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MEDICAL DEVICES ADVISORY COMMITTEE

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GENERAL AND PLASTIC SURGERY

DEVICES PANEL

+ + + + +

MEETING

+ + + + +

Wednesday, March 1, 2000

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The meeting was held in the Ballroom, Gaithersburg Holiday Inn, Two Montgomery Village Avenue, Gaithersburg, Maryland, at 8:00 a.m., Dr. thomas V. Whalen, Chairman, 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

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PRESENT (Continued):

BRENT BLUMENSTEIN, Ph.D., Temporary Voting
Member

BOYD BURKHARDT, M.D., Temporary Voting Member

NANCY A. DUBLER, LLB., Temporary Voting Member

STEPHEN LI, Ph.D., Temporary Voting Member

MICHAEL J. MORYKWA, Ph.D., Temporary Voting
Member

JOHN S. ROBINSON, M.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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(8:06 a.m.)

1
2
3 DR. KRAUSE: Good morning, everyone. I'd
4 like to get the meeting started, please. If everyone
5 could please take a seat.

6 Thank you.

7 We're ready to begin the 56th meeting of
8 the General and Plastic Surgery Devices Panel. My
9 name is David Krause, and I'm the Executive Secretary
10 of the panel. I'm also a biologist and reviewer in
11 the Plastic and Reconstructive Surgery Devices Branch.

12 I'd like to remind everyone that you're
13 requested to please sign in on the attendance sheets,
14 which are available at the tables by the door. You
15 may also pick up an agenda, a panel roster, and
16 information about the meeting at that same table.

17 The information includes about how to find
18 out about future meetings of the panel and other
19 panels.

20 Before turning the meeting over to Dr.
21 Whalen, I'm required to read two statements into the
22 record: the deputization of temporary voting members

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1 statement and the conflict of interest statement.

2 The first statement is the appointment to
3 temporary voting status. Pursuant to the authority
4 granted under the Medical Devices Advisory Committee
5 charter, dated October 27th, 1990, and as amended
6 August 18th, 1999, I appoint the following individuals
7 as voting members of the General and Plastic Surgery
8 Devices Panel for this meeting on March 1st, 2000:

9 Karen Bandeen-Roche;

10 Brent Blumenstein;

11 Boyd Burkhardt;

12 Nancy Dubler;

13 Stephen Li;

14 Michael Morykwas; and

15 John Robinson.

16 For the record, these individuals are
17 special government employees and consultants to this
18 panel or other panels under the Medical Device
19 Advisory Committee. They have undergone the customary
20 conflict of interest review and have reviewed the
21 material to be considered at this meeting, and this is
22 signed by Dr. David W. Feigal, Jr., the Director of

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1 Center for Devices and Radiological Health.

2 The following is the conflict of interest
3 statement.

4 The following announcement addresses
5 conflict of interest issues associated with this
6 meeting and is made a part of the record to preclude
7 even the appearance of an impropriety.

8 To determine if any conflict existed, the
9 agency reviewed the submitted agenda and all financial
10 interests reported by the committee participants. The
11 conflict of interest statutes prohibit special
12 government employees from participating in matters
13 that could affect their or their employees' financial
14 interests.

15 However, the agency has determined that
16 participation of certain members and consultants, the
17 need for whose services outweighs the potential
18 conflict of interest involved, is in the best interest
19 of the government.

20 A waiver has been granted for Dr. Stephen
21 Li and his interests in a firm at issue that could
22 potentially be affected by the committee's

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1 deliberations. The waiver allows this individual to
2 participate fully in the panel's deliberations.

3 A copy of his waiver may be obtained from
4 the agency's Freedom of Information Office, Room 12A-
5 15 of the Parklawn Building.

6 We would like to know for the record that
7 the agency took into consideration certain matters
8 regarding Drs. Burkhardt, Chang, Li, and Morykwas.

9 Dr. Li reported a current interest in a
10 firm at issue, but in matters not related to the
11 panel's agenda. Therefore, the agency has determined
12 that he may participate fully in the deliberation.

13 Drs. Burkhardt, Chang and Morykwas
14 reported past related involvements with firms at
15 issue. Since these are past involvements and there
16 are no continuing financial interests, the agency has
17 determined that these panelists may participate fully
18 in the deliberations.

19 The agency would also like to note for the
20 record that Dr. Wendie Berg, who is making a
21 presentation today, has^{**} acknowledged a previous
22 related financial interest with a firm at issue. Dr.

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1 Berg serves as a consultant to the Radiological
2 Devices Panel, as well as all panels of the Medical
3 Advisory Committee.

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

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

15 Okay. This concludes the required
16 statements, and I would like now to turn this meeting
17 over to Dr. Whalen, the Chair.

18 CHAIRMAN WHALEN: Thank you, Dr. Krause.

19 Good morning. My name is Dr. Thomas
20 Whalen. I'm head of the Division of Pediatric Surgery
21 at Robert Wood Johnson Medical School in Camden, New
22 Jersey, and also the Program Director of the general

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1 surgical residency there.

2 Today the panel will be making
3 recommendations to the Food and Drug Administration on
4 a pre-market approval application, but the next item
5 of business is for those of us on the panel to
6 introduce ourselves. These are the panel members who
7 are giving of their time to help the FDA in these
8 matters, and the FDA staff themselves, who will
9 introduce themselves sitting here at the table.

10 I would ask that each person introduce him
11 or herself, stating his or her specialty, position
12 title, institution, and his or her status on the panel
13 today as voting member, industry or consumer
14 representative, or deputized voting member.

15 And I would start to my left with Dr.
16 Chang.

17 DR. CHANG: I'm Phyllis Chang, an
18 associate professor in the Section of Plastic Surgery,
19 Department of Surgery and Division of Hand and
20 Microsurgery, Department of Orthopedic Surgery at the
21 University of Iowa. I am a voting panel member.

22 DR. MORYKWAS: I am Michael Morykwas. I'm

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1 an assistant professor of surgical sciences in the
2 Department of Plastic and Reconstructive Surgery at
3 the Wake Forest University School of Medicine.

4 MS. DUBLER: I'm Nancy Dubler. I'm
5 Director of the Division of Bioethics at Montifiore
6 Medical Center and a professor of bioethnics at the
7 Albert Einstein College of Medicine in the Bronx. I'm
8 a temporary voting member today.

9 DR. ROBINSON: I'm John Robinson, a
10 rheumatologist, professor of medicine at Loyola
11 University Medical Center in Chicago, Illinois. I'm
12 a deputized voting member today.

13 MS. BRINKMAN: I'm Maxine Brinkman. I'm
14 Director of Women's Services, Mercy Medical Center,
15 North Iowa. I represent Department of Consumer
16 Affairs, and I am a nonvoting member.

17 MS. DOMECUS: My name is Cindy Domecus.
18 I'm Senior Vice President of Clinical Research and
19 Regulatory Affairs for Conceptus, and I'm the industry
20 representative on the panel today.

21 CHAIRMAN WHALEN: Dr. Witten.

22 DR. WITTEN: I'm Dr. Celia Witten. I'm

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1 the Division Director of DGRD in ODE in CDRH and FDA.

2 DR. LI: Stephen Li, senior scientist,
3 Hospital for Special Surgery in New York in the
4 Department of Biomechanics and Biomolecular Design,
5 and I'm a temporary voting member.

6 DR. BLUMENSTEIN: I'm Brent Blumenstein.
7 I'm a biostatistician. I have worked for the American
8 College of Surgeons Oncology Group. I'm deputized.

9 DR. BOYKIN: My name is Joe Boykin. I'm
10 a permanent voting member, a plastic and
11 reconstructive surgeon from Columbia Retreat Hospital,
12 where I'm also the Director of the Wound Healing
13 Center and Burn Program.

14 DR. BANDEEN-ROCHE: I'm Karen Bandeen-
15 Roche, associate professor of biostatistics at Johns
16 Hopkins University in Baltimore. I'm a temporary
17 voting member.

18 DR. BURKHARDT: I'm Boyd Burkhardt. I am
19 a practitioner in plastic surgery in Tucson, Arizona,
20 and I'm a temporary voting member.

21 DR. KRAUSE: I'm David Krause, the panel
22 Executive Secretary.

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1 CHAIRMAN WHALEN: Thank you.

2 I'd like to note for the record that the
3 voting members do constitute a quorum as required by
4 21 Code of Federal Regulations, Part 14.

5 I'd like to next introduce Mr. Phil
6 Phillips, the Deputy Director of the Office of Device
7 Evaluation, who will tell us a little bit about the
8 least burdensome provisions of the FDA Modernization
9 Act.

10 Mr. Phillips.

11 MR. PHILLIPS: Mr. Chairman and members of
12 the panel, I am Phil Phillips. I'm the Deputy
13 Director for Science and Regulatory Policy in the
14 Office of Device Evaluation.

15 Excuse our low tech presentation this
16 morning. I was thinking that I should have put a
17 Power Point presentation on and gone along with the
18 rest, but nevertheless, I hope that you'll find this
19 to be a very informative presentation.

20 The FDA Modernization Act of 1997 was
21 signed into effect back in November of 1997 by
22 President Clinton. Some individuals think that it is

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1 perhaps one of the most significant pieces of
2 legislation in the history of FDA certainly since
3 President Ford signed in the medical device amendments
4 back in 1976.

5 I would encourage anyone who is interested
6 on the panel to learn more about the FDA Modernization
7 Act. You can go to our Web site, and you will find
8 that there's a lot of information on the law, as well
9 as the steps that the agency has taken to actually
10 implement the law.

11 Today I'm going to be talking about two
12 provisions that are included in the law, and it deals
13 with the terms "least burdensome." I'm going to be
14 going through the actual statute itself. I'm going to
15 go through some of the actual mechanisms that we have
16 in implementing the law.

17 The terms "least burdensome" apply in
18 actually two different sections of the FD&C Act. It's
19 Section 513(a) and Section 513(i), and let's look at
20 each one of them very briefly.

21 Under Section 513(a), and this is the one
22 that perhaps will have the most effect on panel

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1 deliberations because it applies to pre-market
2 approval applications. What the law now tells us is
3 that the Secretary shall consider in conjunction with
4 the applicant the least burdensome appropriate means
5 of evaluating device effectiveness that would have a
6 reasonable likelihood in resulting in approval.

7 Now, keep in mind this is the least
8 burdensome, and this applies to the effectiveness
9 requirements as it applies to pre-market approval
10 applications.

11 The second place that the terms "least
12 burdensome" apply is in Section 513(l). This is
13 probably not going to be something that the panels
14 will be as involved in as with pre-market approval
15 applications because this applies to pre-market
16 notification or 510(k) submissions.

17 Yes, indeed, there are some 510(k)'s that
18 go before advisory committees, but it is somewhat
19 unusual. It's more likely that as members of the
20 panel you may receive a homework assignment that deals
21 with a particular pre-market notification submission,
22 and this would be an important part of the statute

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1 that would apply to those activities.

2 Specifically, this says that in making
3 such requests, and this is requests for additional
4 information to determine substantial equivalence of
5 devices, that the Secretary shall consider the least
6 burdensome means of demonstrating substantial
7 equivalence and request information accordingly. So
8 the terms "least burdensome" apply in two different
9 parts of the statute.

10 It's important for everyone to recognize
11 that even though the Congress has told us to consider
12 the least burdensome means of getting devices to
13 market, that the FDA Modernization Act did not change
14 the standard for pre-market clearance and approval.
15 That is, when we deal with pre-market approval
16 applications, it's still reasonable assurance of
17 safety and effectiveness, and when we deal with pre-
18 market notifications, your 510(k) submissions, it's
19 still substantial equivalence. The terms have not
20 changed.

21 As far as the implementation of these
22 procedures, it actually started back in January of

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1 last year. There was an open public meeting that we
2 had. We had a lot of people from the industry that
3 was present. There were consumer groups present.
4 There were professional societies present. It was a
5 half a day's session that we devoted strictly to the
6 terms least burdensome and have been trying to
7 interpret those so that we know exactly how to apply
8 them in our day-to-day activities.

9 Since then we have had internal
10 communications inside the agency. We have also had
11 scientific reviewer training similar to what is going
12 on today, but of course in a little bit more detail
13 because we had much, much more time.

14 There was also a guidance document that
15 was drafted by the agency. It's called the evidence
16 models for the least burdensome means to market. That
17 did appear in the Federal Register back in September
18 of last year.

19 I have included it. It's in your
20 handouts. It's also shown here, the actual Web
21 address so that you'll be able to access that if
22 there's a need for you to access that particular

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1 document.

2 It was a subject of a comment period, and
3 that comment period closed November 30th of 1999.
4 Currently we're in the process of evaluating the
5 different comments that came into the agency on that
6 particular draft guidance document.

7 In addition to the FDA guidance document,
8 there was also a least burdensome industry task force
9 that was convened, and they gave a proposal to the
10 agency back in March of 1999. That agency proposal
11 was incorporated as Appendix D in the FDA guidance
12 document that I just mentioned. So it was subject to
13 the same comment period, which closed November 30th of
14 1999. We were also looking at the comments on this
15 particular aspect of our proposal.

16 We have formulated what I will call an
17 interim FDA definition. The importance to the term
18 "interim" is that this is not final. We do not have
19 final guidance out, but this is an operating
20 definition that we've told our reviewers inside our
21 organization and you as panel members that would be,
22 I think, a reasonable attempt of trying to interpret

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1 exactly what the terms "least burdensome" means.

2 What we said is that least burdensome is
3 a successful means of addressing a pre-market issue
4 that involves the smallest investment of time, effort
5 and money on the part of the submitter and FDA.

6 Now, keep in mind successful means that
7 the applicant has met the statutory criteria:
8 reasonable assurance for a PMA or substantial
9 equivalence for a 510(k).

10 Some have suggested that in order for us
11 to take the least burdensome approach, that we have to
12 actually have a cultural change within our
13 organization. Well, I don't know whether we need to
14 change the entire culture, but clearly we all need to
15 recognize that there can be multiple approaches to
16 satisfying regulatory requirements. There is no one
17 way to address any particular scientific issue.

18 Likewise, we need to communicate and
19 collaborate and also compromise in the interest of
20 public health and some of the decisions that we make.
21 We need to understand not just the letter of the law,
22 but also the spirit of the law, and we need to also

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1 factor issues such as time, effort and money as
2 considerations as part of our decision making as a
3 result of the least burdensome provisions.

4 Least burdensome does not mean that we
5 need to in any way compromise scientific integrity.
6 Clearly, I think we all recognize that scientific
7 endeavors are affected by the availability of
8 resources. Inside the agency and even outside the
9 agency, all research organizations are affected
10 certainly by available resources.

11 Also, good science does, in fact, include
12 issues such as cost effectiveness. Compromise is a
13 necessity for successful research, and lessening
14 regulatory burden may, in fact, serve to enhance
15 scientific progress and advance medicine. That, I
16 believe, is the reason that the Congress put this
17 particular provision into law.

18 What are some of the mechanisms that we're
19 suggesting today that may actually lessen regulatory
20 burden? Well, I think that we all need to insure that
21 all regulatory decisions are made in accordance with
22 relevant statutory criteria. Again, as panel members

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1 you've been trained on issues such as reasonable
2 assurance of safety and effectiveness. That is the
3 statutory criteria that you would apply to pre-market
4 approval applications, and that has not changed as a
5 result of anything that the FDA Modernization Act has
6 done.

7 We need to use the tools provided by the
8 FDA Modernization Act -- that's referred to as FDAMA.
9 You may hear that on occasion -- as well as some of
10 the process reengineering that has actually taken
11 place within the center.

12 Now, for example, we have exemptions for
13 many of the simple Class I devices so that we're not
14 even using resources in clearing these particular
15 types of products. That means that we can divert our
16 resources and your time and efforts into looking at
17 the more significant types of products that pose more
18 risk for the American public.

19 There's also collaborative meetings that
20 we are now required to have with industry as we
21 approach evaluation of different marketing
22 applications. There are also opportunities for third

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1 party review, that is, for certain types of devices.
2 They can take 510(k) submissions and have them
3 actually evaluated by recognized third parties outside
4 of the agency that will make recommendations regarding
5 the clearance of these products to the agency.

6 These are important mechanisms that I
7 think can serve to streamline and lessen regulatory
8 burden.

9 We also need to factor in relevant,
10 publicly available information in our decision making.
11 This is particularly important, I think, for panel
12 members. Since you all are experts, you have a
13 tremendous amount of knowledge. You have a lot of
14 information that's at your fingertips.

15 That publicly available information is
16 something that we should use in our decision making so
17 that we can learn and we can lessen regulatory burden
18 as, in fact, the level of knowledge increases.

19 We need to rely on nonclinical testing for
20 decision making when possible. I mean I think it's
21 one thing that's important to recognize that when you
22 deal with nonclinical testing, in many cases you can

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1 get much more precision in some of our findings than
2 you can actually get from clinical trials.

3 That's not to suggest that clinical trials
4 are not very, very important. They are very
5 important, but I think there's a tremendous amount of
6 information that we can learn from doing some simple,
7 preclinical testing.

8 In the world today, you'll find
9 particularly when we talk about issues such as global
10 harmonization that there's a tremendous amount of
11 effort put into developing standards for different
12 devices and different types of products and different
13 types of scientific methods.

14 We need to rely on conformance with
15 recognized standards as part of our decision making.
16 It is a way that can lessen the burden, and it can
17 certainly streamline our evaluation of different types
18 of medical devices.

19 When clinical data is needed, we need to
20 consider alternatives to randomized control trials,
21 and here specifically I can say we can rely on
22 literature or nonactive controls.

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1 Now, again, there are certainly different
2 situations where you need to have a randomized
3 controlled clinical trial, but likewise, there are
4 other situations where there are other viable
5 alternatives that will address the issues that we're
6 trying to address with the same level of assurance as
7 doing a randomized controlled trial.

8 We also need to use surrogate endpoints
9 where possible to demonstrate device effectiveness.
10 Oftentimes, as you realize, if you look at issues of
11 effectiveness you can talk about long term types of
12 information. If we can find appropriate surrogates,
13 sometimes it can shorten the duration of some of the
14 trials at least for the purposes of clearing different
15 devices to market.

16 What's the bottom line to my remarks this
17 morning? Well, keep in mind that this is still a very
18 early process at trying to interpret the least
19 burdensome provisions and trying to give guidance to
20 our internal reviewers as well as to our advisory
21 committees.

22 But what I would suggest is that we all

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1 factor the least burdensome concepts into all of our
2 pre-market activities. This would include, for
3 example, guidance development and use, regulation
4 development, as well as panel review and
5 recommendation types of activities, such as is
6 occurring today.

7 Above and beyond, I think we all need to
8 remain open minded to alternative proposals for
9 satisfying regulatory requirements. I think I can sum
10 it up. I think that what Congress was trying very
11 much to do by instructing us to take these least
12 burdensome tactics is really trying to inject a degree
13 of common sense into the regulatory process without in
14 any way diminishing the level of safety and
15 effectiveness that we assure the American public.

16 That concludes my remarks, Mr. Chairman,
17 unless you have any questions.

18 CHAIRMAN WHALEN: Do any panel members
19 have questions of Mr. Phillips?

20 (No response.)

21 CHAIRMAN WHALEN: Thank you, sir.

22 MR. PHILLIPS: Thank you for your time.

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1 CHAIRMAN WHALEN: I would like to next
2 introduce Mr. Stephen Rhodes, the Branch Chief of the
3 Plastic and Reconstructive Surgery Devices Branch, who
4 will make some introductory remarks to the panel.

5 Mr. Rhodes.

6 MR. RHODES: Thank you, Dr. Whalen.

7 And good morning. I am Stephen Rhodes,
8 the Branch Chief of the Plastic and Reconstructive
9 Surgery Devices Branch here at the Food and Drug
10 Administration.

11 Welcome, members of the panel, members of
12 the public, and manufacturers to this important three-
13 day meeting of the General and Plastic Surgery Panel,
14 important because it's the first FDA panel meeting to
15 make recommendations on the approvability of any
16 saline filled breast implant, and you will vote on
17 three pre-market approval applications over the next
18 two days.

19 Just a word about the order of the PMAs
20 coming before the panel. It's the order in which the
21 PMAs were received by the agency.

22 Because of the high public interest in

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1 saline filled breast implants, in addition to the
2 regular public comment periods for any PMA discussion,
3 we will have three hours of public comment this
4 morning on general issues related to saline filled
5 breast implants, and two and a half hours on Friday
6 morning for public comment on issues specific to
7 insuring the patients are making informed decisions
8 when considered saline filled breast implants.

9 As a reminder, we will not be discussing
10 silicon gel filled breast implants at this meeting,
11 and I request that the panel members and members of
12 the public limit their comments and discussion to the
13 products being evaluated, saline filled breast
14 implants.

15 Panel members, we appreciate your
16 commitment. Members of the public who have requested
17 time to address the panel, we appreciate your
18 comments, and, manufacturers, we appreciate your
19 participation in presenting the safety and
20 effectiveness data you have collected to the panel and
21 in answering questions that the panel may have.

22 Thank you for your attention, and I'll

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1 turn it back to you.

2 CHAIRMAN WHALEN: Thank you, Mr. Rhodes.
3 Do any panel members have questions of Mr.
4 Rhodes?

5 (No response.)

6 CHAIRMAN WHALEN: We will then now proceed
7 with the open public hearing session of this meeting.
8 All persons addressing the panel are asked to speak
9 clearly into the microphone as the transcriptionist is
10 dependent on this means of providing an accurate
11 record of the meeting.

12 At this time I would like to ask Dr.
13 Krause to give us some instructions for those who will
14 be testifying before the panel.

15 Dr. Krause.

16 DR. KRAUSE: Okay. First and foremost, I
17 would like to thank all of those of you who contacted
18 me and asked for time to speak. I know that it's a
19 big sacrifice to come here. Some of you have come a
20 long way, and we appreciate that.

21 I'd like to give a few instructions before
22 we starting having the speakers come up, requesting

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1 that all persons making statements during the open
2 public hearing of the meeting disclose whether they
3 have financial interests in any medical device company
4 or if their trip to this meeting has been paid for by
5 someone else.

6 Before making your presentation to the
7 panel, in addition to stating your name and
8 affiliation, please address the following questions.
9 I will read the questions into the record at this time
10 so that a rereading by all of the presenters and later
11 in the day will not be necessary. These are the
12 questions for all speakers.

13 Question number one: has your travel
14 and/or accommodations been paid for or will they be
15 reimbursed by someone else? If so, please state who.

16 Question two: please indicate whether you
17 have financial ties, including grants or other
18 compensation with industry or health professional
19 societies.

20 Number three: please indicate whether you
21 are a party to or witness in a pending lawsuit related
22 to breast implants.

1 And question four: do you derive a
2 portion of your income from surgical procedures using
3 saline filled implants or from treating patients with
4 complaints that the patients believe are related to
5 saline filled implants?

6 What we have done this morning is if
7 you're a speaker, you should have registered at the
8 table outside. You will have been assigned a position
9 in which you will testify. What we're going to try to
10 do is get as many of you in in the morning as we can.
11 Probably we will have to break for lunch around 12 to
12 12:15, and some of you may wind up testifying in the
13 early afternoon immediately following lunch.

14 A couple of things that have come up is
15 all of the time for today is full. So we can't have
16 anybody who has not preregistered testifying today.
17 We just have so many people testifying, and we're
18 going to be running late as it is.

19 But there is some time available tomorrow
20 morning, and I think there is some time also available
21 Friday. If you would like to address the panel, you
22 can go to the registration desk outside and let the

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1 people at the desk know that you wish to testify
2 tomorrow. Unfortunately, we can't give anyone who
3 asks to testify tomorrow very much time if a lot of
4 people go up.

5 So if we get, you know, say, three or four
6 people who wish to testify, then we can give everybody
7 about five minutes. If we have 15 people, then we
8 need to restrict that to about two minutes. So it
9 will have to be flexible.

10 Okay. I'd like to now turn the meeting
11 back to the chair.

12 CHAIRMAN WHALEN: Thank you, Dr. Krause.

13 As just alluded to, we will only have time
14 for those individuals who have notified FDA of their
15 request to present in the open session.

16 We are going to begin with individual
17 consumers. Each of them will have five minutes to
18 address the panel, which I'm sure after you answer the
19 four questions thoroughly will leave at least six or
20 seven seconds to make your comments.

21 (Laughter.)

22 CHAIRMAN WHALEN: I would ask that each of

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1 those presenting would pay attention to the timer
2 light which is by the podium so that each and everyone
3 who has been assigned a portion of time will have
4 their just amount of time to speak to the panel.

5 The first individual consumer then to
6 address the panel is listed in the program as Ms.
7 Kitchen.

8 DR. KRAUSE: A quick comment about the
9 timer. You'll get a blinking light at about a minute,
10 and then a red light at five minutes.

11 MS. KITCHEN: Good morning. I'm here in
12 support of saline implants. I think there are a lot
13 of good reasons why saline implants should be
14 available.

15 CHAIRMAN WHALEN: Forgive my intrusion,
16 but --

17 MS. KITCHEN: Oh, oh.

18 CHAIRMAN WHALEN: -- just because you're
19 the first one, even if there's negative answers to
20 those questions, would you just say that at the
21 outset?

22 MS. KITCHEN: Okay. My answers to all of

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1 your questions are no. I had no -- nothing to gain.

2 Okay. I think there are a lot of good
3 reasons why saline implants should be available to
4 people. In my case, I was born with a deformity of
5 right chest, and 20 years ago, I had saline implants.
6 I had breast augmentation surgery using saline
7 implants to correct my deformity, and this surgery
8 changed my life. It camouflaged my deformity and gave
9 me a greater confidence in myself.

10 And I've had no problems with the implants
11 over the course of 20 years and have lived a very
12 healthy, happy life as a result.

13 I encourage you to keep them on the
14 market, and as long as people are notified of the
15 risks and the benefits, I believe they should stay on
16 the market.

17 Thank you.

18 CHAIRMAN WHALEN: thank you.

19 Next is Ms. Faussett.

20 MS. FAUSSETT: Good morning. In answer to
21 the questions, I received an honorarium of \$200 to
22 participate in the workshop yesterday, and I will use

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1 to help pay for my expenses of travel. The honorarium
2 has been paid by a nonprofit research center, CPR for
3 Women and Families.

4 Only a little more than two years ago I
5 had a normal life, and I was a happy, healthy, highly
6 organized and energetic young woman. I had graduated
7 from college with honors, had a career in management,
8 married the man of my dreams, and I had four wonderful
9 children. My youngest is now five.

10 I had enjoyed a robust health all my life
11 and I hadn't missed a day of work due to illness for
12 over ten years. It was after breast feeding my
13 children that I decided to get implants, hoping that
14 they would help to restore my pre-pregnancy shape.

15 My highly respected plastic surgeon had
16 told me that my McGhan saline breast implants would
17 last my entire life and go with me to my grave. The
18 risks he mainly discussed were of a local nature, such
19 as infection, hematoma, a rupture, and I was led to
20 believe that these were easy to remedy.

21 What I didn't know was that the risks were
22 far greater than I was ever told. In January 1998,

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1 eight months after getting my implants, my world
2 crash. My vision became disturbed. I couldn't
3 concentrate and was unable to retain anything I read.
4 I was extremely tired and found that sleep did not
5 refresh me. Mentally it seemed as if a fog had
6 descended upon my brain and clear thoughts and
7 coordination became very difficult for me.

8 I was constantly dizzy and started bumping
9 into walls and had tingling sensations in my hands.
10 My hands were always cold, and I experienced joint
11 pain among other unsettling symptoms.

12 I was frightened by this sudden drastic
13 change in my health. Nothing in my habits or life
14 style had changed with the exception of having
15 received the implants.

16 While my original plastic surgeon
17 downplayed my symptoms, a second plastic surgeon
18 recommended that they be removed and I see a
19 rheumatologist.

20 Blood tests showed an autoimmune response
21 starting as evidence by an elevated rheumatoid factor,
22 as well as a lowered C3 complement and macrocytosis.

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1 I also had a brain MRI which showed a mild degree of
2 atrophy, quite unusual considering I was only 38 years
3 old at the time and have no family history of these
4 problems.

5 I spent the last two years of my life
6 struggling to regain the precious health that I had.
7 The most important step I've taken was to have my
8 saline implants removed. There's no doubt that the
9 implants were harming me in a terrible way, as almost
10 all symptoms have subsided.

11 I thank God that I'm still recovering, but
12 I'm gravely concerned for other women out there who
13 are ill or who will become ill from their implants and
14 who are not properly informed of these dangers.

15 The devastating health problems that
16 ensued after I was implanted with saline implants
17 should never ever be considered acceptable risks,
18 especially since these are not life saving devices.

19 Ask my parents if the risks were
20 acceptable. They had to drive over 2,000 miles to
21 come and help care for me while I was ill. Ask my
22 husband. He had to pay thousands of dollars in

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1 unexpected medical bills and lost me as a supporting
2 partner in taking care of our family. Ask my
3 children. They lost their smiling, nurturing mother
4 and instead were left with a sick woman who could no
5 longer play with them, cook their favorite dinners, or
6 help them with their homework.

7 Ask me if I think the risks are worth it,
8 and I will ask you if you would be willing to let your
9 wife or daughter, mother or sister suffer from
10 destroyed health, loss of career, loss of income,
11 emotional distress, financial distress, and medical
12 system abuse all for the sake of breast implants.
13 Only fools will call these risks acceptable.

14 The information my plastic surgeon gave me
15 was not enough to indicate fully informed consent. He
16 never told me that I was risking the integrity of
17 central nervous system or the functioning of my brain.
18 He never discussed the seriousness of autoimmune
19 disease or the fact that they are incurable.

20 If he had told me that neurologically I
21 was at risk, I would have said, "No, thanks," and
22 walked away. Nowhere in my research about implants

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1 was there any indication of the illnesses that I
2 experienced. It was only after I became ill that my
3 plastic surgeon told me about the FDA booklet on
4 breast implants. Prior to that I did not know it
5 existed.

6 You are mistaken if you think that women
7 will be able to correctly evaluate the risks and make
8 informed decisions about getting breast implants.
9 Women go into the surgery with great anticipation of
10 the benefits. They will not get the information they
11 need until long term studies are done which show how
12 many women become ill and which women are most at
13 risk. That research has not been done, and the
14 manufacturers' research has not answered those
15 questions.

16 Two weeks ago my stepdaughter, who did not
17 know what I went through, wrote to my husband and I
18 asking for \$6,000 for breast implants and informed us
19 she knew all the risks, but upon questioning, she did
20 not know the meaning of capsular contracture or she
21 had never heard of autoimmune diseases.

22 She did not know that the saline in her

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1 implants could grow mold and bacteria over time and
2 cause serious infection in her body. She was not
3 fully informed.

4 She is now only because we informed her of
5 those things, not her plastic surgeon, and she has
6 since chosen not to get implants.

7 The number one mission at the FDA is to
8 protect consumers regarding unsafe medical products.
9 As far as myself and thousands of other women are
10 concerned, they have failed at this mission.

11 Studies are needed to objectively measure
12 how many women have experiences like mine. After long
13 term research is completed, if the FDA improves saline
14 implants, they should all require mandatory
15 disclosures of the kind of ill effects women have
16 experienced from implants like me and warn them of the
17 very serious nature of these problems that result in
18 the loss of jobs, career, incomes, home, family, and
19 well-being, including life itself.

20 Please recommend that saline implants not
21 be approved until more research has been done as to
22 their long term safety.

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1 Thank you.

2 I also have my implants if anyone would
3 like to look at them.

4 CHAIRMAN WHALEN: Thank you.

5 The next speaker is Dr. Melez.

6 DR. MELEZ: My name is Kathleen Melez. I
7 am a breast cancer survivor and an implant survivor.
8 I am a physician practicing in Los Angeles, an
9 immunologist to be training in infectious diseases.

10 I paid all of my expenses to come here
11 today. I have no association with pharmaceutical
12 industry, with medical societies. I have no conflict
13 of interest with the manufacturers here today,
14 although I have a lawsuit against Bristol Myers
15 Squibb.

16 I see breast implant patients only as part
17 of my regular duties to take care of patients in
18 general medical clinics and urgent care facilities.

19 Working on the West Side in Los Angeles,
20 I have seen a number of breast implant patients, both
21 saline and silicon implant patients over the years.
22 Both patients have a variety of manifestations of

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1 foreign body reactions. I would like to mention two
2 problems I am trained to recognize.

3 Breast implantations complain of general
4 malaise, arthralgias, myalgias, peripheral neuropathy.

5 This reminds me. The experiments we did
6 in the laboratory as an immunologist, then we injected
7 rats and mice subcutaneously, under the skin at the
8 base of the tail with small particles, bacteria and
9 oil, and this resulted in systemic illness.

10 I expect the best implants have the same
11 result with small particles, infections, and oil from
12 the envelope causing systemic disease, probably the
13 same way similar to sterile arthritis in artificial
14 joints.

15 The other issue I would like to touch upon
16 is infections. The breast is not sterile tissue. In
17 addition to infections at the time of surgery,
18 infections do occur through the milk ducts. Such
19 infections would stay longer and fester with the
20 foreign body, the implant, in place.

21 Not only the outside of the breast implant
22 getting infected, but the saline itself can harbor

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1 bacteria and fungi well described in the literature.
2 In fact, normal saline bags for infusion have a
3 limited shelf life.

4 I would like to offer into evidence this
5 normal saline bag. This is produced by Baxter. The
6 expiration date is September of this year. My
7 understanding is that saline bags have a shelf life of
8 18 months. Do we expect to change saline breast
9 implants in every patient, in every 18 months? I
10 think these devices are unsafe, and I think they
11 should not be allowed to remain on the market or
12 should not be licensed.

13 Thank you.

14 CHAIRMAN WHALEN: Thank you.

15 The next speaker is Dr. Atagi. Forgive
16 me. Ms. Jennifer Gardner.

17 MS. GARDNER: Good morning. I am
18 traveling to this meeting at my own expense. I have
19 no financial ties to any health professional societies
20 or health industry companies. I am not involved as a
21 witness or party to any pending lawsuits related to
22 breast implants, and I derive none of my income from

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1 medical procedures or treatment of patients in
2 relation to breast implants.

3 My name is Jennifer Gardner, and I would
4 like to thank you for giving me the opportunity to
5 speak to all of you about my experience with breast
6 reconstruction using saline filled breast implants.

7 All my life up until my illness I have
8 been health, fit, and very proud of my appearance. In
9 November 1997, I was diagnoses with advanced breast
10 cancer. Because of the severity of my diagnosis,
11 there was no doubt I would lose my entire breast.

12 I also knew I had the option of
13 reconstructive surgery. After one and a half years of
14 aggressive treatment, I started researching this next
15 step with approval from my oncologist. I selected Dr.
16 Scott Spear at Georgetown University Medical Center.
17 At my first meeting we discussed what my options were
18 and what his recommendations were for my condition.
19 Dr. Spear was extremely compassionate and explained to
20 me the entire procedure and what risks were involved.

21 In September of 1999, I had my surgery.
22 I had a tran flap procedure with an expander with a

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1 saline filled implant where my left breast had been
2 removed. I also chose to have a subcutaneous
3 mastectomy on my right breast, replaced with an
4 expander and a saline implant.

5 I remained in the hospital for four days
6 and recovered at home for the next three weeks. I had
7 no complications during or after my operation.

8 This surgery has changed my life
9 dramatically. It has given me back my self-esteem and
10 sexuality. I cannot look in the mirror and no longer
11 see what this cancer has taken away.

12 I feel that it is vitally important that
13 saline breast implants remain on the market for other
14 women and give them the same chance to look normal and
15 feel like themselves again. Just knowing that that
16 option was out there for me gave me hope that I could
17 get back what I thought was lost forever.

18 I am now 22 months in remission, and I
19 feel happy, healthy, and desirable again.

20 Thank you.

21 CHAIRMAN WHALEN: Thank you.

22 Now, Dr. Atagi.

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1 DR. ATAGI: Good morning. I'm Dr. Tanya
2 Atagi, a plastic surgery -- plastic and reconstructive
3 surgery resident Fellow at the Washington University
4 in St. Louis, Missouri. My research funding stipend
5 and travel expenses are supported by the Washington
6 University School of Medicine and the Division of
7 Plastic and Reconstructive Surgery.

8 I'm not a member of the American Society
9 of Plastic Surgery or a member of the American Society
10 of Aesthetic Plastic Surgery, nor do I represent any
11 of these implant manufacturers. I'm not a witness in
12 or involved in any lawsuits regarding breast implants.

13 As a plastic surgery resident functioning
14 essentially as a surgical assistant, I was involved in
15 the use of breast prostheses and the care of patients
16 with breast implants and was paid a stipend. None of
17 my personal income is derived from breast implant
18 surgery or from treating patients with breast
19 implants.

20 My involvement in breast implant research
21 stems from three primary ^{**} interests, perhaps most
22 obviously because I am a plastic surgeon. I am,

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1 however, particularly interested in the device and
2 product development aspects of breast prostheses
3 because I began my medical career as a biomedical
4 engineer.

5 I'm also especially interested in the
6 psychological effects of breast implants on women
7 undergoing both aesthetic and reconstructive plastic
8 surgery procedures, I think, in part, because I am
9 woman.

10 I'm currently involved in several aspects
11 of breast implant research, including the development
12 of a physical breast model for use in testing breast
13 prostheses and the use of digital three dimensional
14 imagining technology, including noninvasive volumetric
15 analysis and ultrasound evaluation of postoperative
16 changes, and finally, the use of objective measurement
17 techniques to evaluate capsular contracture of the
18 breast.

19 This past year I've also been designing a
20 psychological outcome study of breast augmentation
21 patients, incorporating a battery of reliable and
22 validated psychological test instruments.

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1 Psychological data using normed psychological test
2 surveys to examine breast implant surgery patients has
3 been somewhat scarce, especially in the area of
4 aesthetic surgery.

5 Existing standardized health status and
6 psychological test instruments have been shown to be
7 sensitive in the evaluation of women undergoing breast
8 implant surgery. In addition, more rigorously
9 established tests are becoming available and
10 incorporated into useful prospective studies,
11 including those designed for use in the breast implant
12 population.

13 I have found in my experience that with
14 preoperative and postoperative psychological
15 evaluations conducted for women undergoing both breast
16 augmentation and reconstruction using other implant
17 types is in agreement with other more recent studies.
18 Surveys of women receiving saline implants, including
19 those using both validated test instruments and self-
20 designed questionnaires show that preoperatively the
21 vast majority of women who undergo breast implant
22 surgery, whether for augmentation or reconstruction,

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1 are generally physically healthy and psychologically
2 stable with reasonable surgical expectations. They
3 have a positive view of their bodies and expect to
4 derive psychosocial benefits from their implants.

5 They are not, however, seeking to address
6 serious psychosocial problems related to their
7 breasts, and patients are typically not depressed and
8 psychologically unstable as earlier studies using non-
9 standardized, uncontrolled tests have suggested.

10 Women undergoing implant surgery generally
11 demonstrate mature personalities. They harbor low
12 levels of anxiety and are self-directed. After
13 undergoing implant surgery, patients are less
14 concerned about potential implant problems as they
15 incorporate the implants into their new body image and
16 they exhibit significantly improved levels of self-
17 esteem and improved body image.

18 Women derive statistically significant
19 benefits from their implants. They record measurable
20 benefits and social comfort and express consistently
21 high levels of satisfaction.

22 Informal and formal satisfaction surveys

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1 show that 93 to 99 percent of patients expressing
2 levels of positive satisfaction even in the light of
3 complications.

4 The plastic surgery and psychiatric
5 communities understand the body image and self-esteem
6 are all critical in the overall health status of the
7 individual, and I'm confident that these groups are
8 making concerted, often multi-disciplinary efforts to
9 study and meet the needs of the individual as a whole.

10 In fact, I believe you will hear from a
11 psychologist who studies these issues in plastic
12 surgery patients later in the proceedings.

13 In summary, as an engineer, I think there
14 is convincing evidence that saline breast implants are
15 durable, which you will undoubtedly hear more about
16 later, and as a plastic surgeon, I see tremendous
17 psychosocial benefits to women in improving and in
18 restoring self-image. I see earnest, ongoing efforts
19 to decrease risks and complications and improve
20 techniques and, therefore, outcomes.

21 And as a woman, I feel we are fortunate to
22 have surgical enhancement and restoration

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1 incorporating saline implants as an option to us in
2 the company of informed consent.

3 Overall the very real psychosocial
4 benefits to women are exceptionally important in your
5 consideration of saline implants.

6 Thank you.

7 CHAIRMAN WHALEN: Thank you, Dr. Atagi.

8 Next, Ms. Maura McGinn.

9 Cynthia Scott.

10 Who do we have next? Dr. Anderson,
11 please.

12 DR. ANDERSON: Good morning, panel, and
13 good morning, Mr. Chairman.

14 I answer all of the questions put forward
15 in the negative, except for one. I do care for about
16 62 saline breast implant patients at this time.

17 My name is Norman Anderson. I have no
18 proprietary interest in saline breast implants. I
19 currently serve as a full-time member of the --
20 associate professor of the Johns Hopkins University
21 School of Medicine.

22 As a internist, I do not directly implant

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1 devices into patients. However, I have some
2 familiarity with the regulation of breast implants
3 gleaned from 13 years of between the late 1970s and
4 1992, when I served variously as a consultant, panel
5 member, and chair of the committee which I'm now
6 addressing.

7 From that experience, I well recognize the
8 importance and the pressures that each of you are
9 facing today.

10 Because of that experience, I also began
11 receiving referrals of patients with breast implant
12 problems into my clinic in the mid-1980s. These
13 referrals have steadily expanded over the years, and
14 I've now been privileged to participate in the care of
15 approximately 1,000 breast implant recipients, but
16 only 62 clear-cut saline devices.

17 Because of the vast of these women
18 presented with problems, this sampling bias prevents
19 me in giving you an accurate insight into the general
20 outcome of saline implant usage. However, it has
21 given me an exposure to related complications on the
22 dark side, and I would like to share these with you

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1 today.

2 Now, these comments are also well known to
3 the manufacturers, as I have the opportunity to raise
4 each of these points in an open FDA meeting with the
5 manufacturers in 1993, when they were advised that PMA
6 was about to continue.

7 It is my fervent hope that they now
8 provide sound and reasonable evidence proving the
9 safety of these devices. To my mind, the first issue
10 to be resolved is the long term survival of saline
11 implants. They share the same type of shell that
12 silicone gel implants do.

13 With silicone gel implant review, very few
14 implant ruptures were seen in the first two or three
15 years. However, eight to ten, rapid increase in
16 device failure. Depending upon what series and who
17 you believe, 20 to 80 percent of all of those devices
18 ruptured after ten years.

19 There's also evidence that the shell,
20 silicone shell degrades in the body. Again, this was
21 extensively reviewed in the FDA hearings in 1991 and
22 two, and I only have to give you the anecdotal

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1 experiences of plastic surgeons who had the implant
2 tear as they try to lift it from the body, what's
3 happening to these shell membranes over time.

4 Now, with that, it's also known that the
5 saline implants will deflate with a pinhole, whereas
6 the silicone implant may require a larger rent or tear
7 to have gel extrusion and collapse recognized.

8 With all of that, there is a big concern
9 that the saline implants will show a very high failure
10 rate with time. From our point of view, you also
11 should recognize that folds on that shell have been
12 associated with shell failure over time.

13 I regret to report to you that every
14 saline implant that we have studied with sonograph
15 shows folds. Because of that, the characteristic of
16 the shell change with aging, we believe that saline
17 breast implants carry the potential to achieve the
18 highest failure rates of any device ever presented
19 before the FDA over time.

20 The surgeons have generally replied to
21 this concern saying they're easy to replace: saline
22 in, saline out. The worries here are gel bleed into

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1 the device from the membrane, which has been
2 discussed; fragmentation or leaching from the
3 membrane; and release of material of unknown hazards.

4 Equally important is contracture. All of
5 us had hopes that the saline implant would minimize or
6 avoid device contracture. We're seeing this in at
7 least half of the patients who we're following. It is
8 of interest, and I want to share the patient's
9 description. Early on they complained a bit --

10 CHAIRMAN WHALEN: Excuse me, Doctor. I'm
11 sorry, but I'll need to ask you to summarize, please.

12 DR. ANDERSON: Yes. One of the patient's
13 words were describing a slosh when they move. This
14 goes on to a kind of contracture where they describe
15 the breast as feeling like plastic bubble wrap.

16 We see hernia when these things go
17 through, and then finally, they develop the painful
18 breast.

19 About 15 percent of the saline implants
20 that we're following have breast implant pain, and
21 this is the most pernicious and neglected symptom of
22 the entire breast implant scenario. It can progress

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1 to fibrocytis and frozen shoulder.

2 In my view, PMA approval is being
3 requested for devices that carry a high probability
4 for rupture over time. They may have unknown outcome
5 from the lechate or bleed into the saline. They have
6 very characteristic and worrisome patterns of
7 contracture. They do interfere with the detection of
8 breast cancer. We just don't know the number, and the
9 only way to solve these problems for many women is
10 explantation and mastopexy, and that incurs many
11 problems.

12 Thank you. I have stood on the other
13 side. It's easier to be on this side. I wish you
14 well on your endeavor today.

15 CHAIRMAN WHALEN: Dr. Anderson, would you
16 entertain a question from the panel?

17 DR. ANDERSON: Yes, I would.

18 CHAIRMAN WHALEN: Dr. Burkhardt.

19 DR. BURKHARDT: Thank you, Dr. Anderson.

20 You brought up a couple of issues with
21 which I was not familiar and just need some more
22 information, which I'm sure you have. You indicated

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1 that the saline implants has the same type of shell as
2 the gel filled implants. What do you mean by that?
3 I don't understand.

4 DR. ANDERSON: A generic characterization
5 as the silicone. The manufacturers will talk to you
6 about slight differences in the catalyst and
7 thickness, but in terms of what we believe the
8 biologically important degradation over time and the
9 influence of folds on rupture we think are very
10 similar.

11 DR. BURKHARDT: And in regard to the back
12 bleed of gel in the saline implant --

13 DR. ANDERSON: Yes, sir.

14 DR. BURKHARDT: -- would you explain that
15 to me, please?

16 DR. ANDERSON: In the 1991-92 breast
17 implant hearings on silicon gel, there were long,
18 theoretical discussions on whether or not all bleeding
19 came from the gel inside, and the theory was quite
20 elegantly put forward by presenters from the FDA that
21 even the membrane of the ^{**}silicone device could bleed
22 a few molecules.

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1 DR. BURKHARDT: But you're speaking of a
2 patient who has previously had a silicone gel implant.
3 Where does the gel come from is what I'm trying to
4 figure out.

5 DR. ANDERSON: And the answer is, to turn
6 it around, if you look at the capsular contracture
7 around these devices --

8 DR. BURKHARDT: We're talking about saline
9 filled devices now we're talking about?

10 DR. ANDERSON: Yeah. We have removed six
11 different sets. They all show scar tissue and the
12 granulation reaction, microgranulomas that we see in
13 association with silicone gel.

14 DR. BURKHARDT: Do they show silicone gel
15 in the capsule?

16 DR. ANDERSON: I have never done the X-ray
17 defraction microscopy to prove it. I think that job
18 belongs with the manufacturers behind it.

19 DR. BURKHARDT: So we don't know then?

20 DR. ANDERSON: No. This is a -- I've
21 raised this as a concern, sir.

22 DR. BURKHARDT: Thank you.

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1 DR. ANDERSON: Yeah.

2 CHAIRMAN WHALEN: Thank you.

3 Next listed is Dr. Fritz Barton.

4 DR. BARTON: Good morning. Thank you for
5 the opportunity to be here. I'm Dr. Fritz Barton,
6 clinical professor and past Chairman of the Division
7 of Plastic Surgery at the University of Texas
8 Southwestern Medical School.

9 I've been in clinical practice for 24
10 years and have managed thousands of patients with
11 breast implants. Therefore, a portion of my income is
12 derived from breast implant surgery.

13 My travel expenses are paid for by the
14 American Society for Aesthetic Plastic Surgery, of
15 which I am president.

16 I have no financial ties to any implant
17 manufacturer. I'm neither a witness nor a party to a
18 pending lawsuit relating to breast implants. I am
19 here today on behalf of the many thousands of our
20 patients who tell us that breast implants have made a
21 positive difference in their lives.

22 An increasing number of women today are

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1 choosing breast augmentation to enhance their
2 appearance, nearly a million women in the past decade
3 alone. But why is this procedure so popular?

4 In my experience, most patients become
5 interested after talking to someone else who has had
6 the surgery. Satisfied patients have created the
7 popularity of breast augmentation.

8 The experience of my practice parallels
9 very closely the documented description of the typical
10 breast augmentation patient. The average patient is
11 in her early 30s. Most often she is married and has
12 children. These women do not fit the stereotype so
13 often portrayed. They are responsible, adult women
14 with families, careers, and very normal lives.

15 I've found that women seeking breast
16 augmentation have similar motivations to other
17 cosmetic surgery patients. The idea that women seek
18 breast augmentation for any reason other than their
19 own personal desire is not supported by the
20 literature, nor by my clinical experience.

21 Research has shown that the vast majority
22 of patients who have breast augmentation would make

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1 the same choice again. The high satisfaction rate and
2 the determination that so many women undergo a surgery
3 with the knowledge that it's not perfect suggests just
4 how deeply the benefits are felt.

5 Women have to overcome tremendous
6 obstacles to get this procedure, from societal
7 prejudice to a wealth of misinformation. The fact
8 that so many seek it out speaks to their strong
9 desire.

10 I believe that the vast majority of
11 plastic surgeons try to do a thorough job of informing
12 their patients about both the benefits and the risks
13 of implant surgery. As a physician it is my
14 responsibility to help round out the decision making
15 process.

16 A woman's right to choose breast implants
17 is parallel by her right to be fully informed both of
18 the risks and of the benefits. As with all cosmetic
19 surgery consultations, part of the evaluation is
20 judging the appropriateness of the patient's
21 motivations and expectations. Patients who are felt
22 to have inappropriate motivation or inappropriate or

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1 unreachable expectations are counseled against the
2 surgery.

3 Saline filled breast implants provide
4 important psychological benefits to many women. Given
5 the proven level of safety and efficacy of these
6 devices, women should have the right to choose them
7 either for breast reconstruction or for augmentation.

8 Our responsibility as health professionals
9 is to provide the information by which a patient can
10 exercise her informed consent. The American Society
11 for Aesthetic Plastic Surgery and its 2,800 Board
12 certified plastic surgeon members and candidates are
13 committed to this process.

14 Thank you very much.

15 CHAIRMAN WHALEN: Thank you, Dr. Barton.

16 Next listed is Dr. Gwendolyn Lewis.

17 DR. LEWIS: I am Gwendolyn Lewis, and I'm
18 here as a volunteer to read testimony for three women
19 who had implants who are too sick or poor to come.

20 My answer to all four question is no.

21 In all three testimonies the women were
22 healthy, got implants, got sick, got their implants

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1 removed, and then got better.

2 The first woman I'd read for is Karen
3 Decker, who's from Pennsylvania. She writes:

4 I am a 36 year old mother and wife. Five
5 years ago I decided to have saline implants put in.
6 My surgeon had very positive things to say about them
7 and said they would last a lifetime unless I happened
8 to get in a very bad car accident, and even if that
9 did happen and they ended up rupturing, I would be
10 perfectly safe because they were filled with saline,
11 not silicone.

12 At the time I didn't even know they
13 weren't FDA approved.

14 As soon as I had the implants put in, my
15 breasts became very sensitive, but my doctors kept
16 telling me not to worry, that it was just my hormones.

17 About two years after this, I started
18 having memory problems to the point I couldn't
19 remember things that had happened the night before.
20 I was tired all the time.

21 I went to a ^{**}specialist, but all the
22 results came back normal. I had sharp, jabbing pains

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1 constantly running through my breasts. I also had
2 aches and pains that left me virtually unable to move
3 my joints, and there was overwhelming heat on my own
4 skin.

5 Finally I went to the doctor again, and my
6 ANA test revealed that I had lupus. It's been a
7 little over a month since I've been explanted. My
8 right breast has swelled up twice since then, and each
9 time they had to put a large tube in it for a week to
10 drain.

11 I've been on antibiotics all month, and I
12 still have two infections. The hole is still there,
13 and I have to put an antibacterial ointment on gauze
14 and push it in with a Q-tip.

15 My left breast is healing fine. The hot
16 skin I was having for months went completely away
17 after explantation. I no longer get sharp, jabbing
18 pains through my breast, and my ANA is back normal.
19 I am still tired, but I guess that's normal with the
20 infections.

21 My memory problem is still there, but I
22 hope in time that also changes around.

1 This is from a 29 year old woman, Cheryl.
2 I'm a 29 year old woman who got McGhan textured saline
3 implants in 1996 for cosmetic reasons. About a year
4 later the problems started. Although I had not had
5 health problems in the past, in 1997, I developed a
6 number of allergies.

7 In January of 1999, I was rushed to the
8 emergency room with severe abdominal pain. At the
9 time they diagnosed me with urinary and vaginal
10 infections and sent me home, but the pain never got
11 better, and the infections never went away.

12 I had polyps and infections. Last April
13 my skin all over my body started to burn. It felt
14 like burning inside my veins, and my joints were
15 tremendously painful.

16 I went to several doctors and my blood
17 work all came back normal. In May I went for a
18 mammogram which came back fine, but within three weeks
19 of the mammogram I felt horrible. I had extreme
20 burning and a sense of strong pressure in my chest,
21 particularly around and behind my implants. My eyes
22 and mouth were extremely dry, and soon after I noticed

1 my hair falling out in clumps.

2 I was so fatigued that I couldn't even get
3 myself something to eat and soon found myself out of
4 work. Emotionally this was difficult for me to deal
5 with because I've always been a health and active
6 person. I rarely ever had a cold, even in the middle
7 of flu season. Now at 28 my body was falling apart.

8 It got worse. By July I was so weak that
9 I could barely get up to use the bathroom and get a
10 drink. I was diagnosed with extremely dry eyes.
11 Since 1998, my eyeglass prescription has changed three
12 times. Before that my prescription changed only once
13 in four years.

14 It seems like I couldn't remember anything
15 anymore. I would get up from the couch to go get a
16 tissue, and by the time I had gotten to the restroom,
17 I had no idea what I was doing or getting.

18 I would often become cold, and nothing
19 seemed to be able to warm me up. For instance, I
20 remember feeling like my feet were freezing and
21 decided to put on a pair of socks and wrap a blanket
22 around them.

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1 Two hours later, they still felt cold.
2 Even a heating blanket wouldn't warm me up. My aches
3 and pains were so awful.

4 Last August I decided to remove my
5 implants. I just wanted to feel better. When I was
6 explanted in September, I noticed some of my symptoms
7 going away. My hands weren't swelling anymore. All
8 of my chest pains were gone, and although I am still
9 really tired all the time, I began to be able to do
10 more things for myself.

11 I still have health problems, and I still
12 can't work, and at the age of 29 I find myself with no
13 income and no way to take care of myself.

14 I thank God for my family, friends and my
15 boyfriend who have been supporting me through this,
16 both financially and emotionally. Without their help
17 I would be homeless.

18 I'm glad I'm getting better, but it's not
19 quite quickly enough. I would have loved to have come
20 to this meeting, but my health prevents me from doing
21 so.

22 I see this as flashing to stop.

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1 CHAIRMAN WHALEN: I'm afraid I'll have to
2 ask you to do so.

3 DR. LEWIS: Okay.

4 CHAIRMAN WHALEN: That is your five
5 minutes.

6 DR. LEWIS: Thank you.

7 CHAIRMAN WHALEN: Thank you.

8 I'm sorry. Doctor, Dr. Lewis. Dr.
9 Burkhardt would like to ask you a question if you
10 don't mind.

11 DR. BURKHARDT: Are you a physician?

12 DR. LEWIS: No, I'm a sociologist.

13 DR. BURKHARDT: I see. Is it your
14 position then that because of these tragic stories
15 that other women should not be allowed to have this
16 surgery?

17 DR. LEWIS: I think they should be
18 investigated thoroughly. Yes, I think these tragic
19 stories do point --

20 DR. BURKHARDT: But it's your position
21 that they should not be allowed to have this surgery
22 at the present time. Is that what you're recommending

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1 to the -- because that's what a negative vote on this
2 committee would probably do.

3 DR. LEWIS: Well, I think you're the
4 experts and will have to decide that.

5 DR. BURKHARDT: Thank you.

6 DR. LEWIS: I'm not in a position to do
7 that.

8 CHAIRMAN WHALEN: Thank you, Dr. Lewis.

9 Next listed is Jean Pentolino. Not here.

10 Dr. Cheston Berlin.

11 DR. BERLIN: Good morning. My name is
12 Cheston M. Berlin, Jr. I am Chief of the Section on
13 General Pediatrics in the Department of Pediatrics of
14 the Pennsylvania State University College of Medicine
15 at the Milton S. Hershey Medical Center. I am also
16 university professor of pharmacology at the same
17 institution.

18 In addition to my academic and clinical
19 appointments, I am a member of the Academy for Breast
20 Feeding Medicine, the International Lactation
21 Consultants Association, the American Society for
22 Nutritional Sciences, the American Society for

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1 Clinical Nutrition, and I'm a Board member of the
2 International Board of Lactation Consultant Examiners.

3 I wish to emphasize that I am not
4 representing these organizations, but with to indicate
5 my professional interest in pediatric nutrition,
6 especially in lactation.

7 I'm also a member of the American Academy
8 of Pediatrics and have served as Chair of the
9 Committee on Drugs. At the present time I am Chair of
10 the Network Steering Committee of the National
11 Institutes of Health and Pediatric Pharmacology
12 Research Units.

13 One of my research interests is in the
14 transfer of drugs and chemicals in the human milk. I
15 may be the only person to make a presentation to you
16 this morning on the only purpose that those of us in
17 pediatrics see for the human breast, which is breast
18 feeding.

19 I am paying for my own transportation
20 today from my university professorship fund. I have
21 no financial interest, nor have I consulted with any
22 manufacturer of saline implants.

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1 I have served as a consultant to the
2 pharmaceutical industry, including Pfizer and Merck,
3 Ascent, and Mediva, and I participated in the clinical
4 trial for Mediva.

5 I am neither a witness nor a party to any
6 litigation involving breast implants. I do no surgery
7 involving breast implants, and I do not care for women
8 with complaints they believe are related to breast
9 implants.

10 Because of my interest in the silicone
11 filled implants, I have served as a consultant with
12 both industry and with women with silicone implants.

13 A major thrust in pediatrics over the past
14 25 years has been to increase the incidence of breast
15 feeding 75 percent by the year 2000. We shall not
16 achieve that goal. The best estimation is that now
17 approximately 60 percent of infants are discharged
18 from the hospital, if indeed they stay long enough to
19 be breast fed, and there is a 50 percent attrition
20 rate over the following six months. We are very
21 anxious to change these numbers in a positive trend.

22 One of the frequent reasons for not

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1 starting or for cessation of breast feeding has been
2 the need for a mother to take a medication. She
3 frequently will receive instructions that she must
4 terminate breast feeding.

5 A similar situation exists with regard to
6 exposure to environmental chemicals, including the
7 issue of breast feeding in women with breast implants.
8 The initial implants contained a silicone gel within
9 the silicone based capsule.

10 It has been estimated, as you've heard
11 this morning, that nearly one million women have had
12 breast implants. Many of these have been in the child
13 bearing age. Concern has been raised over the
14 exposure of children to milk from mothers who have had
15 silicone implants. There's only one report in the
16 literature of a group of offspring of mothers with
17 breast implants who had esophageal dismodality
18 (phonetic). This study has been criticized on
19 methodology background.

20 There does not appear to be any secretion
21 of silicone related compounds from human milk from
22 mothers with these implants. Since saline filled

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1 implants would not have the silicone gel interior,
2 this would not even be a hypothetical concern.

3 It is important that we continue our
4 emphasis toward increasing the incidence of breast
5 feeding in the United States. My presentation here is
6 not meant as an endorsement for the cosmetic use of
7 implants, nor for the licensing of these implants for
8 this purpose, but to assert that there should be no
9 concern on the panel's part over any possible medical
10 effect on the offspring of women with implants who
11 choose to breast feed, the so-called second generation
12 effect.

13 At the present time there is no scientific
14 data that would prohibit breast feeding in women with
15 these implants. I'm convinced that, along with my
16 pediatric colleagues, that breast feeding for
17 nutritional, immunological, and psychological reasons
18 is the most important thing that we can offer our
19 children.

20 We need to make a substantial increase in
21 the incidence of breast feeding at all infant ages in
22 this country, and in order to do so we should not

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1 arbitrarily exclude a group of women from nursing
2 because of a hypothetical risk without confirmatory
3 scientific data.

4 There are many reasons for stopping breast
5 feeding, including return to work, onset of maternal
6 disease, need for pumping and storage facilities, and
7 the institution of maternal drug therapy. All of
8 these would interfere with the duration of milk, of
9 lactation.

10 We should not add to this list any other
11 reason without scientific support. There is no
12 scientific data to indicate that breast feeding with
13 saline implants would be hazardous to nursing infants.

14 Thank you.

15 CHAIRMAN WHALEN: Would you entertain a
16 question, Doctor?

17 DR. BERLIN: Yes, sir.

18 DR. BURKHARDT: I'm sorry. I seem to be
19 the only one asking these questions here, but, Doctor,
20 hypothetically if a woman were to develop systemic
21 antibodies toward either the silicone shell or
22 something in the silicone shell, as an expert in

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1 breast feeding, would this be likely to be reflected
2 in any way in the content or quality of the other's
3 milk?

4 DR. BERLIN: I do not think so, Dr.
5 Burkhardt, because of some of the other situations
6 like women with lupus, who have a significant number
7 of antibodies to many, many different tissues. They
8 do not have difficulty, should they wish to choose to
9 nurse.

10 DR. BURKHARDT: So the answer is negative
11 then. It would not be reflected in --

12 DR. BERLIN: I do not think so.

13 DR. BURKHARDT: Thank you.

14 CHAIRMAN WHALEN: Thank you, Dr. Berlin.

15 DR. BERLIN: Is there a question there?

16 CHAIRMAN WHALEN: Yes, Ms. Brinkman.

17 MS. BRINKMAN: My question is you talk
18 about the fact that we're not getting contamination of
19 milk, but implants interfering with the ability to
20 breast feed, what has been your experience?

21 DR. BERLIN: The experience with that is
22 that certainly the type of surgery that is done for

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1 the insertion of the implant might interfere with the
2 ability to nurse. The two things that seem to be very
3 important in breast feeding in women with implants,
4 regardless of their composition, is the site of the
5 incision, particularly if any of the ducts under the
6 nipple have been harmed or if one of the -- the fourth
7 accessory nerve that innervates in the nipple, which
8 comes across from the lateral side, if that's been
9 transected.

10 If that's the case, there may be
11 difficulty particularly with establishment of
12 lactation because of the reflex of nipple to the brain
13 in the mother. So that is a legitimate concern, but
14 that would not affect the infant other than the fact
15 that the mother could not make the milk.

16 MS. BRINKMAN: And is it your
17 understanding this appears to be a common place for
18 the incision for some of the augmentation patients?

19 DR. BERLIN: That is a common place is
20 right under the nipple?

21 MS. BRINKMAN: Yes.

22 DR. BERLIN: Yes.

1 MS. BRINKMAN: Thank you.

2 CHAIRMAN WHALEN: Thank you, Dr. Berlin.

3 Next is Ms. Karen Duhala. No.

4 Well, we'll complete the sequence, and
5 then we'll return to anyone who has shown up late.

6 Ms. Melinda Cloud.

7 MS. CLOUD: Good morning. My name is
8 Melinda Cloud, and I am from Grand Rapids, Michigan.

9 And to answer your first question, since
10 I am on disability, I could not afford to come here.
11 So after asking for some assistance so that I could
12 give a presentation, I was told that my plane fare and
13 room would be paid for by a nonprofit support group
14 for women with implants, Command Trust Network.

15 In answer to your other three questions,
16 the answer is no.

17 I am here today with an unpleasant and yet
18 very necessary story to tell regarding my experiences
19 with saline breast implants. Were it not considered
20 highly inappropriate, I would bear my chest to you
21 right now, for seeing with your own eyes, it would
22 have a greater impact than the words that I can tell

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1 you.

2 To me they are not breasts, but two
3 containers of saline in silicone baggies held in place
4 by skin. Were you to see them, you would see puckers
5 and indentations where the containers have shifted,
6 where the solution has dissipated.

7 Were you to touch them, it would feel like
8 touching a plastic bag that moved beneath a sheath of
9 skin. You could feel the solution slosh. You'd want
10 to take your hand away, and I wouldn't blame you.

11 In 1974, I was a young model and was
12 adamantly advised to have breast augmentation by a
13 physician. I nursed my baby for about a year, and he
14 said I was much too young to have such protic breasts.

15 I also had many cysts in my breast, and
16 the doctor told me that the solution to my problems
17 was to have my breast replaced with silicone implants,
18 which would last a lifetime and permanently end my
19 pain and discomfort. I had no idea that this was the
20 beginning of a long period of pain, suffering and
21 decline.

22 I ended up not have one surgery, but 12,

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1 most of them attempting to remedy severe capsular
2 contracture and deformity. I started with silicone
3 implants and later replaced these with several sets of
4 saline.

5 I had an emergency surgery to deal with a
6 hematoma where blood was literally spurting out of my
7 breast. I had two more surgeries to deal with a near
8 deadly staph infection.

9 In 1987, 13 years after my first surgery,
10 I finally consulted specialists at the University of
11 Michigan Medical center who assured me they would
12 solve my problem once and for all, but they didn't.
13 They couldn't.

14 I had several other surgeries, including
15 getting my first set of saline implants in 1992. They
16 told me my saline implants were the safest kind, but
17 my worst problems started after this surgery.

18 On July 18, 1995, I had my first set of
19 saline implants put in, which were described as a new,
20 greatly improved type of saline implant. I still had
21 a great deal of deformity from all the previous
22 surgeries and the infection of '86.

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1 of my saline implants.

2 This entire mess has cost well over a
3 quarter of a million dollars. Why? Because I, like
4 everyone else, believed saline solutions encased in
5 silicone shells did not cause problems.

6 I have to get up every day and face
7 chronic fatigue, wash up from night sweats, Reynault's
8 syndrome, and moments of excruciating chest pain that
9 has doctors sending me to the emergency room.

10 My immune system has been compromised.
11 I've developed what is known as chemically induced
12 asthma. I have blood in my urine and no one knows
13 why. My muscles have weakened. I get sores on my
14 skin that don't really heal. I have episodes of
15 severe depression, and I can't even pick up my
16 grandchildren.

17 I was once a very strong and health woman.
18 I raised three children alone without the benefit of
19 child support. Illness was not even a consideration.

20 Now I pray every day for God's help to
21 keep my spirits up for I know full well that, plus the
22 blessed love of my family and friends, this is all

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1 that keeps me going.

2 There is little that you can do for me
3 anymore. The damage has been done, but you can help
4 other women. I cannot get my breast implants out. My
5 insurance will not pay for it because it's elective,
6 and they have to pop first or have a great leak, and
7 then no one knows what will happen. I also cannot get
8 reconstructive surgery because I cannot afford it.

9 You are not doing any women any favor by
10 giving them a choice that could leave them financially
11 destitute with no ability to have a failed implant
12 removed, which is my situation today.

13 I would like you to look into the answer
14 of saline implants in place of silicone because
15 there's no proof anywhere for anyone that that's the
16 remedy, and for me it absolutely was not.

17 Thank you for this honor and opportunity
18 to testify before you. I'm going to try once again to
19 trust you to do your part. Please do not recommend
20 the approval of saline implants unless you are
21 convinced that what happened to me won't happen to
22 anyone else.

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1 Thank you.

2 CHAIRMAN WHALEN: Thank you, Ms. Cloud.

3 The next listed speaker is Dr. Ory.

4 DR. ORY: Good morning. I'm Howard Ory.

5 Currently I'm a private consultant in epidemiology.

6 I'm an adjunct professor of epidemiology at the Emory

7 University School of Public Health, and in a past

8 life, I was Deputy Director of the Epidemiology

9 Program at the Centers for Disease Control.

10 My presentation today is very abbreviated
11 from the written report that I submitted to you in
12 collaboration with Dr. Jim Schlesselman. Both Jim
13 and I have consulted with 3M and defended in a breast
14 implant litigation. 3M has paid for my transportation
15 and lodging today.

16 I continue to be involved with lawsuits
17 related to breast implants. Today I will do two
18 things. I'll present a summary of our meta analyses
19 of the more than 20 published epidemiologic studies
20 that examine the association of breast implants and
21 connective tissue diseases.

22 Then I will present the conclusions of

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1 three blue ribbon panels that have examined this
2 issue.

3 This table shows estimates of the relative
4 risk of connective tissue disease among women with
5 breast implants. The values range from 0.3 to 1.2.
6 A summary estimate of the relative risk of connective
7 tissue disease is 0.7.

8 The next four tables examine the most
9 common connective tissue diseases comprising the
10 aggregate diseases in Table 3 there.

11 Estimates of the relative risk of lupus
12 range from zero to 2.3. A summary estimate of the
13 relative risk is 0.7.

14 Estimates of the relative risk of
15 rheumatoid arthritis range from .3 to 1.6. A summary
16 estimate is 1.1.

17 Estimates of the relative risk of
18 scleroderma range from zero to 1.8. A summary
19 estimate is 1.0.

20 Estimates of the relative risk of
21 Sjogren's syndrome range from .2 to 1.5. A summary
22 estimate is 0.8.

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1 An atypical connective -- that's definite
2 connective tissue disease. In atypical connective
3 tissue disease specific to breast implants has never
4 been defined. Lacking a case definition, six studies
5 examine conditions that represent various aspects of
6 atypical connective tissue diseases, such as chronic
7 fatigue syndrome, fibromyalgia, undifferentiated
8 connective tissue diseases. A summary estimate of the
9 relative risk is 0.8.

10 Based on the data I just presented, we
11 conclude that the 25 or so epidemiologic studies now
12 at hand provide sufficient evidence to reassure women
13 that breast implants do not cause autoimmune disease,
14 connective tissue disease, or atypical connective
15 tissue disease.

16 Slide off, please.

17 Three blue ribbon -- I'm now going to
18 switch to the three blue ribbon independent reviews,
19 which were released in 1998 and 1999, presenting
20 scientific evidence concerning the possible
21 association of breast implants and systemic disease.
22 The scientists on these panels were chosen because of

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1 their distinguished credentials and their lack of
2 previous involvement in the issue. The conclusions
3 that they reach about the epidemiologic data are
4 strikingly similar to each other and to our own.

5 The independent review group and panel by
6 the Ministry of Health in the U.K. concludes there's
7 no epidemiologic evidence for any link between
8 silicone gel implants and any established connective
9 tissue disease. If there is a risk of connective
10 tissue disease, it's too small to be quantified.

11 The IRG cannot justify further
12 epidemiologic studies to investigate this hypothesis.
13 Good evidence for the existence of atypical connective
14 tissue disease or undefined conditions, such as
15 silicone poisoning, is lacking.

16 The National Science Panel, empaneled by
17 Judge Sam Pointer, Federal District Judge Pointer,
18 who's in charge of the multi-district litigation.
19 This panel concludes: no association was evident
20 between breast implants and any of the individual
21 connective tissue diseases, all definite connective
22 tissue diseases combined or the other autoimmune

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1 rheumatic conditions.

2 The material presented represents an
3 analysis of the most rigorous and relevant scientific
4 information currently available. It's our informed
5 opinion that a large majority of scientists in our
6 respective disciplines would find merit in our
7 reviews.

8 Finally, the Institute of Medicine
9 essentially concludes the same thing, that there's
10 insufficient evidence to support an association of
11 silicone breast implants with the fine connective
12 tissue diseases. There's no justification for the use
13 of resources and further epidemiologic exploration.
14 The committee finds no convincing evidence for
15 atypical connective tissue disease, rheumatic disease
16 or novel constellation of symptoms in women with
17 silicone breast implants. In fact, epidemiologic
18 evidence suggests there is no novel syndrome.

19 Ladies and gentlemen of the panel, based
20 in part on the 25 studies that I presented to you, the
21 three independent blue ribbon panels conclude that
22 this issue is resolved. Breast implants do not cause

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1 connective tissue disease.

2 Thank you.

3 DR. BANDEEN-ROCHE: Could I ask a
4 question?

5 CHAIRMAN WHALEN: Please.

6 DR. BANDEEN-ROCHE: Couldn't help noticing
7 both in the printed literature and up there that the
8 Hennekens study was notably sort of out of line with
9 the others and that it had higher estimates of risk.
10 I understand that this could happen by random chance
11 alone, et cetera.

12 So my question to you is: are you aware
13 of anything about the Hennekens study that
14 systematically makes it different than the others?
15 Was it a more or less representative population? Was
16 it better or worse done?

17 I'd appreciate your comments on that.

18 DR. ORY: The Hennekens study relies of
19 self-reports of both implants and diagnoses. It was
20 conducted during the time of maximum media attention
21 to this, and the authors themselves notes that there's
22 a substantial likelihood of selection bias of the

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1 people who entered the study, driving the relative
2 risks up.

3 In fact, of the target population, only 25
4 percent of the target population entered the study.
5 So there is a substantial likelihood for selection
6 bias.

7 The other thing I didn't have time to
8 present is that I've done the meta analyses both with
9 and without Hennekens, as has Dr. Hulka of the
10 National Science Panel, and essentially you come to
11 the same conclusions. The relative risks of all the
12 connective tissue disease that you study hover around
13 1.0, with or without Hennekens.

14 CHAIRMAN WHALEN: Ms. Brinkman.

15 MS. BRINKMAN: Is it my understanding that
16 these studies are done on silicone gel implants?

17 DR. ORY: They're done on both, and the --

18 MS. BRINKMAN: What percent of saline
19 implants are included in these studies?

20 DR. ORY: It's hard to tell. Most of the
21 studies didn't -- were unable to make that assessment.
22 The best way I could give you of looking at them is

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1 that Dr. Hulka of the National Science Panel broke out
2 silicone gel studies in her meta analysis and also
3 showed a relative risk of about one. So I think you
4 can infer that the relative risk for saline implants
5 would have to be one since the overall risk is near
6 one.

7 DR. BURKHARDT: May I ask a question?

8 DR. ORY: Yes, sir. Dr. Burkhardt.

9 DR. BURKHARDT: What does a relative risk
10 of one mean?

11 DR. ORY: A relative risk of one means
12 that the risk of the particular disease you're
13 studying in women with implants is the same as in the
14 controls, women without implants.

15 CHAIRMAN WHALEN: Is Ms. Brent available?

16 MS. PATRICIA BRENT: Good morning, and
17 thank you very much for having me here. My name is
18 Patricia Brent. This is my daughter, Catherine Brent.
19 I breast fed her while implanted with a
20 saline/silicone implant.

21 In answer to the questions, my travel has
22 been paid for by my husband. He is not happy about

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1 this.

2 Do I have financial ties? No. Are you a
3 witness or party to a pending lawsuit? Yes. It was
4 filed in 1991. I have not resolved it. Catherine is
5 also a party to a lawsuit. It was filed in 1995. It
6 has not been resolved.

7 And do I derive a portion of my income?
8 No.

9 I am here to voice my concerns and the
10 concerns of many other mothers about the saline
11 portion of our mammary gland implants. I will be
12 referring to these as mammary gland implants because
13 the function of the breast is to breast feed.

14 My implants were put in in December of
15 1982. I was a healthy woman of child bearing years.
16 I had them put in because I had nursed my four older
17 children. I had the surgery to make my breasts look
18 the way they did before I nursed. It was a path down
19 vanity lane. It was a sin.

20 I had -- I had my four other older
21 children. In 1982 I was implanted. In 1984 I got
22 pregnant with Catherine. Catherine was born in

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1 January of 1985, and under advice of my physician, my
2 pediatrician, and from what I knew, it was perfectly
3 safe for me to breast feed. That is what is still
4 being told to young women. I disagree.

5 When I was explanted, my breast implants
6 had grown black aspergillus niger fungus and bacteria.
7 This was in the implant upon explantation. Black
8 aspergillus niger fungus and unknown microorganisms is
9 not a good thing to have in a mammary gland,
10 especially when you are breast feeding.

11 I will now let Catherine read a letter.
12 It was an E-mail actually that she sent to the "Oprah
13 Winfrey Show." I did not watch this program.
14 Catherine watched this program. This is Catherine's
15 response to the "Oprah Winfrey Show."

16 MS. CATHERINE BRENT: According to your
17 show today, it was stated that breast implants were
18 safe for pregnancy and breast feeding. I would like
19 to tell you that the doctor on your show lied because
20 if he referred to the FDA, it is not known whether a
21 mother's breast implants can have an effect on the
22 fetus.

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1 I am a 14 year old girl who's suffering
2 from chronic inflammatory demyelinating
3 polyneuropathy, esophageal motility disorder and
4 gastroesophageal reflux disease. My young sister is
5 also sick. We are the children my mother had after
6 she got breast implants. She nursed us after she was
7 told it was safe. Are four older siblings are in
8 perfect health.

9 I would just like to tell you to research
10 what you say before you air a lie.

11 Thank you very much. I would like to be
12 on your show so I can tell my story, my sister's, my
13 mother's, and all of the thousands of children sick
14 from these unsafe implants.

15 Thank you. Catherine.

16 And please go to the FDA Web site.

17 MS. PATRICIA BRENT: I heard back from the
18 "Oprah Winfrey Show" approximately two months later.
19 It was from their legal department. It broke my heart
20 because I know that if the legal department gets
21 involved, I will not get the truth. People will not
22 be told the truth.

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1 I am now going to show you my breast
2 implants with the fungus, and I'm going to show you a
3 baby bottle that has black fungus on it. I do not
4 know. I did not have this cultured. I do not know if
5 this is aspergillus niger as mine was, but I ask you
6 to look at the two of these and tell me, tell me as a
7 mother it is safe for me to breast feed with this in
8 my body.

9 I know I have had six children. I am a
10 professional at this. I had natural childbirth for my
11 last five births. I know what to do with my body when
12 I am pregnant. I know what to eat. I know what not
13 to eat. I know what medication to take and what not
14 to take, and I listen to my doctors.

15 Doctors do not know. The average
16 pediatrician does not know that this fungus can be in
17 the implant. Whether it comes through into the breast
18 milk, I feel that it does. I feel that unequivocally
19 this is what has harmed my child.

20 There is no family history of this, and I
21 will just pass this along.

22 I have one thing to say, and this is from

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1 Cindy Morrissy, who has three girls. Her daughter
2 Hillary has scleroderma. Please listen to what she
3 has to say because she could not be here today because
4 of her children. They are too ill.

5 We have to have confidence, confidence in
6 the physicians. How can we have confidence if you do
7 not know the full picture? You do not know. You do
8 not know what this does to a nursing child or via the
9 placenta. You do not have these answers.

10 Upholding medicine in its greatest,
11 grandest form is do no harm. Please, please, as you
12 consider putting these on the market, do no harm.

13 Cindy also says: acceptable risks. One
14 would need to greatly define the term "acceptable
15 risk" because when I had those implants I was never
16 told it could grow fungus and have this bacteria in
17 it, and my child was given no acceptable risk.

18 On Monday, the Supreme Court allowed a
19 case to go forward in -- it was from South Carolina.
20 Please forgive me if I don't get this exactly right,
21 but I know that it's about the fetus having rights,
22 and my child had no informed consent. I had no

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1 informed consent. That is absolutely wrong.

2 Catherine and my daughter Christine were
3 part of Dr. Jeremiah Levine's original study in 1992.
4 Catherine and Christine both have the esophageal
5 motility disorder and the reflux. None of my other
6 children have it, and Catherine since that study has
7 been diagnosed with the chronic inflammatory
8 demyelinating polyneuropathy.

9 I will give this to you.

10 CHAIRMAN WHALEN: Thank you, Ms. Brent.

11 MS. PATRICIA BRENT: Thank you.

12 CHAIRMAN WHALEN: Returning to some of the
13 other speakers who I believe have arrived, I'm told
14 Ms. Angus is available.

15 MS. ANGUS: Excuse me if I sniffle. That
16 last testimony really, really touched me.

17 Anyway, okay. Here we go. Are we
18 rolling? I've got what, five minutes? That's it?
19 Okay.

20 My name is Annie. I'm from Vancouver,
21 Canada. I think I might be the only Canadian up here,
22 down here. My travel and accommodation have not been

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1 paid for, nor will I be reimbursed by someone else.
2 I do not have financial ties, including grants or
3 other compensation, with industry or health
4 professionals or societies. I am not a witness or a
5 party to a pending lawsuit related to breast implants,
6 and I do not derive a portion of my income from
7 surgical procedures using breast implants or from
8 treating patients with complaints about breast
9 implants.

10 In other words, I represent myself and all
11 of the other Jane Does out there or all of the Annies,
12 Carols, Lauras, Miriams, and whoever else you want to
13 call them who are too ill or too broke to be here.

14 I am giving this testimony with the hope
15 that women will be spared the ill health that I have
16 experienced as a result of being implanted with saline
17 breast implants manufactured by Mentor. I am not
18 seeking any monetary compensation for my suffering.
19 No amount of money can compensate me for what I have
20 lost.

21 In the spring of 1995, my husband and I
22 were looking into the possibility of having my breast

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1 augmentation. I was 33 years old and was then in very
2 good health. My third child had been born a year
3 earlier, and my breasts were small and saggy.

4 I consulted our family physician and
5 sought a second opinion from a well reputed plastic
6 surgeon. I was concerned about the bad reputation of
7 silicone implants and did not want to do anything that
8 would jeopardize my health.

9 Both physicians assured us that saline
10 implants were completely safe. I was told that with
11 saline implants there were only two risks. One was of
12 the implant rupturing, which is not a threat to one's
13 health. The other possible negative side effect that
14 I became aware of were the ingredients that could be
15 a partial loss of sensation in the breast area.

16 I was given statistics, and the incidence
17 of rupturing and lost feeling and became convinced
18 that only a minority experience these effects, between
19 .0 percent and four percent.

20 Having thought that I was well informed,
21 I consented to the surgery and signed a waiver
22 declaring that I would not pursue litigation if there

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1 were any complications. This act of weighting one's
2 rights is in hindsight intentionally disempowering and
3 needs to be readdressed.

4 In June of 1995, I underwent a breast
5 augmentation with saline implants performed by a
6 Canadian Board certified plastic surgeon. After a few
7 months, I realized that the numb sensation in my
8 general breast area was not going away, and that I was
9 hypersensitive in the areola and nipple area, which is
10 a painful and irritating sensation.

11 I was told by my plastic surgeon that it
12 could take up to two years for the nerve endings to
13 heal. I kept waiting, hoping that all of the sharp
14 pains in my breast were signs that the sensations were
15 returning to what I had known prior to my surgery.

16 Two years later I still could not stand
17 for my breasts to be touched, and now that I have had
18 the implants removed, my breasts still have about 30
19 percent of the feeling that they had originally had.
20 It has been tragic for me to have to deal with this
21 loss of feeling and lack of pleasure for the rest of
22 my life.

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1 If I had any idea that improving my
2 appearance would jeopardize my ability to feel
3 pleasure, I would never have played this game of
4 Russian roulette.

5 One year after the implantation, it became
6 obvious that I had developed capsular contracture. My
7 right breast was softer than the left one, which was
8 as hard as a softball. I had followed my plastic
9 surgeon's instruction to massage my breasts daily to
10 keep them soft, but it hadn't helped.

11 Also, there were dense lumps all around
12 the top of the left implant that were visible if I was
13 to wear certain clothing, like this top that I'm
14 wearing now. I couldn't even wear a top like this
15 before because you would see lumps sticking out on the
16 top of my breast.

17 Within a year of having an operation that
18 was supposed to improve my appearance, I became very
19 self-conscious about appearing to be deformed. The
20 head of plastic surgery at the University of British
21 Columbia, by the way, has stated that up to 40 percent
22 of implants may rupture or develop capsular

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