front of you so
17 I'll simply summarize my main points.
18 Surgeons counsel their patients about a
19 planned operation and then the patients are asked by
20 their surgeons whether they understand the nature of
21 the procedure to be performed and the patients must
22 then give their consent for the operation to continue.

1 This process is known as informed consent and it is
2 perhaps the most important issue in the medical device
3 patient labeling debate.
4 The college agrees that it is vital for any
5 woman considering a breast implant procedure, or any
6 operation for that matter, to be well informed about
7 all the possible risks associated with the procedure
8 as well as with the device being used.
9 The key portion of the information exchange
10 must take place in the surgeon's office and it must be
11 individualized to the patient's particular
12 circumstances. Pamphlets, booklets, and video tapes
13 are extremely helpful. We do use this kind of
14 material. We supply that to patients anytime we're
15 discussing a planned procedure with them.
16 The college believes very strongly that any
17 patient guidance materials must emphasize the need for
18 patients to discuss any concerns with their surgeon,
19 and to perhaps even more importantly thoroughly review
20 their expectations and to individualize the patient's
21 care. **
22 Indeed, after reading some of the studies

1 and the reports that have been compiled on the breast
2 implant issues, many of use have concluded that the
3 greatest risks involved with breast implants probably
4 isn't imposed by the implant itself but by incomplete
5 information for the patient.
6 Many patients simply have unrealistic
7 expectations as to what an implant will do. For
8 example, patients must understand that breast implants
9 do not last forever and that certain complications
10 including those that require trips back to the
11 operating room sometimes even years later can occur.
12 We certainly support this panel's effort to
13 ensure that breast implant patients have access to
14 comprehensive thoughtful material that can be used in
15 obtaining and providing truly informed consent. But,
16 again, we believe very strongly that such material
17 must emphasize the surgeon's pivotal role in that
18 process.
19 It's also essential that the material
20 provided to patients differentiate clearly between the
21 risks and complications associated with breast
22 implants that have been scientifically proven and

1 those that have not.

2 Certainly patients should be provided with
3 information about the more controversial issues that
4 have been raised about breast implants, but not to the
5 point that their attention is diverted away from a
6 thorough review of the potential risks that are, in
7 fact, known to be associated with these devices.

8 Again, what is most important is that
9 patients consent to these procedures with realistic
10 expectations and a good understanding of the risks and
11 benefits involved.

12 Now I would like to discuss the issue of the
13 waiting period. The college strongly advises that
14 imposing or suggesting any sort of waiting period as
15 part of the restrictions the FDA may place on these
16 devices.

17 For one thing, there simply is no accepted
18 or medically appropriate period that can be
19 recommended. Any interval chosen will be entirely
20 arbitrary. On a practical level, the need to schedule
21 an operating room and the surgeon's time after the
22 initial patient consultation produces a de facto

1 waiting period for nearly all operations including
2 breast implant procedures.
3 It's really hard to imagine just what would
4 be accomplished by an arbitrarily imposed waiting
5 period and exactly who would benefit from it. In
6 fact, there's a very real potential for needless
7 inconvenience and maybe even some harm for some
8 patients. As you know, those patients who choose to
9 receive implants for aesthetic purposes are exercising
10 an individual choice and they must pay for these
11 rather expensive operations themselves. They are not
12 likely to be acting on impulse and they have often
13 thought through this decision very carefully.
14 On the other hand, my breast cancer patients
15 who op for immediate reconstruction after a mastectomy
16 have a sense of urgency of obtaining their care. They
17 may not have access to a plastic surgeon before their
18 cancer operation has been scheduled. I certainly
19 would not want an arbitrarily imposed waiting period
20 to impact on my patient's care for her breast cancer.
21 To conclude, let me say again that all
22 surgeons are obliged to provide informed consent to

1 their patients. The controversy surrounding these
2 devices you are considering today serves only to
3 amplify this point.
4 We welcome the efforts by the FDA, the
5 Institute of Medicine, and others to ensure that
6 materials are available to assist surgeons in this
7 important responsibility.
8 I thank you for the opportunity to appear
9 before you today and I'll welcome any questions that
10 you may have.
11 DR. WHALEN: Thank you, Dr. Willey. I
12 apologize for mispronouncing your name.
13 DR. WILLEY: Thank you.
14 DR. WHALEN: Are there any questions?
15 Thank you.
16 Next we'll hear from Dr. Mark Jewell from
17 the American Society of Aesthetic Plastic Surgery.
18 Dr. Jewell.
19 DR. JEWELL: Thank you. Good morning. My
20 name is Dr. Mark Jewell. I'm here today representing
21 the American Society for Aesthetic Plastic Surgery
22 which will reimburse my expenses for travel and

1 accommodations. I have no financial ties to industry
2 or other health professional societies.
3 I'm not a witness or party to any pending
4 lawsuit relating to breast implants. As a board
5 certified plastic surgeon with an active cosmetic and
6 reconstructive practice, I derive a portion of my
7 income from breast procedures including those that use
8 implants.
9 I thank the panel for this opportunity to
10 address the topic of patient informed consent. I have
11 a particular interest in this subject having
12 researched and written the patient consultation
13 resource book which is published by the American
14 Society of Plastic Surgeons and used by more than 40
15 percent of plastic surgeons in the United States.
16 This is a book that is also written in
17 Spanish that has consents. This research book
18 provides over 30 examples of plastic surgery and
19 informed consent documents for breast augmentation,
20 reconstruction, and revision.
21 My discussion today will not venture into
22 the medical legal aspects of informed consent, though

1 certainly these are of importance to physicians and
2 patients. Our interest here today, I believe, is in
3 the contribution of informed consent to quality
4 patient care and specifically to the education of
5 patients considering breast implants.
6 The process of informed consent is an
7 opportunity for the physician or surgeon to build a
8 relationship of respect and trust with the patient.
9 At the same time it fulfills one of the physician's
10 most important responsibilities ensuring that patients
11 are given information that enables them to make
12 informed choices about their health care.
13 First and foremost the doctor/patient
14 relationship must be an ethical one. It follows that
15 a physician must respect the patient's rights to self-
16 determination and autonomy in rational decision
17 making. Both require that necessary information upon
18 which a decision is to be made is disclosed to the
19 patient.
20 Understanding a risk is a crucial element of
21 this decision-making process. However, effectively
22 communicating risk is a complex task. The first

1 question that arises is whether it's necessary to
2 address all conceivable risks or only those that occur
3 frequently, or those of recognized importance.
4 Whether risk is material is a function of
5 its frequency of occurrence and severity. It is
6 obviously prohibitive and unrealistic to expect
7 physicians to discuss with their patients every risk
8 of a proposed treatment no matter how small or remote.
9 Because of the controversial nature
10 surrounding breast implants, I believe the candidates
11 for saline-filled breast implants want and expect the
12 most comprehensive approach to informed consent. This
13 would start with a discussion of appropriate
14 indications for surgery, general description of the
15 procedure, and alternatives should be reviewed.
16 This is particularly important for breast
17 reconstruction patients who have a variety of surgical
18 options. A discussion of risks should differentiate
19 between inherent risks of the device and potential
20 complications that are specific to all surgical
21 procedures.
22 Inherent risks of saline breast implants

1 would include such occurrences as capsular
2 contracture, implant deflation, rupture, and
3 degradation. Implant rippling and wrinkling should
4 also be covered. Discussions should be held with
5 regards to changes in nipple and skin sensation
6 following surgery. Patients should be advised of the
7 potential for surface contamination of implants during
8 surgery. Be told that implant displacement and
9 extrusion may occur. A seroma can occur following a
10 breast implant placement. And there certainly are
11 unknown risks.
12 Nonsurgical complications. These are
13 associated with a variety of operations such as
14 infection, bleeding, scarring, unsatisfactory result,
15 allergic reaction to medications used during surgery
16 and afterwards, the risk of surgical anesthesia, and
17 unknown risks.
18 I believe it's also important to provide
19 patients with other advisory information regarding
20 breast imaging. Also talk about the effect of
21 implants, that there is no known risk on fertility,
22 pregnancy, or breast feeding. Disclose to patients

1 that there is no known risk of implants with regards
2 to breast disease. Discuss with patients from the
3 information from the IOM that there is no known risk
4 of autoimmune disease.
5 Also discuss with patients that there are
6 potential for good long-term results, although changes
7 in breast shape and size may naturally occur not
8 relating to the implant procedure. Also, finally
9 disclose to the patient that there is the potential in
10 the future for the need for revision, replacement, or
11 removal type surgery, each of which does carry risk.
12 The items that I have mentioned are not
13 inclusive of all the recommended elements of informed
14 consent. For example, patients are entitled to know
15 the medical and scientific consensus about the
16 potential health effects, if any, of saline-filled
17 breast implants. Fortunately, the result of recently
18 published studies, as well as a scientific data by the
19 IOM and other bodies, there is reasonable assurance
20 that there is general safety and efficacy of saline-
21 filled breast implants.
22 Outcome data also confirms the benefits of

1 breast implants far outweigh the risks. However,
2 quantifying risks for patients still remains a
3 somewhat difficult area. For example, in the case of
4 saline implants we can now provide data from several
5 well-designed studies showing the incidence of implant
6 deflation over a given period of time. Yet, some
7 patients may have difficulty relating to this
8 technical data. As a consequence, they may
9 underestimate or overestimate the significance of a
10 particular risk.
11 As much as possible we should attempt to
12 relate medical risks to familiar risks that patients
13 encounter in their daily lives. We should attempt to
14 provide alternative methods of communication of the
15 same information. For example, written text, graphs,
16 or illustrations may be useful.
17 We must not consider informed consent to be
18 simply a listing of all the negatives that could occur
19 with a surgical procedure. A signed form may
20 constitute evidence that a patient consented to a
21 procedure but does not prove that the consent was
22 informed.

1 In the case of saline implants patients also
2 have the right to know what benefits can reasonably be
3 expected from a successful operation. They have
4 reached the point of considering breast implants
5 because they believe the surgery will offer them a
6 positive experience.
7 They should be informed about the high rate
8 of patient satisfaction with breast augmentation and
9 breast reconstruction. They should be made aware that
10 women undergoing these procedures often experience
11 increased self esteem, greater self confidence, and
12 more satisfying intimate relationships.
13 How detailed informed consent document can
14 be made before it's considered information overload is
15 debatable. I believe that we should be more concerned
16 with the completeness rather than the conciseness of
17 this. Despite the vast array of resources available
18 today for medical information, there is no substitute
19 for the relationship of trust between patients and
20 their doctors.
21 Certainly plastic surgeons must spend
22 adequate time in consultation with their patients.

1 It's typical for a patient and it's urgent to set
2 aside a full hour or more for the first consultation.
3 Perspective patients often come back for a second
4 consultation after reviewing the literature and the
5 other information that the physician has provided.
6 Responsible plastic surgeons welcome the
7 opportunity to help ensure a patient's fully informed
8 consent. We know from experience that our happiest
9 patients are those that have entered into a surgical
10 procedure with a complete understanding of both risks
11 and benefits.
12 With regards to a waiting period, our view
13 is this is entirely unnecessary. This is not the kind
14 of procedure for which the consultation is on Monday
15 and the surgery is on Tuesday. The situation with
16 breast reconstruction may be different. A patient's
17 decision about breast reconstruction with implants if
18 it is to be performed at the time of mastectomy often
19 must be made quickly in order not to delay cancer
20 care. Imposing a mandatory waiting period in this
21 situation would be medically unwise.
22 We wish to welcome today's examination of

1 informed consent issues in which to play a major role
2 in developing more effective patient communication.
3 I'm happy to share with the panel examples of informed
4 consent documents included in the patient consultation
5 resource book. I brought several of these with me and
6 we'll leave them for your review.
7 These documents represent plastic surgeons'
8 best efforts to provide patients with complete
9 information on breast augmentation and reconstruction
10 options. I believe that with the recent scientific
11 studies that have been presented in the course of
12 these hearings, these documents can be updated and
13 made even more useful for patients.
14 In addition, our growing understanding of
15 the best ways to communicate risk such as through
16 comparisons to common occurrences in everyday lives
17 can be incorporated in the future to help patients
18 relate to complex medical information.
19 The 2,800 members and candidates of the
20 American Society for Aesthetic Plastic Surgery look
21 forward to continuing dialogue with the FDA concerning
22 consumer education on the risks and benefits of saline

1 breast implants. Thank you.

2 DR. WHALEN: Thank you, Dr. Jewell.

3 Any questions?

4 DR. BURKHARDT: I have a question for Dr.

5 Jewell.

6 Dr. Jewell, based on your personal

7 experience in private practice, approximately what

8 percentage of patients who come in to see you

9 requesting elective breast augmentation will then

10 reject the procedure on the basis of this extensive

11 informed consent document that you present to them

12 saying, "No, I don't want to do that. I didn't

13 realize that was too risky for me."

14 DR. JEWELL: I would say that's a very small

15 percentage. Maybe one or two percent. Most patients

16 when they come to the office have already made up

17 their mind that they wish to undergo this procedure

18 after thinking about it for some length of time.

19 DR. BURKHARDT: Within the last year can you

20 think of a single patient who has turned down the

21 operation on the basis of these documents?

22 DR. JEWELL: No, sir. In fact, I think they

1 welcome the document because it has educational value.
2 It serves as a medium to develop additional questions
3 during the consultation period.
4 DR. BURKHARDT: Thank you.
5 DR. WHALEN: Thank you.
6 We next will hear from Dr. Bailey of the
7 American Society of Plastic Surgeons.
8 DR. BAILEY: Good morning, Mr. Chairman,
9 members of the panel. I appreciate very much the
10 privilege of standing before you this morning and
11 commenting on the topic of informed consent. I'm a
12 board certified plastic surgeon in my 27th year of
13 practice in Houston, Texas.
14 I also have been licensed to practice law in
15 Texas for the past 20 years, although I try to avoid
16 it as much as possible. I'm past Chair of our
17 Professional Liability Committee for the now ASPS and
18 member of the Board of Trustees of the Texas Medical
19 Association.
20 When the State of Texas established the
21 Texas Medical Disclosure Panel I was appointed to that
22 body and that was a body that put together a list of

1 procedures, both medical and surgical, with
2 accompanying items which should be disclosed to
3 patients for these procedures.
4 DR. WHALEN: Dr. Bailey, could you address
5 the four questions that were posed?
6 DR. BAILEY: Yes, sir. My expenses here
7 have been paid for by the ASPS. In Houston and Texas
8 in general we had a rather -- sort of a hotbed of
9 litigation. I think I'm still named in four or five
10 suits which at this point have not been settled with
11 the plaintiff. I hold no financial interest in any
12 breast implant company. There is a fair sized group
13 of plastic surgeons in Houston who have filed suit
14 against two of the manufacturers who are not in this
15 process just to ensure that we're at the table during
16 settlement procedures by these individuals. I've had
17 no judgments or paid no settlements in any of these
18 cases.
19 DR. WHALEN: Is any portion of your income
20 still derived from --
21 DR. BAILEY: I do a moderate number of
22 augmentation mammoplasties in my practice. Yes, sir.

1 DR. WHALEN: Thank you.

2 DR. BAILEY: As I said, I'm representing the
3 American Society of Plastic Surgeons. A little bit of
4 my background. My dad is a physician, retired,
5 general practice. His father was a physician as well
6 in general practice. I look at informed consent from
7 the perspective which perhaps is slightly different
8 from some of my colleagues because the tradition of
9 medical practices in my family is very strong and I
10 consider myself a physician first and a plastic
11 surgeon second.

12 I also grew up the older brother of three
13 younger sisters and have a daughter and two
14 granddaughters so I find myself someone protective of
15 the women in my practice who come in for various
16 procedures.

17 I think Dr. Jewell has presented an
18 excellent overview of the process of informed consent
19 and I think he alluded to the fact that there is legal
20 informed consent which has its connotations. But
21 informed consent, in my viewpoint, is a communication
22 process which far exceeds the value that you might

1 attribute to a legal informed consent.

2 I think that we are obligated and should

3 convey essentially all the information that's been

4 presented to you here today to our patients, not

5 because they will base their decision to have the

6 surgery or not have the surgery on the things that are

7 disclosed to them generally because they have

8 generally made up their mind.

9 I share Dr. Jewell's experience in that I

10 can't really recall the last patient who upon hearing

11 these bits of information have declined to have the

12 procedure. It affords both parties the benefit of

13 sitting face to face and sort of assessing one another

14 not only medically but more or less personally and

15 psychologically and this is extremely important.

16 To specifically address, however, the items

17 that we convey to these patients, some of them are for

18 information only but there are a few, I think, that

19 are extremely important. The way I arrived at these

20 extremely important items of information, I asked

21 myself if my daughter was in an office of a plastic

22 surgeon in Austin, Texas, what if he did not relate to

1 her what items would perhaps cause me some serious
2 concern if not anger. I emphasize these specific
3 items much more to my patients than I do to the less
4 important items.
5 With respect to interacting with the
6 patients, it's not uncommon to be sitting in front of
7 a very young patient where you feel like nothing that
8 you're saying is being heard. I think that we have to
9 address ourselves as physicians to belaboring some of
10 these points and perhaps imposing our own waiting
11 period and insisting that they come back for a second
12 consultation.
13 I think that is the type of waiting period
14 that is more natural. I think it should be imposed by
15 the physician where he has a patient where he really
16 sort of doubts the motivation. The other thing that
17 we sometimes see, although fortunately not too often,
18 is a mother who is pushing an augmentation on a
19 daughter because of her early life experiences, or a
20 boyfriend or a husband.
21 I'm very uncomfortable with these
22 situations. It's not uncommon for me to refuse two or

1 three patients a month based on some of these concerns
2 when they are actually candidates physically for the
3 procedure.
4 After we've gone through all these bits of
5 information, I think our final role is to sit down and
6 refine what we are going to do if we are indeed going
7 to proceed with this process. I would like to point
8 out one thing that I do emphasis and I would emphasis
9 to my daughter if she were contemplating this surgery
10 are the shortcomings.
11 I think one of the problems here is we have
12 paired organs and I can tell you that whenever you do
13 two operations, whether it's on two people or two
14 operations on the same person, they never come out
15 exactly the same. We could sit here and say,
16 goodness, the complication rate, if we call this a
17 complication, is extremely high.
18 I would stress to my daughter that if she
19 cannot mentally deal with the fact that one of her
20 breasts might be slightly more firm than the other or
21 that she may feel ripples in her implants, just assume
22 that she's going to have it and don't do it. These

1 two things I don't particularly consider complications
2 are common enough that I think these are a couple of
3 the things that need to be stressed.
4 With respect to spherical contracture many
5 times when I've had a patient who for years has had
6 breast implants they will develop a very mild
7 shrinkage of the scar capsule around an implant. If
8 I took anybody into the room and wouldn't let them
9 compare the two breasts, most physicians examining the
10 so-called more firm breast would feel that it was
11 normal. But on comparison with the other side would
12 have to agree with the patient that there is some
13 moderate shrinkage of the capsule. I think these
14 things need to be emphasized to the patient.
15 The last thing that has not been mentioned
16 that I do emphasize to my patients is if they have a
17 minor shortcoming such as a mild firmness of one
18 breast over the other or rippling, it takes a
19 courageous surgeon to deny them a second surgery
20 because in our elements that influence us in making
21 our decisions, we cannot let the emotional side of our
22 judgment override the scientific.

1 Of the severe problems that I have seen in
2 consultation with breast augmentation surgery,
3 essentially all of these patients have had multiple
4 surgeries. Many of these patients upon completing my
5 consultation when I tell them that there's really
6 nothing I can do will state, "You know, it wasn't that
7 bad the first time. I wish I had never had the second
8 surgery."
9 I think that's all the pertinent material I
10 would have to offer you here today and I would be
11 happy to entertain any questions.
12 DR. WHALEN: Dr. Bandeen-Roche.
13 DR. BANDEEN-ROCHE: I'm just curious when
14 you think about your daughters, what are the one or
15 two safety related things that you would talk to them
16 about? You know, complications or pain, that sort of
17 thing.
18 DR. BAILEY: The things that I feel the
19 strongest about?
20 DR. BANDEEN-ROCHE: Yes.
21 DR. BAILEY: Our anesthesia and with the
22 advent of the pulse oximeter, I am not -- all of my

1 children have had surgeries and, of course, there's
2 anxiety there but I am not really worried about the
3 safety with respect to life threatening issues.
4 Infections, I've had two in 27 years so I
5 would certainly mention that to her. The main things,
6 I think, are the imperfections because these minor
7 imperfections are what usually lead to a second or
8 third surgery.
9 Visualize a young guy who has just gone into
10 plastic surgery and he's a year or two into practice
11 and he has a lady come in with maybe sort of a strong
12 personality who is maybe a little overly upset about
13 a very mild difference in the softness of her two
14 breasts.
15 This plastic surgeon has tremendous pressure
16 as a new person in the community to have this person
17 satisfied with her result. A lot of times they
18 haven't developed the judgment or the courage to say,
19 "Look, it's not bad enough." A lot of times a patient
20 won't let the discussion end there.
21 So the things I would stress to my daughter
22 are if you have the rippling, it's relatively common.

1 The difference in feel is relatively common. Those
2 are the two main things I would stress to her, the
3 slight imperfections that we see from time to time.
4 Then the third is to avoid secondary surgeries if
5 possible, not to force that issue.
6 DR. BANDEEN-ROCHE: And one more thing,
7 although, Chair, please cut me off if we need to be
8 mindful of the time. For any of the first three
9 speakers, just a very brief comment on we know that
10 among all human beings some are less effective
11 communicators than others. Some are more neglectful.
12 Some are even unethical. Most doctors are wonderful
13 but occasionally a woman will have a surgeon who is
14 less effective. Do you propose safeguards in terms of
15 gate keeping for those women?
16 DR. BAILEY: Well, you know, I grew up in
17 the household of a wonderful physician and that rubbed
18 off so I'm very conscious of that. Sometimes I'm very
19 embarrassed by conduct. Not just other plastic
20 surgeons but certainly other physicians as well.
21 I think it's unfortunate but I think we need
22 these hearings. I think we need to come up with a set

1 of facts that should be communicated because, you're
2 right, some physicians do not communicate adequately
3 with their patients. I think you're going about this
4 perhaps in the best and probably the only way by
5 coming up with an acceptable informed consent.
6 DR. WHALEN: Well, just before we proceed to
7 the next question since that was asked of all three,
8 do either Dr. Jewell or Dr. Willey have any response
9 to that question?
10 DR. JEWELL: Well, I think there is a need
11 for a sort of uniform national standard of informed
12 consent with regards this type of medical device. As
13 I testified earlier, you know, just signing a consent
14 form is not informed consent. I mean, there has to be
15 a dialogue between the physician, or the surgeon in
16 this case, and the patient with regards to answering
17 their questions.
18 I think some type of form that does have
19 plain English explanations of risks and consequences
20 in relating it to real events that a patient
21 experiences in real life is meaningful versus just a
22 laundry list of everything that can go wrong and that

1 the benefits of the operation should be also discussed
2 in the informed consent document.
3 I'm happy to leave this book with the panel
4 today for you to review.
5 DR. WHALEN: Dr. Willey.
6 DR. WILLEY: I would echo the same that
7 having a standard list of information available for
8 patients is valuable for patients and I think patients
9 like that. I don't think that standard list can
10 individualize a patient's care and I think that's the
11 dialogue that needs to occur. That's what a patient
12 needs to hear from the surgeon.
13 The patients also need to trust themselves
14 that they are getting that dialogue to occur. They
15 are getting the information they need. They are
16 getting it applied to themselves. That if they aren't
17 getting that information, they have the option to see
18 someone else.
19 DR. WHALEN: Dr. Willey, while you're at the
20 podium, Dr. Morykwas had a question.
21 DR. WILLEY: Yes.
22 DR. MORYKWAS: Actually, it's a very short

1 two-part question, if I may. In your personal
2 experience what's the average interval between
3 diagnosis and a mastectomy and what is the shortest
4 time interval that you've ever observed?
5 DR. WILLEY: I try not to let more than two
6 or three weeks go by between the time I've told the
7 patient she needs a mastectomy and the time that she
8 actually had definitive therapy. I would say the
9 average is around 10 days to two weeks. I would say
10 the shortest is two to three days.
11 DR. MORYKWAS: Thank you.
12 DR. WHALEN: Ms. Dubler, a question for Dr.
13 Willey?
14 MS. DUBLER: Yes. The theory of informed
15 consent and the practice developed in a context in
16 which the doctor and the patient were in a private
17 relationship. Physicians now advertise and especially
18 cosmetic plastic surgery is the subject of
19 advertisement. "Do something nice for yourself today.
20 Get some new breasts."
21 Should we treat physicians who advertise
22 their wares and, therefore, are attempting to convince

1 women to get this procedures, should we treat them
2 differently? How should we think about that issue?
3 That's for all three of you.
4 DR. WHALEN: I would just insert for the
5 record that Dr. Willey is a general surgeon and deals
6 with breast disease. So perhaps that question needs
7 to be answered in part also by the other gentlemen.
8 MS. DUBLER: No, I'd like to address this to
9 all three.
10 DR. WHALEN: Okay.
11 MS. DUBLER: Thank you.
12 DR. WILLEY: Well, advertising of medical
13 services is certainly an issue. I believe that if a
14 surgeon has the credentials to do the operation that
15 they are planning to do, the issue of advertisement is
16 not necessarily to be factored into that. That
17 doesn't release them from the obligation to
18 communicate with their patients, nor does that make
19 them someone I think should be considered differently.
20 It's still a process that needs to be gone
21 through. Yes, they may make their initial contact
22 with the patient by an advertisement but that doesn't

1 sidestep the whole issue of informed consent with that
2 individual patient. I don't think that we need to
3 treat that necessarily differently as long as that
4 process is occurring after the initial contact.
5 MS. DUBLER: Do you think it raises any
6 issues of conflict of interest to a different level?
7 DR. WILLEY: Well, in some regards some of
8 us advertise our services. Maybe it's by word of
9 mouth of the patient. Maybe it's by the medical
10 societies we join and, therefore, our name is on a web
11 site. Or maybe it's because you pay for an ad to be
12 put in a newspaper or magazine.
13 The conflict of interest arises in that as
14 a plastic surgeon, for instance, you are making money
15 off of that procedure. That's how you make a living
16 and the more procedures you do, the more money you are
17 going to make. The more patients you bring in for
18 that procedure, the more money you are going to make.
19 I don't think that negates the professionalism of the
20 physician or the organization.
21 DR. WHALEN: Dr. Bailey, would you like to
22 answer that question?

1 DR. BAILEY: I think the Supreme Court dealt
2 with, you know, it was forced to become accepted when
3 lawyers initially advertised. The Supreme Court said
4 that professionals were permitted to advertise through
5 freedom of speech. Generally speaking the standard
6 that's been applied is that you cannot put anything
7 into an advertisement that is false or deceptive and
8 so these advertisements have to be very carefully
9 crafted to avoid potential conflicts of interest.
10 Most of the states have mechanisms to -- our
11 State Board of Medical Examiners, if I were to see an
12 ad that I thought misrepresented the services or were
13 deceptive, I can contact our State Board of Medical
14 Examiners and they will take action in that respect.
15 DR. WHALEN: Dr. Jewell.
16 DR. JEWELL: Thank you. I think we do have
17 to differentiate here between marketing activities to
18 attract patients and address that separately for
19 informed consent. As Dr. Bailey said, I think there
20 are issues of false and deceptive advertising that
21 need to be addressed whether you materially
22 misrepresent your qualifications, training, cure, or

1 efficacy. I think that has to be separated from the
2 issue of informed consent.
3 All patients need informed consent to
4 undergo a surgical procedure. There are certainly
5 significant variations in the type of advertising from
6 some that is very distasteful and inappropriate to
7 professional advertising or marketing of one's
8 services. I think we are dealing with two separate
9 issues here. Thank you.
10 DR. WHALEN: Thank you.
11 Dr. Burkhardt.
12 DR. BURKHARDT: No.
13 DR. WHALEN: Any other questions? Dr.
14 Blumenstein.
15 DR. BLUMENSTEIN: I have a question for Dr.
16 Bailey and then a question for all three. Why is it
17 that you imagine a surgeon in Austin for your
18 daughter?
19 DR. JEWELL: Because that's where she lives.
20 Or a surgeon in Dallas for my baby sister. Same
21 thing.
22 DR. BLUMENSTEIN: That just struck me as a

1 more serious question. The material in informed
2 consent oft times contains numbers like probabilities
3 and risk percents and things of that nature. How do
4 you feel that patients -- what level of understanding
5 do patients have of these numbers? I don't want to
6 put you on the spot by asking you what level of
7 understanding you have.
8 DR. JEWELL: Well, my standard statement
9 that I make to my patients is I'll say a very few
10 people have this particular problem but if you are the
11 person that has it, it doesn't matter how many don't.
12 In deciding on this surgery, think about it. Think
13 about what if it happens to me. Just because it's a
14 small percentage, don't dismiss it completely.
15 If the worry of that particular problem is
16 a deterrent, then you shouldn't have the surgery. I
17 sort of make the analogy to if you want to drive a
18 Miata in Houston, Texas, on the freeway, I guess you
19 can do that. I think everybody knows the potential
20 problems you might have with that when you have an
21 altercation with an 18-wheeler. If you do, you're
22 dead and the other people that have the Miatas and

1 don't have the accident are okay.

2 I think you just have to sort of put it in

3 perspective for the patient because that's just the

4 way it is. If you get the complication, it's very

5 little consolation that others don't have it.

6 DR. WHALEN: Did you wish for the other two

7 to address that?

8 DR. BLUMENSTEIN: If they have comments on

9 that issue.

10 DR. JEWELL: I think in terms of risk

11 discussions with patients, I always tell a patient

12 that they have done something very risky which is

13 drive an automobile to my office. Yet, you don't get

14 in the automobile predicated on thinking that you're

15 going to have a crash.

16 Risk, of course, comes down to frequency and

17 severity. Talking about infections, I've been in

18 practice for 20 years. I've been using breast

19 implants for over 22. I've never had an infection.

20 I talk to my patients about that with regards to the

21 issue of infection.

22 With regards to risk, I think it's also good

1 to quantify it in terms of severity and whether there
2 is a solution to the problem should it occur. In most
3 situations there is a reasonable solution to the
4 occurrence of risk or a complication.
5 I also talk to patients that the ultimate
6 complication of any surgical procedure is death and
7 that they do have to consider that, although it's
8 extremely remote. Thank you.
9 DR. WHALEN: Dr. Willey.
10 DR. WILLEY: I think it's extremely
11 important for patients to have some idea of the number
12 that is being discussed whether that's two percent or
13 80 percent. I think patients do appreciate having
14 some idea of what may be expected. However, my
15 standard line to patients is that statistics fall
16 apart when applied to an individual.
17 Although you can talk about large
18 populations of people and say that 80 percent of these
19 people had a good outcome, again when it's an
20 individual, they have to look at all the possibilities
21 and if that complication occurred in them, it's 100
22 percent for them.

1 Although I think the numbers are important
2 because it gives them some sense of the frequency of
3 problems, they have to understand that it doesn't
4 necessarily extrapolate to their own personal
5 experience.
6 DR. WHALEN: Thank you.
7 The last question, Ms. Dubler.
8 MS. DUBLER: I actually have two brief
9 questions on different topics. One is the ability to
10 comprehend and to judge the wisdom of behavior we hope
11 rises with age. Would you prohibit someone from under
12 18 from getting a breast implant for augmentation?
13 I'm not talking about for reconstruction or deformity.
14 Would you discourage patients in their low 20s? In
15 other words, are there any age guidelines that you
16 use?
17 My second question is a little different,
18 which is we've heard over the last two days that some
19 of the complications may have far more to do with
20 surgical technique than with the device. Therefore,
21 would you have any suggestion about how we might deal
22 with the issue that more qualified surgeons probably

1 do a better job. As cosmetic surgery becomes a source
2 of great income, it may attract people who are less
3 able.
4 First the age question and then the ability
5 question.
6 DR. JEWELL: I think the age question is a
7 very good question. I personally impose -- I would
8 not operate on a 17-year-old. I know that
9 occasionally they are getting operated on.
10 Theoretically at 18 they should be entitled to come in
11 and talk to you about having this procedure done.
12 It raises another question. I have seen 20-
13 year-old women who were physics majors that are more
14 mature than I am. You are sitting there, you are
15 having the discussion, they are paying attention, they
16 are understanding everything perhaps better than 90
17 percent of the augmentation patients you have
18 regardless of age. I had one recently and it's a
19 wonderful feeling to have someone listening to you and
20 understanding what you're saying.
21 Generally speaking when I deal with my very
22 young patients I spend a little more time on the long

1 term problems or occurrences. I tell all of these
2 people that they are probably going to have at least
3 one or two deflations during the next 50 years and
4 maybe more than that. I emphasize that.
5 I personally have sort of a self-imposed
6 size limitation that I put on the implants depending
7 on the amount of breast tissue they have. I don't
8 like to put in an especially large implant into
9 someone and stretch the tissue out excessively. That
10 is not a problem in the immediate term.
11 It becomes a problem if you have to take
12 that implant out 10 or 15 years later and it may be
13 sort of hard to manage to keep that breast looking
14 decently. There are considerations with respect to
15 age that I think are a little different if you're
16 talking to, say, a 35-year-old woman versus somebody
17 in their early 20s.
18 The problem that you also run into is -- I
19 see many of the panel have raised kids -- you sort of
20 notice as your children are in the early 20s and
21 certainly in the teens that its immediate
22 gratification now. Don't bother me with the details.

1 I find that a lot of the younger people are
2 not -- I don't feel like they are really listening and
3 so sometimes I will impose a second visit on them or
4 have them, you know, spend more time reading over the
5 material and come back and sort of show me that they
6 have an understanding of it.
7 DR. BURKHARDT: May I ask one question? I'm
8 sorry.
9 DR. WHALEN: Is it brief?
10 DR. BURKHARDT: It's brief.
11 DR. WHALEN: Dr. Burkhardt.
12 DR. BURKHARDT: Dr. Bailey, I'm going to put
13 you on the spot for a second here. One of the jobs
14 this committee has is to evaluate this process and
15 decide whether it's effective. I have a six-page
16 permit here in front of me for breast augmentation
17 that people are supposed to sign. Obviously one of
18 the ways we can evaluate it's effectiveness is looking
19 at how it works in legal defense. I ask you that
20 because you're an attorney. How are we to measure the
21 effectiveness of this process? I've just asked Dr.
22 Jewell and he's had nobody -- this is the permit he

1 uses I assume. He hasn't had anybody in the last year
2 turn the operation down after they've signed this
3 thing. It looks like a mortgage document.
4 DR. BAILEY: I think mortgage document is
5 even more onerous than this. I think certainly in
6 theory most people maybe with a little explanation
7 from the physician can certainly understand every
8 aspect of what's in the six-page document.
9 DR. BURKHARDT: Is this process measurable
10 is what I'm asking.
11 DR. BAILEY: I don't know what you would
12 measure to tell you the honest truth. I think we are
13 obligated to give this information to people. I feel
14 very, very strongly that they should have access to
15 this information. The fact that it usually doesn't
16 influence them is a function of the fact that most of
17 them have friends, acquaintances and so forth that
18 have had this surgery done. Many of them have parents
19 now that have had it done and notwithstanding the
20 deliberations of this committee, this has been a very
21 well accepted well tolerated and popular operation.
22 In spite of the fact that we do have complications,

1 very few people have to have these implants out. I
2 think it's partly that. They listen to what you have
3 to say but they haven't the experiences of the
4 negative experiences.
5 DR. BURKHARDT: Thank you, Mr. Chairman.
6 DR. WHALEN: Thank you.
7 A request has been made to hear the other
8 physicians. I'll allow Dr. Jewell but I would ask in
9 the interest of time since we're not dealing with a
10 plastic surgeon in Dr. Willey that we just hear from
11 Dr. Jewell.
12 DR. JEWELL: Right. You've mentioned that
13 the issue of this surgical technique, the
14 augmentation, mammoplasty, attract the unqualified and
15 untrained practitioners. I think, of course, any
16 physician can call themselves a cosmetic or plastic
17 surgeon and go to a weekend course.
18 The heritage of general surgery and plastic
19 surgery, I think, best prepares one to do this type of
20 breast surgeries. I think it is also known that the
21 more you do of an operation, the better you do with
22 regards to your results. I think having experience is

1 no substitute for any other sort of training. Thank
2 you.
3 DR. WHALEN: Thank you. We'll be shifting
4 to hearing from individual consumers, so for the
5 timekeeper these will be five minute limits.
6 We first will hear from Ms. Mary McDonough.
7 MS. MCDONOUGH: Good morning. My name is
8 Mary McDonough and to participate in this hearing my
9 travel expenses were paid for by the Sheridan Group.
10 I am involved in litigation along with other women who
11 are part of the global settlement with manufacturers
12 of silicone and saline breast implant. No part of my
13 income is derived from breast implants.
14 Just to try and make this brief, I would
15 like to have my testimony just for the record, the
16 whole thing. I'm going to try and orally be as brief
17 as I can.
18 I'm hear today as a breast implant survivor.
19 I am a mom and I am an actress. Like many of the
20 other actresses in my field, I thought it was
21 necessary to have implants to succeed in front of the
22 camera. I underwent a surgery device of silicone

1 breast implants. The health problems I began to
2 experience are not unlike those that you've heard from
3 women over the past couple of days.
4 I won't go into the details. However, I do
5 want to say that I thought I was making an informed
6 decision. I asked my doctor tough questions and I
7 consulted with my friends who had received implants.
8 I read the very little information that was available.
9 When I began experiencing pain and chronic fatigue and
10 was eventually diagnosed with Lupus, I actually blamed
11 myself for making a professional decision which has
12 had a devastating long-term effect on my life and
13 health.
14 That was in 1985. Today after talking with
15 a lot of implanted women who have had many similar
16 experiences, I have a much different view. I did not
17 receive true informed consent, nor did the thousands
18 of women who have received saline and silicone breast
19 implants.
20 My concern for women who have gotten or may
21 be considering implants has led me to become involved.
22 In 1998 I helped Senator Boxer and Congressman Gene

1 Green launch a legislative effort to bolster
2 information and informed consent and encourage
3 independent research of silicone breast implants.
4 Just last summer I met with Dr. Fiegal along with
5 other silicone implant women to discuss the FDA's
6 oversight of breast implants.
7 Once I became involved friends, colleagues
8 began telling me about their horror stories with
9 breast implants. Their health problems led me to
10 believe that saline is hardly a safe alternative to
11 silicone.
12 This panel's endorsement of these devices
13 despite the lack of convincing long-term safety data
14 means that we just have to find other ways to protect
15 women. Approval of a supposedly life-enhancing
16 medical device with so many postmarking conditions is
17 hardly a wringing endorsement for their safety.
18 So now with the PMAs behind us, I think the
19 course of action is to really safeguard the future of
20 women with an informed consent document. Some how a
21 piece of paper is supposed to make up for the
22 manufacturer's insufficient mechanical testing,

1 revision data, and retrieval analysis.

2 It's supposed to make up for inaccurate
3 labeling and risk estimates. And it's supposed to
4 make up for the plastic surgeon's obligation to fully
5 inform their patients of the potential complications
6 and reoperations and a doctor's chosen surgical
7 procedures.

8 The public comment over the past couple of
9 days has been discounted by the members of this panel
10 so I hope that finally today the FDA and this panel
11 are listening to the patients. There are a number of
12 measures that the Federal Government could implement
13 to better protect women and preserve their health and
14 their quality of life. These measures include
15 conducting independent research, establishing an
16 independently operated patient database and retrieval
17 program, and strengthening informed consent.

18 My first recommendation for the NIH and the
19 FDA is to conduct the independent research that is so
20 desperately needed in this area. I fear that saline
21 breast implants are going to follow the dubious path
22 of the silicone breast implants. I hope we can learn

1 from all of the past mistakes and ensure independent
2 research is conducted not only on silicone but also on
3 saline implants.
4 This past summer the Institute of Medicine
5 concluded first reoperations and local complications
6 are frequent enough to be a cause for concern and to
7 justify the conclusion that they are the primary
8 safety issue with breast implants.
9 Second, risks accumulate over the lifetime
10 of the implant but quantitative data on this point are
11 lacking from modern implants and deficient
12 historically.
13 Third, information concerning the nature and
14 relatively high frequency of local complications and
15 reoperations is an essential element of adequate
16 informed consent for women undergoing breast
17 implantation.
18 The IOM review reinforced the need to study
19 women for a very long period of time, as much as 20
20 years to accurately assess the health effects of those
21 implants. Furthermore, almost no research is being
22 done to track mastectomy patients who suffer from

1 local complications at a much higher rate than other
2 breast implant recipients.
3 My second recommendation is to strengthen
4 the informed consent. Recently there has been a lot
5 of focus on the inadequacies of informed consent in
6 clinical trials. As you've heard, insufficient and
7 inaccurate information has posed many problems for
8 women in the breast implant trials.
9 Even the Institute of Medicine as some have
10 recognized that women are not being adequately warned
11 of rupture, painful local complications, and multiple
12 surgeries. Until independent research is available
13 and able to answer the long-term safety questions
14 surrounding breast implants, women at the very least
15 they need to be informed about what we do know, the
16 high rate of deflation, reoperations, and local
17 complications.
18 Issues surrounding breast feeding of
19 children should be stated to reflect that there is a
20 lack of scientific study to even determine potential
21 side effects to offspring. The likelihood of an
22 inaccurate mammogram --

1 DR. WHALEN: Ms. McDonough, could you draw
2 it to a conclusion?
3 MS. MCDONOUGH: Yes. Finally, the informed
4 consent really needs to address the financial
5 implications and the risks related to insurability and
6 employment, and the psychological effects not only of
7 the positive outcomes but also the negative ones.
8 Thanks.
9 DR. WHALEN: Thank you.
10 Next, Ms. Liz Macleod.
11 MS. MACLEOD: Good morning. I answered the
12 four questions yesterday. Should I do so again?
13 DR. WHALEN: Yes, please.
14 MS. MACLEOD: Okay. I'm Liz Macleod. My
15 travel arrangements and accommodations have been paid
16 for by my husband and my support group, United
17 Silicone Survivors of the World - New Mexico. The
18 answer to the remaining questions is no.
19 I had a breast implant in '83 and I didn't
20 feel I received enough information to give any
21 semblance of informed consent. The surgery was very
22 popular and held out to be wildly successful over a

1 sustained period of time.

2 I assumed that there was Government

3 oversight for the safety and quality of the device

4 being inserted into my chest. Apart from the normal

5 warnings stressing the risk of anesthesia, as we've

6 heard those risks stressed today, the other risks were

7 presented as rare, slight, mostly aesthetic, and all

8 easily correctable.

9 My doctor was caring and compassionate and

10 he reassured me. He really had my trust. I never

11 doubted my safety even when I questioned my doctor

12 about consequences I might face as a result of this

13 surgery. I was young and I think I spent more time

14 trying to evaluate whether to spend the money on a

15 vacation or on getting my breasts to look the way I

16 thought I wanted them to look.

17 I would like to thank now after having

18 experienced very bad results that I would choose

19 differently if I knew about things like shell

20 permeability, saline expiration, gel bleed, biological

21 reactivity, multiple surgery risks, frequent need for

22 such surgeries, the various health complications that

1 women have had. I would want to know about the
2 possible bad results in terms that I could understand.
3 I wish I had been told that these devices
4 were unregulated and I wish I had been told that there
5 hadn't been appropriate and adequate study of women
6 who had received implants. I would like to have known
7 about failure rates. I would want to know that the
8 devices degrade in vitro and that it is much simpler
9 to put them in than to take them out. I would
10 definitely have wanted to know why having an implant
11 would make it impossible for me to get health
12 insurance from many insurers.
13 I would want to have it expressly pointed
14 out to me that it is in the financial interest of both
15 manufacturers and plastic surgeons for these devices
16 to fail. It is in some ways ironic that there is that
17 conflict between the patient interest and the
18 financial interest. I'm not saying the moral interest
19 but the financial interest of these other parties.
20 For every failed implant a surgeon will be
21 paid to explant the device and likely to replace it.
22 For every failed implant there is a probability that

1 it will be replaced by another manufactured implant.
2 Effectively these parties have a repeat customer of
3 the industry and there is no expanse in acquiring that
4 customer. You don't have to advertise to a woman who
5 has no choice after complications arise.
6 To my mind, labeling and consent are not a
7 panisea in this matter. To the contrary, expecting
8 the consumer to wade through this quagmire of issues
9 and information and reach an intelligent decision
10 about the safety of the particular implant in her case
11 is patently absurd.
12 A woman isn't likely to consider getting an
13 implant from a doctor she doesn't trust implicitly.
14 I think medical trust will always tromp written
15 warnings. You can't control what a doctor will tell
16 his patient.
17 As one panel member suggested yesterday,
18 legislation of surgeon conduct is like herding cats.
19 We don't know what will be stressed or emphasized by
20 any of the doctors but, as we've heard the doctors
21 here today, I think their concerns are still largely
22 about aesthetic risks. They still talk about the fact

1 that you may have to replace these. They don't talk
2 about how serious explanation surgery can be. The
3 fact that just giving consent once results in the need
4 to continue. You've given up all your consent for an
5 ongoing process.
6 The effective outcome of elaborate informed
7 consent is to place the entire burden of the risk of
8 using these dangerous products more squarely on the
9 shoulders of the woman user. By fixing responsibility
10 in anticipation of the expected problems, we assure
11 that when something goes wrong, the woman will bear
12 the burden of the risks both physically and
13 financially and likely legally.
14 I don't think it's appropriate to expect
15 patients to maintain their own records of their
16 implants or to decide whether to enter a registry or
17 to interpret physician labeling, or to even remind a
18 surgeon to wash his hands. When you consider these
19 questions, please consider whether we want a doctor's
20 obligations to his patients to be best summarized in
21 these kinds of cases by the words of the hippocratic
22 oath or by the words caveat emptor, let the buyer

1 beware. Thank you.

2 DR. WHALEN: Thank you.

3 Next, Ms. Lisa Hickey.

4 MS. HICKEY: Good morning. Thank you. I am

5 a flight attendant for a major airline and I've also

6 had breast implant experience with problems. I have

7 a lot of friends who've had problems. I paid for my

8 own expenses to be here today.

9 I'm here to ask you if you would permanently

10 implant a defective device near your vital organs,

11 then sign a waiver releasing liability and agree to

12 become uninsurable. Approval of these devices will

13 result in that outcome for many women. Women you have

14 or have had implants are being denied coverage just

15 recently, a month ago. Not for complications but for

16 health care coverage.

17 Unfortunately, Mentor and McGhan have a 15-

18 year history of repeatedly violating laws of good

19 manufacturing practices. I have a hard time believing

20 that today all problems are corrected and products are

21 safe.

22 According to these 483s under reporting of

1 complications has occurred. Adverse events have been
2 omitted from safety data. Saline patients are
3 required to sign waivers agreeing to not claim implant
4 related problems which means problems are kept quiet.
5 There is no long-term data on implant exposure or
6 breast feeding. Absent of data does not mean absence
7 of problems.
8 Women want these products because they
9 believe it is safe and effective. They are lured into
10 the safety of benign salt water, have complication,
11 and then may qualify for revision surgery with
12 silicone gel implants. Do you realize that saline
13 device failure causing deformity or need could put a
14 woman at even higher risk with revision surgery using
15 silicone gel-filled implants?
16 After the '92 moratorium sponsors were
17 required to collect data on silicone gel implant
18 users. The FDA was supposed to monitor the studies.
19 I asked the FDA today what percentage of those
20 patients were followed for the five-year period
21 required by the study. Can you answer?
22 DR. WHALEN: Maybe you can make your

1 statement but it's not appropriate to be asking
2 questions. Thank you.
3 MS. HICKEY: It is my understanding that
4 follow-up was as low as 30 percent. Can we be assured
5 there will be better accountability with these saline
6 devices?
7 There appears to have been a successful
8 system of seeming collaboration between doctors,
9 manufacturers, and possibly the FDA to preserve the
10 economic success of the products rather than patient
11 safety. Full disclosure of all potential problems
12 will help a patient with true risk assessment. the
13 IOM states that risks accumulate over time.
14 Women should be prepared for repeat
15 surgeries leading to ultimate and final removal. Each
16 repeat surgery results in loss of breast tissue.
17 Women should understand that they may be left with
18 scarred mutilated breasts smaller than when they began
19 the implant process.
20 Had sponsors conducted long-term 15 to 20-
21 year studies, patient satisfaction would have
22 decreased resulting in different recommendations by

1 this panel regarding effectiveness. The bottom line?
2 Breast size initially increases, eventually decreases.
3 Patient satisfaction in the short-term is high and in
4 the long-term is low.
5 My 14-year-old daughter is on this trip with
6 me today. She has see too often the devastating
7 effects of these failed non-lifesaving devices on many
8 of my friends and coworkers. Money for her college
9 education paid for my device failures. Device failure
10 can effect an entire family. Device failure can
11 effect a woman's life permanently. Device failure is
12 eminent so patients should be warned. Thank you.
13 DR. WHALEN: Ms. Hickey, thank you. I
14 realize that was emotional but I need to ask you
15 please before you sit down, you answered one of the
16 four questions but not the other three. I'm sorry.
17 You said you paid for your own travel expenses. Could
18 you address the other three questions, please.
19 MS. HICKEY: I'm sorry. I don't know what
20 the other three questions are.
21 DR. WHALEN: Are you involved in any
22 litigation?

1 MS. HICKEY: I am not involved in litigation
2 at all.
3 DR. WHALEN: I'm sure you don't derive any
4 income from insertion of breast implants.
5 MS. HICKEY: I do not get any income from
6 breast implants.
7 DR. WHALEN: And you have no relationship to
8 the manufacturers of any of these devices?
9 MS. HICKEY: I have no relation to
10 manufacturers.
11 DR. WHALEN: Thank you.
12 DR. BANDEEN-ROCHE: Could I ask a very brief
13 question?
14 MS. HICKEY: Yes.
15 DR. BANDEEN-ROCHE: Could I just ask you
16 were your medical problems ever reported to what would
17 be considered a systematic database where it ever
18 would have been analyzed? If not, then why do you
19 feel that the data never got into such a database?
20 MS. HICKEY: My doctor -- my plastic surgeon
21 assured me over and over that my implants were not
22 causing my problems so I went to another doctor and

1 had them removed and my problems resolved themselves.
2 In the adjunct study, which I participated in, that
3 doctor -- I left that doctor so he doesn't know what
4 happened to me.
5 DR. BANDEEN-ROCHE: Thank you very much.
6 DR. WHALEN: Ms. Brinkman.
7 MS. BRINKMAN: You said that you were -- are
8 you denied health insurance currently because of your
9 past history with implants?
10 MS. HICKEY: I'm a flight attendant for a
11 major airline and we have a plan where we can take
12 leave of absence as requested. Our group coverage --
13 I do have coverage with my group plan which is about
14 $600 a month. When we apply for interim policies with
15 a major carrier of insurance that you've all heard of,
16 their medical risk department told us that we are
17 uninsurable because we've had implants even though we
18 no longer have implants. We had them and we are not
19 covered at all.
20 DR. BURKHARDT: Could I just comment that
21 the usual thing that we see in practice is that
22 insurance companies will not cover procedures that are

1 related to or complications of cosmetic surgery.

2 MS. BRINKMAN: But is that the same as

3 denying all health insurance?

4 MS. HICKEY: This is health care coverage

5 period for sore throats, office visits. We've been

6 denied coverage.

7 DR. BURKHARDT: I don't disbelieve you.

8 That's just not the usual pattern that we see.

9 DR. WHALEN: Thank you.

10 MS. HICKEY: Thank you.

11 DR. WHALEN: Before the next speaker I'll

12 just interject, lest I be misunderstood during that

13 last speaker, there are certainly multiple avenues

14 that anyone from the public can address questions to

15 the FDA and have them satisfactorily entered and I'm

16 sure people at the desk or during breaks would be

17 happy to inform them of what that is.

18 During this session, however, only questions

19 that are asked by the panel to be entertained are

20 those that are appropriate and has to do with time

21 flow and the entire conduct of our operation.

22 Next, Dr. Roberta Gartside.

1 DR. GARTSIDE: Thank you very much. My name
2 is Dr. Roberta Gartside and I'm a practicing plastic
3 surgeon in the northern Virginia area. I am a member
4 of the American Society of Plastic Surgeons and a
5 fellow of the American College of surgeons.
6 My travel here today was paid for by myself.
7 I have no ties to implant manufacturers. I am not
8 involved in any lawsuits involving breast implants.
9 As a practicing plastic surgeon a portion of my income
10 is derived from the use of breast implants for both
11 cosmetic and reconstructive purposes.
12 As a plastic surgeon practicing in Fairfax
13 County I would like to share my experiences using
14 breast implants over the past 11 years. I treat women
15 for both post-mastectomy reconstruction and cosmetic
16 enhancement of the breasts.
17 For women facing mastectomy the goal is to
18 provide them with as symmetrical and natural new
19 breast as possible. Reconstruction after mastectomy
20 generally involves one major operation and frequently
21 additional procedures to continually work to the goal
22 of symmetry.

1 This is the same for both implant
2 reconstruction and autogenous tissue reconstruction.
3 Those steps include creation of the breast mound,
4 modification of the opposite breast if necessary, and
5 nipple and areolar reconstruction.
6 For women seeking cosmetic enhancement, the
7 goal is to determine their motives and realistic
8 expectations. All women are informed of the potential
9 risks and complications in my practice. Outside of
10 the inherent risks of surgery those complications
11 include, but are not exclusive to, capsular
12 contracture, rupture, infection, interference with the
13 detection of breast cancer, change in nipple
14 sensation, and breast feeding issues.
15 In my personal practice out of 325 implants
16 inserted for both cosmetic and reconstructive reasons,
17 there have been four deflations for no apparent reason
18 since 1995. Two additional inflations did occur, one
19 following a motor vehicle accident and another was
20 punctured during a needle aspiration in a post-
21 mastectomy patient. Women are informed prior to their
22 surgery that implants are mechanical devices and like

1 any other mechanical device can fail.

2 Following surgery all my patients are given
3 a card with their implant information and after
4 completing their initial post-surgical follow-ups, I
5 recall all my patients at one year after surgery.

6 In general, many patients do not come back
7 for this one year follow-up. Those patients in
8 general are not experiencing any problems. For those
9 who do have questions or concerns, this one-year
10 reminder prompts them to come in and address any
11 issues.

12 The time spent with patients prior to
13 surgery is well worth it, more than any amount of
14 written material or waiting periods. The transmission
15 of incomplete or misinterpreted information can have
16 far reaching implications.

17 In my own practice this face-to-face
18 consultation with patients resulted in the fact that
19 the day after Connie Chung broadcast her program on
20 silicone breast implants, my office received only one
21 phone call. However, over the following year I saw
22 women seeking breast reconstruction who either did not

1 want to hear about breast implants at all, or chose a
2 longer and more complicated form of reconstruction
3 with a longer recovery or no reconstruction.
4 I fear the possibility of the same situation
5 starting again. Just yesterday I saw a woman in my
6 office who is seeking breast reconstruction for an
7 upcoming mastectomy. She and her husband both heard
8 the news reports of this hearing the night before and
9 became very alarmed and concerned over the fact that
10 the news media was reporting an extremely high
11 complication rate for implants. I needed to spend
12 twice the normal amount of time reviewing for her and
13 her husband the data and its interpretation.
14 I would like to state that the relationship
15 between physicians and their patients is extremely
16 important. It can be the patient's best source of
17 medical information because we were able to put things
18 in perspective. Thank you very much.
19 DR. WHALEN: Thank you.
20 Next is Ms. Dorothy Stull.
21 MS. STULL: Thank you very much. To answer
22 the four questions, I've had no one help me with my

1 travel. I'm a local resident here in Maryland. Do I
2 have any financial ties? No. I'm not a witness to
3 any party pending related to breast implants. I do
4 not derive -- I'm a housewife and I have no financial
5 income from this.
6 I would like to -- my name is Dorothy Stull
7 and I would like to thank the panel for letting me
8 speak today. I'm a wife, mother, and a grandmother.
9 I was diagnosed four years ago with breast cancer
10 followed by a modified mastectomy with immediate
11 reconstruction using a saline-filled breast implant.
12 Needless to say I was devastated to be
13 physically fit one day and told you have cancer the
14 next. After much research, reading, and talking with
15 family, friends and doctors, I chose the saline-filled
16 breast implant. It meant that I would wake up from
17 surgery with two breasts, a complete woman.
18 As I was making this decision in my life, I
19 could only remember seeing my sister who also had
20 breast cancer with scars and a heavy prothesis she had
21 to wear daily. Twenty-five years ago she had no
22 choice. Thanks to a good doctor and saline-filled

1 breast implants, I did.

2 Being an active person in sports, I was able

3 to get back into my active life of playing golf,

4 tennis, and feeling good about my appearance, wearing

5 a bathing suit to swim and water ski with my active

6 sons. I can truthfully say I have not had any

7 problems with my saline-filled implant and feel very

8 strongly that women should have a choice.

9 Breast reconstruction has helped me overcome

10 the shock of losing a breast and maintaining my self-

11 esteem. Besides, my husband is happy with my

12 appearance.

13 It is my hope that the saline-filled breast

14 implant remain an option for all women with breast

15 reconstruction and augmentation. Thank you for

16 listening.

17 DR. WHALEN: Thank you.

18 Next we'll hear from Dr. Saul Puszkin.

19 DR. PUSZKIN: Hello. Good morning,

20 everybody. Members of the panel, thank you. Please

21 wake up a few minutes. I'll try to be brief.

22 If I were to write the guidelines or the