

1 permission or the authorization or the consenting
2 form, I don't think any women will have a silicone or
3 saline breast implant in their body.

4 DR. WHALEN: Dr. Puszkin, forgive me, but
5 could you answer the four questions?

6 DR. PUSZKIN: I'm answering in the slide.
7 Okay. I'm Dr. Saul Puszkin and I'm affiliated with
8 Columbia University. I have my private laboratory of
9 the Health Sciences Consultant Group. I am involved
10 in the litigation on the side of the patients who had
11 breast implants or their relatives. Some of the
12 lawyers hired me to testify about what I find in the
13 pathology of these patients. I do not -- the expenses
14 were paid by the laboratory. I do have income from
15 some of the pathology I do.

16 Okay. I don't know what you heard in the
17 last three days but very briefly this is the mammary
18 gland. It's a very sensitive area. During my years
19 as Professor of Pathology and Molecular and Cellular
20 Pathology at Mt. Sinai I worked with latex particles
21 injecting them in the mammary gland of animals.

22 I found it exquisitely sensitive and very

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1 highly immunogenic in the sense of responding
2 immunogenically to latex particles. Silicone became
3 another agent and I understand there are publications
4 saying that silicone gel is immunogenic.

5 We are dealing now with saline implant which
6 is coated by an elastomer made of silicone
7 polydimethylsiloxane. When you put that implant in
8 the body of a lady, after a short while a very thick
9 scar is formed and when the implant is removed either
10 by leakage or other complications, contractures,
11 calcifications, inflammation, and infection, this is
12 the result of that surgery.

13 This is what I get in the laboratory and
14 have worked with over 2,700 patients, analyzed over a
15 similar number of implants, and about 20 percent of
16 them were saline. My experience is over 500 pair of
17 implants of saline that came to the lab to be analyzed
18 by me and find out the complications they had.

19 Now, very briefly. I don't know if you can
20 see. These are my statements. Polydimethylsiloxane
21 makes the elastomer which is a chemical which
22 crosslink and have holes or pores just like a blood

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1 vessel. It has gaps in its structure so things can
2 penetrate either in or out.

3
4 There are ethyl bridges which I don't have
5 to tell you too much. I'm sure if you're on the panel
6 you are highly qualified. I see several Ph.Ds with
7 your names there. The rigidity is due to the number
8 of crosslinks. If you will have a very little
9 crosslinked polydimethylsiloxane network, we will have
10 a gel. If we have it highly crosslinked, we are going
11 to have a rubber type material. That's the one that
12 is being used in the elastomer.

13 My concern is that at the bottom field
14 studies analyze silicone stability to cellular
15 reactive molecules. In the three minutes that I have
16 left, or 3½, I'm going to try to convey to you this
17 impression from a scientific and from my professional
18 and background experience.

19 This is a structure. Assuming this model --
20 I copy it from a cartoon used to teach extracellular
21 matrix which is very similar to the one that we have
22 in the elastomer shell. These are the linear

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1 molecules that are crosslinked by ethyl bridges but
2 there are large gaps so if this is elastomer, things
3 can move from the saline compartment out, or things
4 can move from the tissue compartment into the implant
5 and there is migration.

6 Cellular migration hides the flexibility,
7 especially macrophages which are able to migrate into
8 bone structure. Imagine that they can find themselves
9 into the implant, especially when they see such a
10 large body implanted in a very sensitive area to which
11 they come in response to all kinds of chemical
12 stimuli.

13 Inside a saline implant we have all kinds of
14 materials form in there. These are the walls. This
15 is high magnification, about 5,000 times magnified, of
16 the content of saline after a year in the body. These
17 are the walls of the macrophages and other kind of fat
18 cells that have been able to infiltrate the implant.
19 They become trapped in the saline and they become a
20 good source of decay and a good source of -- just to
21 proliferate in there and decay and to transform
22 themselves.

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1 Several materials are formed. This is a
2 kind of web-like organic material crystals that are
3 formed from the reaction of the saline with the
4 elastomer shell.

5 There are micro organisms that sometimes
6 find themselves inside. This is an amoeba found in one
7 of the implants.

8 This is a large magnification.

9 These are all kinds of precipitates from the
10 macrophage chemicals that have formed with the
11 reaction of the saline and the salt that has been
12 released from the elastomer shell.

13 These are the particles of elastomer shell,
14 the silicone, that have been released from the implant
15 surface and found their way into the tissue.

16 And then you form granulomas in there. This
17 is a granuloma. This is highly reactive surrounded by
18 lymphocyte and they are trying to fight, to fend off
19 this kind of an offense forming a reaction that the
20 body, the tissue react against these implant.

21 I think I'm coming close to the next slide,
22 or the last few slides. I apologize for the excess of

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1 time.

2 DR. WHALEN: We need to have you conclude.

3

4 DR. PUSZKIN: Okay. I can answer more
5 questions. So my opinion is that the saline implants
6 do have to have, if they are going to be ever used, an
7 expiration date. The patient should know that this
8 expires. Like saline when we have a bag and we have
9 an infusion they have an expiration date. If they are
10 in the body and they are warm and they are subjected
11 to all kinds of movement, this material will decay and
12 it will fail and it will require multiple surgeries.
13 I don't think that this is a very good product. Thank
14 you.

15 DR. WHALEN: Thank you.

16 DR. BURKHARDT: I have a question.

17 DR. WHALEN: Dr. Burkhardt.

18 DR. BURKHARDT: Dr. Puszkin, have you
19 published your material and is it available to us from
20 a peer review journal?

21 DR. PUSZKIN: Yes. It has been published in
22 the Journal of Clinical Pathology. It's not easy to

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1 publish kind of adverse material to silicone breast
2 implant in the United States so this is an
3 international journal published in Argentina which is
4 my mother country. I have been invited teach there
5 because Argentina is a haven for implantation.

6 DR. BURKHARDT: You've answered my question,
7 sir. Thank you very much.

8 DR. PUSZKIN: Yes, I do. I'll send it to
9 you without even a request.

10 DR. WHALEN: Thank you.

11 Next we'll hear from Dr. Britta Ostermeyer.

12 DR. OSTERMEYER SHOAI B: Good morning and
13 thank you very much for the opportunity. I am a
14 physician trained in neurology and I helped treating
15 patients who had local and systemic problems from
16 silicone breast implants for eight years in Houston,
17 Texas. I have since moved on and started to train in
18 a second specialty. I'm currently a resident in
19 psychiatry at Columbia University in New York City.

20 I paid my own way to come here and I
21 testified as a treating physician on my patients'
22 behalf in the past. I have no relationships to

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1 manufacturers and I do not derive any income out of
2 breast implants.

3 I would like to show you a small slide
4 presentation and then give you my thoughts and
5 conclusions. Among the women with breast implants
6 that I have treated there was a subpopulation of women
7 who only received saline implants and these patients
8 had presented to us with local and systemic problems
9 after they had received saline implants.

10 This is an overview of the problems they
11 reported to us. These women were healthy previously.
12 They had no other medical problems and since they had
13 a combination out of these problems that was similar
14 in the women that we saw and there was no other cause,
15 we strongly felt after several years of research and
16 seeing these patients that there might be a cause or
17 link between receiving the medical device and getting
18 these symptoms.

19 I'm showing you some pictures of patients
20 that I have seen. You are supposed to see a reddish
21 rash in the lower extremities. This is a lady who had
22 saline implants and developed vasculitis which is

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1 inflammation in her blood vessels. She had strokes in
2 the brain and she developed a gangrene and as a result
3 her little pinky had to be amputated.

4 This lady had saline breast implants only
5 and also had systemic autoimmune disease which is
6 Lupus like and those are her skin rashes.

7 This lady had saline implants, also systemic
8 inflammatory responses, and those are her skin rashes.

9 This is a spec scan which shows how the
10 blood flow in the brain is distributed and we found
11 findings similar of those seen in Alzheimer's and
12 women with systemic illness.

13 We measured autoantibodies which is an
14 objective indicator of systemic inflammatory responses
15 and there were lots of findings.

16 We also did sural nerve and muscle biopsies
17 and had a high number of abnormalities. This is a
18 sural nerve. You are supposed to see fibers all over
19 the picture and you see gaps because this nerve had
20 lost fibers due to inflammatory reactions.

21 The implant capsule was examined from women
22 who had saline implants showed silicone in the

1 surroundings. The surrounding chest wall muscle was
2 biopsied and showed abnormalities and also showed
3 silicone and chronic inflammatory reactions in the
4 surrounding of the implant.

5 My conclusions are that saline implants can
6 evoke systemic and local inflammatory responses.
7 There are objective abnormalities and I believe that
8 more data needs to be collected about saline implants.

9 My conclusions are that patients need to be
10 aware of the risk of local injury as well as local
11 inflammatory responses that can be very painful and
12 can cause chest pain. There is a risk of systemic
13 injury and especially in those women who already have
14 an underlying autoimmune tendency, these women are at
15 higher likelihood of developing systemic problems.

16 I think it's important that surgeons make
17 sure to their patients that they do understand that
18 breast implants including saline implants don't fix a
19 long list of psychological and psychiatric problems
20 including body image problems, depression, anxiety,
21 and marital problems.

22 Surgeons should explore the patient's

1 expectations about the surgery and emphasize that
2 surgery may not solve their problems and that, as a
3 matter of fact, adverse effects may take place.

4 My last thing is about a comment on the
5 insurance situation. There was a patient earlier you
6 said that she couldn't receive medical insurance
7 anymore. My experience over eight years is that
8 either patients are excluded from coverage if the
9 disease that they encountered is a result of breast
10 implants.

11 Once the women are labeled or diagnosed with
12 a problem related to implants, they can no longer
13 receive medical coverage. If they lose their old
14 coverage and they want to obtain new medical
15 insurance, it's a problem because once you are ill
16 with them, you continue medical care and the insurance
17 companies know that. Thank you so much.

18 DR. WHALEN: Thank you. Seeing no
19 questions, we'll take a 10-minute break and then
20 reconvene. Thank you.

21 (Whereupon, at 10:10 a.m. off the record
22 until 10:25 a.m.)

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1 DR. WHALEN: Thank you. We'll resume. We
2 are now going to proceed to testimony from those
3 representing consumer groups and consumer information
4 providers so each of these speakers are allotted if
5 they need it 10 minutes. The first to address us is
6 Ms. Marlene Keeling of the Chemically Associated
7 Neurological Disorders.

8 MS. KEELING: My name is Marlene Keeling.
9 My airfare was paid for by Chemically Associated
10 Neurological Disorders but I am paying for my other
11 expenses. I settled my private lawsuit in 1996
12 against the manufacturer who made my defective
13 implants. Because I feel so strongly I have dedicated
14 my small settlement to addressing patient information,
15 informed consent, and product liability labeling
16 issues.

17 I did not receive informed consent in 1978
18 and women still are not receiving true informed
19 consent today. The present informed consent appears
20 to be primarily written to allow the manufacturers to
21 escape legal liability. I will attempt to give as
22 many examples as possible within the 15 minutes I have

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1 been allotted.

2 Failure, rupture, and reoperation rates,
3 what the product insert says. Patients should be
4 advised that their implants may deflate, result in
5 asymmetry and require replacement surgery.

6 Improvements in design, manufacture, and
7 surgical techniques have contributed to lower rates of
8 deflation reported in the most recent studies. In
9 these studies that they referred to was in 1988 and
10 1990.

11 Our breast implants may not last a lifetime.
12 Our product history indicates an overall reported
13 average rupture rate of approximately 1 percent. The
14 FDA estimates that rupture rates are generally between
15 1 to 4 percent. What the informed consent says,
16 "Breasts implants may not last a lifetime."

17 What the Institute of Medicine report of
18 July '99 says, "Several studies have addressed the
19 frequency of reoperations after implantation with both
20 saline and gel-filled implants." The Mayo study
21 reported a 23.8 percent rate after 7.8 years of
22 follow-up. It appears that a significant number of

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1 women can expect additional procedures in the first
2 five years after implantation.

3 Local complications. What the product
4 insert says. "Improvement in device design and
5 surgical techniques have contributed to declining
6 rates of capsular contracture. The current risk of
7 clinically significant capsular contracture is low.
8 Acute infection around breast implants occur
9 frequently after augmentation with slightly higher
10 rates associated with reconstruction.

11 Extrusion has been reported as an infrequent
12 complication. Breast implants may complicate the
13 interpretation of mammography images by obscuring some
14 underlying breast tissue. Calcification is rare.
15 Chest wall deformity has been reported in rare cases."

16 What the informed consent says. "Several
17 surveys have shown that over 90 percent of women are
18 pleased with the results. Complications are uncommon.
19 Calcium deposits are benign and cause no problems. If
20 the envelope containing the saline portion breaks, the
21 saline is absorbed harmlessly by the body within
22 hours.

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1 Since the breast is compressed during
2 mammography it is possible but rare for an implant to
3 rupture. Very rarely the implant may change positions
4 or break through the skin. Many women with breast
5 implants have nursed their babies successfully."

6 What the IOM report says. "The committee
7 concluded local complications occur frequently and are
8 the primary safety issue. Among the others these
9 include overall reoperations, rupture or deflations,
10 contractures, infections, hematomas and pain. Based
11 on the review of the current research, women can
12 expect early postoperative complications after
13 reconstruction with implants by 30 to 40 percent.

14 The IOM concluded published reports of
15 patient satisfaction might be misleading because most
16 surveys are carried out by plastic surgeons and before
17 the likely appearance of some complications. Saline
18 implants are more prone to wrinkling, fold flaws,
19 surface abrasion, and consequent deflation.

20 In reconstructed patients skin wrinkling has
21 been reported to occur in^{as} many as 26 percent of
22 cases. The committee concluded that modern first-year

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1 deflations of saline implants might be in the order of
2 1 to 3 percent and this percentage would rise closely
3 with time.

4 Microscopic calcification has been reported
5 in 10 to 33 percent of capsules. It can occasionally
6 be severe causing pressure atrophy of breast and
7 underlying muscle tissue. Gram positive bacteria are
8 often located in a bioslime film on the surface of the
9 implant where they are largely protected by antibiotic
10 action and they presumably contribute to infections."

11 The McGhan LST found 1.1 and 6.9 percent of
12 breasts with infections after saline augmentation.
13 Implants themselves, implant pockets or capsules and
14 nipple secretions have yielded 23.5 to 89 percent
15 positive bacteria cultures.

16 Dow in '94 suggest that the presence of
17 subclinical infection or contaminations may contribute
18 to systemic signs of symptoms such as fatigue,
19 myalgia, arthralgia, and diarrhea among others.
20 Hematoma was the indication for reoperation in 3.5
21 percent in the Mayo series*. The experience of one
22 plastic research clinic, 5 to 10.3 percent of patients

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1 were reoperated for hematoma.

2 The aggregate figures for contracture in
3 published research on saline implanted women is 40.5
4 percent. Capsule formation, especially under the
5 muscles, may result in nerve compression and pain.
6 Usually pain with late onset 8 percent and 30 percent
7 of reconstruction and augmentation patients
8 respectively represent contracture pain.

9 As Wallace in '96 discussed, pain like
10 sensory change, which is of similar frequency, is not
11 surprising given the damage to the nerves, to the
12 breast and nipple during implantation and
13 reconstruction surgery. See values of 41.6 percent
14 permanent nipple sensory changes, 41 percent Hetter
15 '79, 18 percent decrease in sensation Hetter '91,
16 nerve damage and paresis 1990, and partial to complete
17 sensory loss in the nipple of 70 percent and in the
18 whole breast of 12 percent after augmentation.
19 Whether silicone from the degrading shell crosses the
20 placenta has not been evaluated in women.

21 Surgery with an incision around the nipple
22 was almost five times more likely to be associated

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1 with insufficient milk production. About 30 percent
2 of breast implant augmentations are carried out
3 through an incision around the nipple. The frequency
4 of lactation insufficiency was slightly increased in
5 women with implants, 64 percent compared to women
6 without implants 7 percent.

7 Another small study of women with saline
8 implants found 39 percent reported breast feeding
9 problems. Data on whether cancer detection is
10 impaired by implants do not allow definite conclusion,
11 although it is clear that implants do interfere with
12 screening mammography by obscuring a variable part of
13 breast tissue, distorting breast architecture, and
14 especially in the presence of firm contractures, which
15 remember happens in a high percent of cases, makes a
16 proper examination with proper compression of the
17 breast more difficult and occasionally impossible.

18 All of the above information from the IOM
19 report with percent of risk is the type of information
20 necessary for a woman to make informed choice or give
21 her informed consent. **

22 Listed under risks in the informed consent

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1 is toxic shock syndrome. According to recent research
2 1999 there has been a rise in the number of
3 nonmenstrual cases of toxic shock syndrome based on
4 data compiled 1979-1996 perhaps related to a
5 substantial increase in prosthetic devices and
6 postoperative infections since 1980.

7 What is the percent of risk of this
8 potentially fatal condition? In the last few days I
9 have heard percentage of risk of local complications
10 that are startling high. Breast cancer survivors need
11 to know they can expect a 95.2 percent complication
12 rate in five years. Young women of childbearing age
13 in their 20s choosing implants for augmentation need
14 to know they can expect a 60 percent or higher rate of
15 complications within five years.

16 Women who are facing revision after learning
17 their gel-filled implants have ruptured need to have
18 accurate complication rates should they choose to be
19 reimplanted with saline or with an additional gel-
20 filled implant.

21 I heard you vote*to eliminate the revision
22 category. If this is so, it is unacceptable. I heard

1 McGhan state that only women with prior implants with
2 leaf valves that fail are reimplanted with implants
3 with leaf valves. If leaf valves have an unacceptable
4 failure rate, they should be recalled by the FDA.

5 DR. WHALEN: Ms. Keeling, could you
6 conclude, please?

7 MS. KEELING: Yes. I have listed my
8 recommendations and I'll be glad if I don't have
9 additional time -- I've traveled here at great expense
10 and I hate that you don't have time to hear my
11 recommendations but I will give them to you in
12 writing.

13 DR. WHALEN: If another of the speakers is
14 willing to yield to you, we'll be happy to do so.

15 MS. KEELING: That's okay. I will -- I just
16 want to point out the Nuremberg Code states that women
17 and all individuals should have an informed consent
18 and that we have an extremely high failure rate. It's
19 now at 65,720 adverse reports to the FDLA alone on
20 saline filled implants. I thank you for listening to
21 my concerns and suggestions for improving consumer
22 protection. Thank you.

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1 DR. WHALEN: Thank you.

2 MS. BRINKMAN: I have a question.

3 DR. WHALEN: Ms. Brinkman.

4 MS. BRINKMAN: Ms. Keeling, I would like to
5 hear your indications or your comments, your
6 recommendations.

7 MS. KEELING: All right. Is that acceptable
8 to the panel?

9 DR. WHALEN: You mean you want to hear the
10 completion of her talk even though she's beyond her
11 time limit?

12 MS. BRINKMAN: I want to hear her list of
13 recommendations.

14 DR. WHALEN: Well, unfortunately she's
15 already exceeded her time limit. If someone else is
16 willing to exceed time to her, we can entertain it.

17 MS. BRINKMAN: Can I ask her that question
18 then, what is your list of recommendations?

19 DR. WHALEN: Please complete your talk.

20 MS. KEELING: Thank you. With regards to
21 product labeling, the IOM report states, "It seems
22 reasonable to conclude that both the physical and

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1 chemical characteristics of implants should be spelled
2 out clearly in product changes, introductions, and
3 investigations because they may influence patient
4 reactions and patient health.

5 My recommendations would be this: (1) A
6 complete list of all of the chemicals used in the
7 manufacture of breast prosthesis must be provided along
8 with material safety data sheets to the patient.
9 Chemical analysis of the elastomer shell including the
10 pageant valve must be provided. The identification of
11 releasible chemicals must be provided to identify
12 potentially toxic chemicals and estimate the upper
13 limits of the chemicals that could be released to the
14 patient.

15 (2) At the initial consultation a patient
16 must be given a copy of the current product insert,
17 current FDA breast implant information booklet,
18 current informed consent with any specific patient
19 contraindication, and view a video showing local
20 complications.

21 (3) At the time of surgery the physician
22 must complete and give to the patient an

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1 identification card with patient specific device
2 information and list of chemicals. The FDA must
3 mandate that every breast implant informed consent
4 include the statement, "The Food and Drug
5 Administration has not formally approved these devices
6 as safe and effective because the manufacture has not
7 provided the FDA adequate scientific evidence to prove
8 their safety and effectiveness if the device is not
9 approved."

10 Those are basically my recommendations.
11 Thank you.

12 MS. BRINKMAN: Thank you.

13 DR. WHALEN: Are there questions? Thank
14 you.

15 Next we'll hear from Ms. Diana Zuckerman
16 from the National Center for Policy Research for Women
17 and Families.

18 DR. ZUCKERMAN: The answer to the four
19 questions is no. I'm Dr. Diana Zuckerman. I'm the
20 Executive Director of the National Center for Policy
21 Research for Women and Families which is a nonprofit
22 organization dedicated to improving policies that

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1 affect the health and well being of women and
2 families.

3 Our mission is to translate complicated
4 research and medical information into usable
5 information that can be easily understood by the
6 public, the media, and policy makers. For this reason
7 and for other reasons of the work I've done in the
8 past, I'm particularly interested in informed consent
9 issues.

10 My interest goes back from when I was in
11 academia doing research at Harvard and Yale, to when
12 I was working in the House of Representatives in the
13 Senate, work on informed consent issues on federally
14 funded research, and in the nonprofit world where I've
15 been in the last few years.

16 I should also mention I'm writing some
17 articles, one in particular for a medical journal on
18 the issue of informed consent for breast cancer
19 patients.

20 I'm very concerned about the gap between
21 oral and written informed consent and that's something
22 that has been raised before and something that I think

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1 we need to talk about a lot. Obviously from listening
2 to the doctors who have testified here, the plastic
3 surgeons in particular, they are going to say how well
4 their patients are doing when they talk to new
5 patients. That's very understandable because I truly
6 believe that they would not be plastic surgeons if
7 they didn't think their patients were doing very well.

8 I don't think doctors are going to
9 intentionally harm their patients. I think they do
10 the procedures that they think are most effective and
11 they believe in the work that they do. Because they
12 believe in the work that they do, they are going to
13 tell their patients that.

14 They are going to tell their patients, "I've
15 never had a patient with an infection or one in the
16 last umpteen years." They are going to say, "My
17 patients are very satisfied." They are going to say,
18 "This is the procedure I would recommend to my wife or
19 my daughter." They believe it and it's true. It is
20 what they would recommend.

21 They might even say things like the
22 statement we heard earlier this morning, "You are

1 going to have more satisfying intimate relationships,"
2 even though I don't think we have heard any data to
3 that effect and I don't think that was the standard
4 used when you were voting on effectiveness yesterday
5 and the day before.

6 I don't know how you can control what
7 doctor's say but you certainly can try to help control
8 how much of that is based on data and how some kind of
9 recommendations about what they can say and what has
10 to be based on data rather than their own anecdotal
11 information.

12 I also ask you in your formulation in
13 deciding what you think needs to be done to really
14 listen to the patients. I am very concerned that
15 patients have spoken for five minutes each. Very few
16 questions have been asked. I have been talking to
17 patients about this issue for many years and I learn
18 something every single time.

19 Insurance is a very important issue for
20 these women. It may not be a medical issue *pe se* but
21 if a woman has a procedure that puts her in a position
22 that she cannot be insured for the rest of her life on

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1 anything, I'm not just talking about on issues related
2 to her breasts, that is a very, very serious piece of
3 information that she must have. It's not true, I
4 don't believe, of all insurance companies but it's
5 true of a surprising number of them.

6 Another thing I want to just mention because
7 of the work that I've done particularly with breast
8 cancer patients and also with implant patients is a
9 number of women that I have spoken to through the
10 years who have told me things like their doctors said
11 to them when they had fibrocystic breast disease,
12 which many of you know is not even a disease, or when
13 they had stage 1 breast cancer, or when they had a
14 noninvasive breast cancer and they were told, "Let's
15 be really careful. I recommend that you get a
16 mastectomy and then we'll get you breast implants and
17 you'll be better than new."

18 It's that kind of advice that I think we
19 really have to be concerned about, the gap between
20 what these women are being told and what the research
21 actually shows. That is particularly true for breast
22 cancer patients and that's actually something I'm

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1 focusing on. There is a whole research literature
2 published in major journals such as the New England
3 Journal of Medicine and JAMA talking about informed
4 consent issues for breast cancer patients and what
5 they are told about what their options are.

6 There is also, as we've heard the last two
7 days, quite a gap between how the manufacturers
8 understand their own data and how the FDA presented
9 it. I found that fascinating. It was like listening
10 to two different studies.

11 When you change the denominator, you change
12 everything. These are small changes but they make
13 tremendous difference as to what the results are. Who
14 determines what the results are and how that is
15 explained? I'm afraid that it should not be the
16 manufacturers. Obviously they have their own way of
17 looking at things but some of these are not issues of
18 opinion. They are issues of how you analyze data
19 statistically correctly. It has to be done correctly
20 but it also has to be explained in ways that patients
21 really can understand. **

22 I also think it's terribly important that

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1 because there are some negative consequences of these
2 kinds of surgeries that are incontrovertible. I'm
3 talking about some cosmetic problems of clearly that
4 there are some women, we don't know the numbers, who
5 end up looking a lot worse when their surgery is
6 over. I don't mean immediately after but down the
7 road look a lot worse than when they started.

8 I think there should be photographs in any
9 kind of informed consent document. A video tape would
10 be nice, too, but I think a booklet that is clear,
11 easy to understand, with photographs not just of what
12 can look good but of what some of the negative
13 consequences can be. I think that is very important.

14 I think it's also very important that you
15 all understand and that the patients understand that
16 to some extent implant surgery, any kind of implant
17 surgery makes changes that are permanent. If a women
18 gets breast implants tomorrow and she wants them taken
19 out later, her breasts will have already changed. You
20 can't just put them in and take them out and expect to
21 look the same afterwards. ~~Eve~~ If you have no problems
22 you're not going to look the same.

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1 Women have to understand that and it's
2 particularly hard, I think, when you're 18 and
3 thinking about it. They have to understand the
4 irrevocable nature of surgery, that certain changes
5 are going to be made and you can't change back again.
6 Even if you think there are -- even if you think the
7 risks are not great, there still are risks and they
8 have to understand what those risks are and they have
9 to understand that you can never go back to exactly
10 where you were to begin with.

11 I've talked to many women who had
12 augmentation who started out with small breasts and by
13 the time their implants were taken out for the second
14 or third set, they ended up with almost no breast
15 tissue at all.

16 The last thing I want to focus on, which I
17 mentioned in earlier testimony, has to do with what do
18 we know or what don't we know about systemic disease.
19 I agree that there is no conclusive evidence that
20 breast implants cause systemic disease, but I don't
21 agree with the statements that there is evidence that
22 they don't cause systemic disease. I was disappointed

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1 and surprised that it seemed that one of the
2 assumptions of this panel to start with was that we
3 are not going to talk about systemic disease because
4 we don't think that breast implants cause systemic
5 disease.

6 As I mentioned in the handout that I gave
7 you what seems like a year ago but might have been a
8 day or two ago, if you look at all the major studies
9 of connective tissue disease, all the epi studies, the
10 ones that are talked about by the Institute of
11 Medicine and they are talked about by Marcia Angel and
12 they are talked about by all the experts on this,
13 there are 17 studies that are most widely quoted and
14 only one of them separately analyzes women with saline
15 implants. Only one.

16 By the way, that's also the only study that
17 looks at mastectomy patients with saline implants
18 separately. We have almost no information about
19 reconstruction patients and we have no separate
20 analysis of saline implants. Let me say what that
21 means. That means that many of the studies have no
22 women with saline implants.

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1 The other studies have mostly women with
2 silicone gel implants and a very small number with
3 saline implants. Guess what? When they analyze them,
4 this is what they do. First they analyze them all
5 together and so you have saline implants, maybe 5 or
6 10 percent of the population, clearly not much
7 information, and then they analyze them separately
8 looking only at silicone gel. Those are what the
9 analyses are. There are no analyses of the saline
10 except in one study.

11 I also mentioned before, and I want to
12 reiterate, the NIH is doing studies. NCI is actually
13 doing studies on systemic disease. They are doing a
14 study of 13,000 implant patients. That does include
15 saline, although again it's a minority. They are
16 looking at breast cancer, other cancers, and
17 connective tissue disease. FDA needs to look at those
18 studies. They are not published yet.

19 There is a scientific advisory committee.
20 I happen to be on it so I can tell you that some of
21 those data are written up but they are not published
22 yet but I'm assuming that they would be available to

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1 FDA since they are coauthored by an FDA employee.

2 In closing, since I'm seeing the red light,
3 I just want to say that I think it's terribly
4 important that in informed consent women be told what
5 is known and what is not known. That's what I spend
6 all my time doing. It's not enough just to say we
7 don't have evidence of something.

8 If there is no research on it, or course
9 there is no evidence on it. We can't say it's there
10 but we can't say it's not there. Specifically with
11 systemic diseases but also even with the prevalence
12 and incidence of some of these local complications.

13 DR. WHALEN: Dr. Burkhardt.

14 DR. BURKHARDT: I have a question. Thank
15 you very much. I enjoyed that. What kind of study
16 would you use to convince yourself personally that
17 breast implants, either gel or saline, do not cause
18 systemic illness? What kind of study would be
19 acceptable to you?

20 DR. ZUCKERMAN: Of course, we would all
21 prefer perspective study bttt there are problems with
22 perspective studies. I mean, it would be really nice

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1 to start out with the women who just got implants
2 recently and follow them for as many years as
3 possible. The disadvantage, of course, is it takes
4 longer and --

5 DR. BURKHARDT: And if they get ill, how
6 would you know that was or was not related to their
7 implants?

8 DR. ZUCKERMAN: Well, that's the nature of
9 research. You have a control group.

10 DR. BURKHARDT: I guess that's what I'm
11 asking you because it's been done with control groups,
12 as you know.

13 DR. ZUCKERMAN: You would have to have -- I
14 mean, obviously this is not a double-blind study. We
15 know that. There are a couple of things you could do.
16 First of all, you could have comparison samples of
17 women of the same age and health status, and probably
18 socioeconomic status and whatever else you think
19 influences health, and follow those women over time as
20 well.

21 One of the terribly important things that
22 seems to be missing from all the manufactures studies

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1 is that you would have the person determining their
2 health status not be their practicing physician, not
3 be their plastic surgeon.

4 DR. BURKHARDT: Who would you recommend?

5 DR. ZUCKERMAN: Any other doctor who has no
6 conflict of interest financially. I mean, somebody
7 who would be paid to do that as part of the study. If
8 you were doing retrospective studies, which I think is
9 obviously a quicker way to do things, and that is what
10 was done with the NCI study, then you do to some
11 extent what NCI did which is you identify patients.

12 They identified the patients through the
13 doctors, not through the lawyers as some people have
14 charged. You identify the patients through the
15 doctors. You get the records for all the patients
16 they have seen. You have to do very aggressive
17 follow-up to find out where they are now because who
18 knows whether the doctor has seen them in the last few
19 years.

20 You have follow-up done through medical
21 exams -- through medical exams by doctors who are not
22 -- they can't be blind, I don't think, but they can be

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1 at least not paid by anybody, not have any kind of
2 financial conflict of interest of finding or not
3 finding whether a women has a particular illness.

4 The other thing that I would really like to
5 see is that those medical exams cover a wide variety
6 of diagnoses and symptoms and not just rare disease
7 like scleroderma.

8 DR. BURKHARDT: Thank you.

9 DR. WHALEN: Ms. Brinkman.

10 MS. BRINKMAN: Dr. Zuckerman, you have given
11 us a lot of information on what you feel needs to be
12 in a product. We're talking about informed consent.
13 I think that developing the product will be relatively
14 easy compared to developing the process. What are
15 some of your thoughts and recommendations on the
16 process?

17 DR. ZUCKERMAN: I'm glad you asked that
18 because I had meant to talk about it and I forgot. I
19 ran out of time anyway. I actually just very recently
20 was talking to Joan Pitkin who is a state legislature
21 in Maryland. She was instrumental. I had never met
22 her before. We had talked on the phone years ago.

1 She was instrumental in passing an informed consent
2 law on breast implants in Maryland. I asked her what
3 she thought.

4 I saw her just a few months ago and she said
5 it was a total waste of time. She said that the law
6 passed but the doctors didn't use the brochure. They
7 developed a very good brochure. She said, "I've
8 actually never seen it." She said the problem was the
9 doctors wouldn't distribute it and even if they did
10 distribute it, she wasn't at all sure what they were
11 saying that would negate what was in it.

12 Let me also say in informed consent issues
13 with breast cancer patients there was a study recently
14 that was published, I think in the New England Journal
15 but I'm not sure, that talked about informed consent
16 laws that women newly diagnosed with breast cancer be
17 given a pamphlet about lumpectomy and mastectomy and
18 what other options they have.

19 What they found in the study was that there
20 was an initial increase in women getting lumpectomies
21 which decreased quite rapidly and a year or so later
22 the numbers were exactly the same as before so there

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1 was a sense that they had in that research that the
2 doctors were basically initially being a little bit
3 more careful and cautious about providing all the
4 information but that ultimately women are making
5 decisions based on what their doctors tell them.

6 I'm not sure I'm answering your question.
7 I'm agreeing with you how difficult it is. That's one
8 of the reasons why I think a picture is worth -- not
9 to be trite here -- a picture is worth a thousand
10 words.

11 If you have a booklet that has some woman
12 who has serious breast deformities as a result of her
13 implants, even though it should be explained that this
14 may not be a common occurrence, I think that goes a
15 long way in protecting women to at least get them
16 engaged in this process and to get them to understand
17 that there are real risks involved that I think no
18 amount of words written on a page is going to convey.

19 I also, of course, would like to see some
20 kind of monitoring by some outside group in terms of
21 what the doctors actually are saying. If you ask the
22 patients they will tell you -- oh, let me just say, I

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1 met with some breast cancer activists a couple of
2 weeks ago. These were women who were not particularly
3 interested in the implant issue.

4 I was just talking to them about their
5 experiences and every single one of them thought that
6 saline breast implants were FDA approved and perfectly
7 safe. Not only that, but -- I mean, these are
8 activists. These were people who had come to
9 Washington for a federally funded couple-of-day
10 conference. These are not your typical people so they
11 knew a lot. Several of them had saline implants.
12 They were just shocked to learn they had never been
13 FDA approved.

14 They had been told from the get go that
15 these were approved and perfectly safety. Again, that
16 gets into this issue. It's not just the women who are
17 now unhappy saying, "Oh, nobody ever told me." That's
18 my point here. It's all the women that I've talked to
19 whether they were happy or unhappy and they are
20 telling me the same thing.

21 DR. WHALEN: Thank you.

22 Next we'll hear from Ann Stansell from the

1 United Silicone Survivors -- I'm sorry. I'm sorry.
2 Martha Murdock is next, National Silicone/Saline
3 Implant Foundation.

4 MS. MURDOCK: My name is Martha Murdock and
5 I am the founder of the National Silicone/Saline
6 Implant Foundation. We support survivors of medical
7 implant devices. I am not compensated or retained by
8 industry or anyone else. I did pay my own way to this
9 meeting. I am in litigation with one of the
10 manufacturers.

11 That's all I have to tell you about me, that
12 I'm from Texas. I guess you can tell that.

13 Society force feeds both females and males
14 a definition of a beautiful body. Beautiful young
15 women grace the covers of magazines that line the
16 supermarket checkout standards and these images serve
17 as the source of shame for those staring down at a bag
18 of cookies sitting right there front and center in the
19 grocery cart.

20 On the other hand, consider what you see is
21 not what you always get when you're looking at the
22 fronts of those magazines. Advertisers paint a

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1 prettier picture than reality often times guarantees.

2 Ladies and gentlemen, your body is unique.

3 It will carry you through every season of life so why

4 not take care of it? Taking care of your body is

5 similar to taking care of your car. For your car to

6 run properly you must put gas in the tank and oil in

7 the engine. The same is true for your body.

8 I for one am tired of having my body used as

9 a guinea pig because that's exactly what they have

10 done. They have used the women to do their

11 experiments on. I don't know why they don't use the

12 women to do the research on.

13 I would like to discuss some informed

14 consent issues to be considered. The manufacturers of

15 saline breast implants claim that women who get saline

16 breast implants get informed consent prior to their

17 surgical procedure. How can a woman truly give

18 informed consent if she is not provided with all the

19 information that the manufacturers knew about their

20 products? The manufacturers cannot do this because

21 they continue to deny all they know.

22 Rarely ever does a surgeon tell a patient

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1 these medical devices have never been approved by the
2 FDA. There are numerous reports of silicone shells
3 filled with medicogrates, isotonic saline causing
4 autoimmune and other diseases. All implants leak
5 because the silicone shells are porous.

6 The silicone shell will slough off silicone
7 particles which may migrate throughout the body and
8 lodge in your major organs. The implant manufacturer
9 who previously advertised implants would last a
10 lifetime actually knew at that time they would fall
11 apart in five years. The manufacturers of saline-
12 filled breast implants still have never tested their
13 products to determine if there would be long-term
14 health risks prior to putting their new implants on
15 the market.

16 Any patients nightmare is just beginning
17 when they decide to take the chance of having saline
18 implants in their body. Within a short time of
19 receiving implants, a formerly healthy individual may
20 begin to have strange and unexplained medical
21 problems. One day that patient's doctor writes in
22 this patient's report that the patient has many

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1 illnesses. He also makes a note that this patient has
2 saline implants.

3 The result of that, bingo. No more life
4 insurance. No more health insurance. No more
5 insurance ever. No one told that patient that within
6 two years they would never be able to get any kind of
7 life or medical insurance. I worked in the industry
8 and as an assistant to the group actuary and I know
9 they have the statistics. Why do not the other
10 manufacturers and industry representatives?

11 Manufacturers of saline-filled breast
12 implants claim that patients who get saline implants
13 are provided package inserts prior to their surgical
14 procedures. I personally never saw one. I can't find
15 a friend that ever saw one of any kind. Furthermore,
16 how can a patient truly give informed consent if they
17 are not provided with all the information the
18 manufacturer knows about these products.

19 Do those patients have the right to receive
20 this information? My answer is absolutely yes. Do
21 they have the right to destroy their body in making
22 their decision? I guess they do. I wouldn't.

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1 If any patient is told the truth that saline
2 implants were never tested and determined to be safe
3 for long-term human implantation, the implants would
4 leak saline into your body from the implant shell and
5 could travel to all your major organs and on and on
6 the same thing, but they don't tell their patients
7 these things.

8 What is wrong with hundreds of thousands of
9 women whose only common denominator is a silicone
10 envelope filled with a saline solution as an implant?
11 On one hand the manufacturers claim saline breast
12 implants are safe and do not cause health problems.
13 They claim these women have illnesses that don't exist
14 diagnosed by greedy doctors taking advantage of a
15 valid concern that this untested product might be the
16 cause, or at least a contributor to the medical
17 problems the women are experiencing.

18 Could thousands of doctors treating hundreds
19 of thousands of women for the same illness or the same
20 symptoms or similar problems be that wrong? Could
21 laboratories all over the country testing and
22 evaluating the blood and specimens from these women be

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1 manipulating and orchestrating the test results so it
2 appears these women have illnesses that don't exist?
3 Or is it more likely than not the breast implant
4 manufacturers have another reason to promote the
5 fallacy of the illness that doesn't exist?

6 Reasonable minds would wonder. If a
7 silicone shell filled with isotonic saline breast
8 implants are truly safe and do not cause health
9 problems, why is the same insurance company insuring
10 the saline implant manufacturers and then refusing to
11 pay health claims of women with breast implants? If
12 saline implants are safe, why did the manufacturers
13 only begin testing once the silicone implants were
14 pulled off the market and restrained to only a few?

15 Do the insurance companies know something
16 that we don't know? You bet they do. They have all
17 the information in one form or another. If the
18 members of this committee are sincerely looking for
19 the truth, ask yourself how can so many women have an
20 illness that doesn't exist which can be diagnosed,
21 quantified, qualified, by scientists, epidemiologists,
22 and researchers, not to mention the treating

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1 permission or the authorization or the consenting
2 form, I don't think any women will have a silicone or
3 saline breast implant in their body.

4 DR. WHALEN: Dr. Puszkin, forgive me, but
5 could you answer the four questions?

6 DR. PUSZKIN: I'm answering in the slide.
7 Okay. I'm Dr. Saul Puszkin and I'm affiliated with
8 Columbia University. I have my private laboratory of
9 the Health Sciences Consultant Group. I am involved
10 in the litigation on the side of the patients who had
11 breast implants or their relatives. Some of the
12 lawyers hired me to testify about what I find in the
13 pathology of these patients. I do not -- the expenses
14 were paid by the laboratory. I do have income from
15 some of the pathology I do.

16 Okay. I don't know what you heard in the
17 last three days but very briefly this is the mammary
18 gland. It's a very sensitive area. During my years
19 as Professor of Pathology and Molecular and Cellular
20 Pathology at Mt. Sinai I worked with latex particles
21 injecting them in the mammary gland of animals.

22 I found it exquisitely sensitive and very

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1 highly immunogenic in the sense of responding
2 immunogenically to latex particles. Silicone became
3 another agent and I understand there are publications
4 saying that silicone gel is immunogenic.

5 We are dealing now with saline implant which
6 is coated by an elastomer made of silicone
7 polydimethylsiloxane. When you put that implant in
8 the body of a lady, after a short while a very thick
9 scar is formed and when the implant is removed either
10 by leakage or other complications, contractures,
11 calcifications, inflammation, and infection, this is
12 the result of that surgery.

13 This is what I get in the laboratory and
14 have worked with over 2,700 patients, analyzed over a
15 similar number of implants, and about 20 percent of
16 them were saline. My experience is over 500 pair of
17 implants of saline that came to the lab to be analyzed
18 by me and find out the complications they had.

19 Now, very briefly. I don't know if you can
20 see. These are my statements. Polydimethylsiloxane
21 makes the elastomer which is a chemical which
22 crosslink and have holes or pores just like a blood

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1 vessel. It has gaps in its structure so things can
2 penetrate either in or out.

3
4 There are ethyl bridges which I don't have
5 to tell you too much. I'm sure if you're on the panel
6 you are highly qualified. I see several Ph.Ds with
7 your names there. The rigidity is due to the number
8 of crosslinks. If you will have a very little
9 crosslinked polydimethylsiloxane network, we will have
10 a gel. If we have it highly crosslinked, we are going
11 to have a rubber type material. That's the one that
12 is being used in the elastomer.

13 My concern is that at the bottom field
14 studies analyze silicone stability to cellular
15 reactive molecules. In the three minutes that I have
16 left, or 3½, I'm going to try to convey to you this
17 impression from a scientific and from my professional
18 and background experience.

19 This is a structure. Assuming this model --
20 I copy it from a cartoon used to teach extracellular
21 matrix which is very similar to the one that we have
22 in the elastomer shell. These are the linear

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1 molecules that are crosslinked by ethyl bridges but
2 there are large gaps so if this is elastomer, things
3 can move from the saline compartment out, or things
4 can move from the tissue compartment into the implant
5 and there is migration.

6 Cellular migration hides the flexibility,
7 especially macrophages which are able to migrate into
8 bone structure. Imagine that they can find themselves
9 into the implant, especially when they see such a
10 large body implanted in a very sensitive area to which
11 they come in response to all kinds of chemical
12 stimuli.

13 Inside a saline implant we have all kinds of
14 materials form in there. These are the walls. This
15 is high magnification, about 5,000 times magnified, of
16 the content of saline after a year in the body. These
17 are the walls of the macrophages and other kind of fat
18 cells that have been able to infiltrate the implant.
19 They become trapped in the saline and they become a
20 good source of decay and a good source of -- just to
21 proliferate in there and decay and to transform
22 themselves.

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1 Several materials are formed. This is a
2 kind of web-like organic material crystals that are
3 formed from the reaction of the saline with the
4 elastomer shell.

5 There are micro organisms that sometimes
6 find themselves inside. This is an amoeba found in one
7 of the implants.

8 This is a large magnification.

9 These are all kinds of precipitates from the
10 macrophage chemicals that have formed with the
11 reaction of the saline and the salt that has been
12 released from the elastomer shell.

13 These are the particles of elastomer shell,
14 the silicone, that have been released from the implant
15 surface and found their way into the tissue.

16 And then you form granulomas in there. This
17 is a granuloma. This is highly reactive surrounded by
18 lymphocyte and they are trying to fight, to fend off
19 this kind of an offense forming a reaction that the
20 body, the tissue react against these implant.

21 I think I'm coming close to the next slide,
22 or the last few slides. I apologize for the excess of

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1 time.

2 DR. WHALEN: We need to have you conclude.

3

4 DR. PUSZKIN: Okay. I can answer more
5 questions. So my opinion is that the saline implants
6 do have to have, if they are going to be ever used, an
7 expiration date. The patient should know that this
8 expires. Like saline when we have a bag and we have
9 an infusion they have an expiration date. If they are
10 in the body and they are warm and they are subjected
11 to all kinds of movement, this material will decay and
12 it will fail and it will require multiple surgeries.
13 I don't think that this is a very good product. Thank
14 you.

15 DR. WHALEN: Thank you.

16 DR. BURKHARDT: I have a question.

17 DR. WHALEN: Dr. Burkhardt.

18 DR. BURKHARDT: Dr. Puzskin, have you
19 published your material and is it available to us from
20 a peer review journal?

21 DR. PUSZKIN: Yes. It has been published in
22 the Journal of Clinical Pathology. It's not easy to

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1 publish kind of adverse material to silicone breast
2 implant in the United States so this is an
3 international journal published in Argentina which is
4 my mother country. I have been invited teach there
5 because Argentina is a haven for implantation.

6 DR. BURKHARDT: You've answered my question,
7 sir. Thank you very much.

8 DR. PUSZKIN: Yes, I do. I'll send it to
9 you without even a request.

10 DR. WHALEN: Thank you.

11 Next we'll hear from Dr. Britta Ostermeyer.

12 DR. OSTERMEYER SHOAI B: Good morning and
13 thank you very much for the opportunity. I am a
14 physician trained in neurology and I helped treating
15 patients who had local and systemic problems from
16 silicone breast implants for eight years in Houston,
17 Texas. I have since moved on and started to train in
18 a second specialty. I'm currently a resident in
19 psychiatry at Columbia University in New York City.

20 I paid my own way to come here and I
21 testified as a treating physician on my patients'
22 behalf in the past. I have no relationships to

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1 manufacturers and I do not derive any income out of
2 breast implants.

3 I would like to show you a small slide
4 presentation and then give you my thoughts and
5 conclusions. Among the women with breast implants
6 that I have treated there was a subpopulation of women
7 who only received saline implants and these patients
8 had presented to us with local and systemic problems
9 after they had received saline implants.

10 This is an overview of the problems they
11 reported to us. These women were healthy previously.
12 They had no other medical problems and since they had
13 a combination out of these problems that was similar
14 in the women that we saw and there was no other cause,
15 we strongly felt after several years of research and
16 seeing these patients that there might be a cause or
17 link between receiving the medical device and getting
18 these symptoms.

19 I'm showing you some pictures of patients
20 that I have seen. You are supposed to see a reddish
21 rash in the lower extremities. This is a lady who had
22 saline implants and developed vasculitis which is

1 inflammation in her blood vessels. She had strokes in
2 the brain and she developed a gangrene and as a result
3 her little pinky had to be amputated.

4 This lady had saline breast implants only
5 and also had systemic autoimmune disease which is
6 Lupus like and those are her skin rashes.

7 This lady had saline implants, also systemic
8 inflammatory responses, and those are her skin rashes.

9 This is a spec scan which shows how the
10 blood flow in the brain is distributed and we found
11 findings similar of those seem in Alzheimer's and
12 women with systemic illness.

13 We measured autoantibodies which is an
14 objective indicator of systemic inflammatory responses
15 and there were lots of findings.

16 We also did sural nerve and muscle biopsies
17 and had a high number of abnormalities. This is a
18 sural nerve. You are supposed to see fibers all over
19 the picture and you see gaps because this nerve had
20 lost fibers due to inflammatory reactions.

21 The implant capsule was examined from women
22 who had saline implants showed silicone in the

1 surroundings. The surrounding chest wall muscle was
2 biopsied and showed abnormalities and also showed
3 silicone and chronic inflammatory reactions in the
4 surrounding of the implant.

5 My conclusions are that saline implants can
6 evoke systemic and local inflammatory responses.
7 There are objective abnormalities and I believe that
8 more data needs to be collected about saline implants.

9 My conclusions are that patients need to be
10 aware of the risk of local injury as well as local
11 inflammatory responses that can be very painful and
12 can cause chest pain. There is a risk of systemic
13 injury and especially in those women who already have
14 an underlying autoimmune tendency, these women are at
15 higher likelihood of developing systemic problems.

16 I think it's important that surgeons make
17 sure to their patients that they do understand that
18 breast implants including saline implants don't fix a
19 long list of psychological and psychiatric problems
20 including body image problems, depression, anxiety,
21 and marital problems.

22 Surgeons should explore the patient's

1 expectations about the surgery and emphasize that
2 surgery may not solve their problems and that, as a
3 matter of fact, adverse effects may take place.

4 My last thing is about a comment on the
5 insurance situation. There was a patient earlier you
6 said that she couldn't receive medical insurance
7 anymore. My experience over eight years is that
8 either patients are excluded from coverage if the
9 disease that they encountered is a result of breast
10 implants.

11 Once the women are labeled or diagnosed with
12 a problem related to implants, they can no longer
13 receive medical coverage. If they lose their old
14 coverage and they want to obtain new medical
15 insurance, it's a problem because once you are ill
16 with them, you continue medical care and the insurance
17 companies know that. Thank you so much.

18 DR. WHALEN: Thank you. Seeing no
19 questions, we'll take a 10-minute break and then
20 reconvene. Thank you.

21 (Whereupon, at 10:10 a.m. off the record
22 until 10:25 a.m.)

1 DR. WHALEN: Thank you. We'll resume. We
2 are now going to proceed to testimony from those
3 representing consumer groups and consumer information
4 providers so each of these speakers are allotted if
5 they need it 10 minutes. The first to address us is
6 Ms. Marlene Keeling of the Chemically Associated
7 Neurological Disorders.

8 MS. KEELING: My name is Marlene Keeling.
9 My airfare was paid for by Chemically Associated
10 Neurological Disorders but I am paying for my other
11 expenses. I settled my private lawsuit in 1996
12 against the manufacturer who made my defective
13 implants. Because I feel so strongly I have dedicated
14 my small settlement to addressing patient information,
15 informed consent, and product liability labeling
16 issues.

17 I did not receive informed consent in 1978
18 and women still are not receiving true informed
19 consent today. The present informed consent appears
20 to be primarily written to allow the manufacturers to
21 escape legal liability. I will attempt to give as
22 many examples as possible within the 15 minutes I have

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1 been allotted.

2 Failure, rupture, and reoperation rates,
3 what the product insert says. Patients should be
4 advised that their implants may deflate, result in
5 asymmetry and require replacement surgery.

6 Improvements in design, manufacture, and
7 surgical techniques have contributed to lower rates of
8 deflation reported in the most recent studies. In
9 these studies that they referred to was in 1988 and
10 1990.

11 Our breast implants may not last a lifetime.
12 Our product history indicates an overall reported
13 average rupture rate of approximately 1 percent. The
14 FDA estimates that rupture rates are generally between
15 1 to 4 percent. What the informed consent says,
16 "Breasts implants may not last a lifetime."

17 What the Institute of Medicine report of
18 July '99 says, "Several studies have addressed the
19 frequency of reoperations after implantation with both
20 saline and gel-filled implants." The Mayo study
21 reported a 23.8 percent rate after 7.8 years of
22 follow-up. It appears that a significant number of

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1 women can expect additional procedures in the first
2 five years after implantation.

3 Local complications. What the product
4 insert says. "Improvement in device design and
5 surgical techniques have contributed to declining
6 rates of capsular contracture. The current risk of
7 clinically significant capsular contracture is low.
8 Acute infection around breast implants occur
9 frequently after augmentation with slightly higher
10 rates associated with reconstruction.

11 Extrusion has been reported as an infrequent
12 complication. Breast implants may complicate the
13 interpretation of mammography images by obscuring some
14 underlying breast tissue. Calcification is rare.
15 Chest wall deformity has been reported in rare cases."

16 What the informed consent says. "Several
17 surveys have shown that over 90 percent of women are
18 pleased with the results. Complications are uncommon.
19 Calcium deposits are benign and cause no problems. If
20 the envelope containing the saline portion breaks, the
21 saline is absorbed harmlessly by the body within
22 hours.

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1 Since the breast is compressed during
2 mammography it is possible but rare for an implant to
3 rupture. Very rarely the implant may change positions
4 or break through the skin. Many women with breast
5 implants have nursed their babies successfully."

6 What the IOM report says. "The committee
7 concluded local complications occur frequently and are
8 the primary safety issue. Among the others these
9 include overall reoperations, rupture or deflations,
10 contractures, infections, hematomas and pain. Based
11 on the review of the current research, women can
12 expect early postoperative complications after
13 reconstruction with implants by 30 to 40 percent.

14 The IOM concluded published reports of
15 patient satisfaction might be misleading because most
16 surveys are carried out by plastic surgeons and before
17 the likely appearance of some complications. Saline
18 implants are more prone to wrinkling, fold flaws,
19 surface abrasion, and consequent deflation.

20 In reconstructed patients skin wrinkling has
21 been reported to occur in^{as} many as 26 percent of
22 cases. The committee concluded that modern first-year

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1 deflations of saline implants might be in the order of
2 1 to 3 percent and this percentage would rise closely
3 with time.

4 Microscopic calcification has been reported
5 in 10 to 33 percent of capsules. It can occasionally
6 be severe causing pressure atrophy of breast and
7 underlying muscle tissue. Gram positive bacteria are
8 often located in a bioslime film on the surface of the
9 implant where they are largely protected by antibiotic
10 action and they presumably contribute to infections."

11 The McGhan LST found 1.1 and 6.9 percent of
12 breasts with infections after saline augmentation.
13 Implants themselves, implant pockets or capsules and
14 nipple secretions have yielded 23.5 to 89 percent
15 positive bacteria cultures.

16 Dow in '94 suggest that the presence of
17 subclinical infection or contaminations may contribute
18 to systemic signs of symptoms such as fatigue,
19 myalgia, arthralgia, and diarrhea among others.
20 Hematoma was the indication for reoperation in 3.5
21 percent in the Mayo series*. The experience of one
22 plastic research clinic, 5 to 10.3 percent of patients

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1 were reoperated for hematoma.

2 The aggregate figures for contracture in
3 published research on saline implanted women is 40.5
4 percent. Capsule formation, especially under the
5 muscles, may result in nerve compression and pain.
6 Usually pain with late onset 8 percent and 30 percent
7 of reconstruction and augmentation patients
8 respectively represent contracture pain.

9 As Wallace in '96 discussed, pain like
10 sensory change, which is of similar frequency, is not
11 surprising given the damage to the nerves, to the
12 breast and nipple during implantation and
13 reconstruction surgery. See values of 41.6 percent
14 permanent nipple sensory changes, 41 percent Hetter
15 '79, 18 percent decrease in sensation Hetter '91,
16 nerve damage and paresis 1990, and partial to complete
17 sensory loss in the nipple of 70 percent and in the
18 whole breast of 12 percent after augmentation.
19 Whether silicone from the degrading shell crosses the
20 placenta has not been evaluated in women.

21 Surgery with an incision around the nipple
22 was almost five times more likely to be associated

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1 with insufficient milk production. About 30 percent
2 of breast implant augmentations are carried out
3 through an incision around the nipple. The frequency
4 of lactation insufficiency was slightly increased in
5 women with implants, 64 percent compared to women
6 without implants 7 percent.

7 Another small study of women with saline
8 implants found 39 percent reported breast feeding
9 problems. Data on whether cancer detection is
10 impaired by implants do not allow definite conclusion,
11 although it is clear that implants do interfere with
12 screening mammography by obscuring a variable part of
13 breast tissue, distorting breast architecture, and
14 especially in the presence of firm contractures, which
15 remember happens in a high percent of cases, makes a
16 proper examination with proper compression of the
17 breast more difficult and occasionally impossible.

18 All of the above information from the IOM
19 report with percent of risk is the type of information
20 necessary for a woman to make informed choice or give
21 her informed consent. **

22 Listed under risks in the informed consent

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1 is toxic shock syndrome. According to recent research
2 1999 there has been a rise in the number of
3 nonmenstrual cases of toxic shock syndrome based on
4 data compiled 1979-1996 perhaps related to a
5 substantial increase in prosthetic devices and
6 postoperative infections since 1980.

7 What is the percent of risk of this
8 potentially fatal condition? In the last few days I
9 have heard percentage of risk of local complications
10 that are startling high. Breast cancer survivors need
11 to know they can expect a 95.2 percent complication
12 rate in five years. Young women of childbearing age
13 in their 20s choosing implants for augmentation need
14 to know they can expect a 60 percent or higher rate of
15 complications within five years.

16 Women who are facing revision after learning
17 their gel-filled implants have ruptured need to have
18 accurate complication rates should they choose to be
19 reimplanted with saline or with an additional gel-
20 filled implant.

21 I heard you vote*to eliminate the revision
22 category. If this is so, it is unacceptable. I heard

1 McGhan state that only women with prior implants with
2 leaf valves that fail are reimplanted with implants
3 with leaf valves. If leaf valves have an unacceptable
4 failure rate, they should be recalled by the FDA.

5 DR. WHALEN: Ms. Keeling, could you
6 conclude, please?

7 MS. KEELING: Yes. I have listed my
8 recommendations and I'll be glad if I don't have
9 additional time -- I've traveled here at great expense
10 and I hate that you don't have time to hear my
11 recommendations but I will give them to you in
12 writing.

13 DR. WHALEN: If another of the speakers is
14 willing to yield to you, we'll be happy to do so.

15 MS. KEELING: That's okay. I will -- I just
16 want to point out the Nuremberg Code states that women
17 and all individuals should have an informed consent
18 and that we have an extremely high failure rate. It's
19 now at 65,720 adverse reports to the FDLA alone on
20 saline filled implants. I thank you for listening to
21 my concerns and suggestions for improving consumer
22 protection. Thank you.

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1 DR. WHALEN: Thank you.

2 MS. BRINKMAN: I have a question.

3 DR. WHALEN: Ms. Brinkman.

4 MS. BRINKMAN: Ms. Keeling, I would like to
5 hear your indications or your comments, your
6 recommendations.

7 MS. KEELING: All right. Is that acceptable
8 to the panel?

9 DR. WHALEN: You mean you want to hear the
10 completion of her talk even though she's beyond her
11 time limit?

12 MS. BRINKMAN: I want to hear her list of
13 recommendations.

14 DR. WHALEN: Well, unfortunately she's
15 already exceeded her time limit. If someone else is
16 willing to exceed time to her, we can entertain it.

17 MS. BRINKMAN: Can I ask her that question
18 then, what is your list of recommendations?

19 DR. WHALEN: Please complete your talk.

20 MS. KEELING: Thank you. With regards to
21 product labeling, the IOM report states, "It seems
22 reasonable to conclude that both the physical and

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1 chemical characteristics of implants should be spelled
2 out clearly in product changes, introductions, and
3 investigations because they may influence patient
4 reactions and patient health.

5 My recommendations would be this: (1) A
6 complete list of all of the chemicals used in the
7 manufacture of breast prosthesis must be provided along
8 with material safety data sheets to the patient.
9 Chemical analysis of the elastomer shell including the
10 pageant valve must be provided. The identification of
11 releasible chemicals must be provided to identify
12 potentially toxic chemicals and estimate the upper
13 limits of the chemicals that could be released to the
14 patient.

15 (2) At the initial consultation a patient
16 must be given a copy of the current product insert,
17 current FDA breast implant information booklet,
18 current informed consent with any specific patient
19 contraindication, and view a video showing local
20 complications.

21 (3) At the time of surgery the physician
22 must complete and give to the patient an

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1 identification card with patient specific device
2 information and list of chemicals. The FDA must
3 mandate that every breast implant informed consent
4 include the statement, "The Food and Drug
5 Administration has not formally approved these devices
6 as safe and effective because the manufacture has not
7 provided the FDA adequate scientific evidence to prove
8 their safety and effectiveness if the device is not
9 approved."

10 Those are basically my recommendations.
11 Thank you.

12 MS. BRINKMAN: Thank you.

13 DR. WHALEN: Are there questions? Thank
14 you.

15 Next we'll hear from Ms. Diana Zuckerman
16 from the National Center for Policy Research for Women
17 and Families.

18 DR. ZUCKERMAN: The answer to the four
19 questions is no. I'm Dr. Diana Zuckerman. I'm the
20 Executive Director of the National Center for Policy
21 Research for Women and Families which is a nonprofit
22 organization dedicated to improving policies that

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1 affect the health and well being of women and
2 families.

3 Our mission is to translate complicated
4 research and medical information into usable
5 information that can be easily understood by the
6 public, the media, and policy makers. For this reason
7 and for other reasons of the work I've done in the
8 past, I'm particularly interested in informed consent
9 issues.

10 My interest goes back from when I was in
11 academia doing research at Harvard and Yale, to when
12 I was working in the House of Representatives in the
13 Senate, work on informed consent issues on federally
14 funded research, and in the nonprofit world where I've
15 been in the last few years.

16 I should also mention I'm writing some
17 articles, one in particular for a medical journal on
18 the issue of informed consent for breast cancer
19 patients.

20 I'm very concerned about the gap between
21 oral and written informed consent and that's something
22 that has been raised before and something that I think

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1 we need to talk about a lot. Obviously from listening
2 to the doctors who have testified here, the plastic
3 surgeons in particular, they are going to say how well
4 their patients are doing when they talk to new
5 patients. That's very understandable because I truly
6 believe that they would not be plastic surgeons if
7 they didn't think their patients were doing very well.

8 I don't think doctors are going to
9 intentionally harm their patients. I think they do
10 the procedures that they think are most effective and
11 they believe in the work that they do. Because they
12 believe in the work that they do, they are going to
13 tell their patients that.

14 They are going to tell their patients, "I've
15 never had a patient with an infection or one in the
16 last umpteen years." They are going to say, "My
17 patients are very satisfied." They are going to say,
18 "This is the procedure I would recommend to my wife or
19 my daughter." They believe it and it's true. It is
20 what they would recommend.

21 They might even say things like the
22 statement we heard earlier this morning, "You are

1 going to have more satisfying intimate relationships,"
2 even though I don't think we have heard any data to
3 that effect and I don't think that was the standard
4 used when you were voting on effectiveness yesterday
5 and the day before.

6 I don't know how you can control what
7 doctor's say but you certainly can try to help control
8 how much of that is based on data and how some kind of
9 recommendations about what they can say and what has
10 to be based on data rather than their own anecdotal
11 information.

12 I also ask you in your formulation in
13 deciding what you think needs to be done to really
14 listen to the patients. I am very concerned that
15 patients have spoken for five minutes each. Very few
16 questions have been asked. I have been talking to
17 patients about this issue for many years and I learn
18 something every single time.

19 Insurance is a very important issue for
20 these women. It may not be a medical issue *pe se* but
21 if a woman has a procedure that puts her in a position
22 that she cannot be insured for the rest of her life on

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1 anything, I'm not just talking about on issues related
2 to her breasts, that is a very, very serious piece of
3 information that she must have. It's not true, I
4 don't believe, of all insurance companies but it's
5 true of a surprising number of them.

6 Another thing I want to just mention because
7 of the work that I've done particularly with breast
8 cancer patients and also with implant patients is a
9 number of women that I have spoken to through the
10 years who have told me things like their doctors said
11 to them when they had fibrocystic breast disease,
12 which many of you know is not even a disease, or when
13 they had stage 1 breast cancer, or when they had a
14 noninvasive breast cancer and they were told, "Let's
15 be really careful. I recommend that you get a
16 mastectomy and then we'll get you breast implants and
17 you'll be better than new."

18 It's that kind of advice that I think we
19 really have to be concerned about, the gap between
20 what these women are being told and what the research
21 actually shows. That is particularly true for breast
22 cancer patients and that's actually something I'm

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1 focusing on. There is a whole research literature
2 published in major journals such as the New England
3 Journal of Medicine and JAMA talking about informed
4 consent issues for breast cancer patients and what
5 they are told about what their options are.

6 There is also, as we've heard the last two
7 days, quite a gap between how the manufacturers
8 understand their own data and how the FDA presented
9 it. I found that fascinating. It was like listening
10 to two different studies.

11 When you change the denominator, you change
12 everything. These are small changes but they make
13 tremendous difference as to what the results are. Who
14 determines what the results are and how that is
15 explained? I'm afraid that it should not be the
16 manufacturers. Obviously they have their own way of
17 looking at things but some of these are not issues of
18 opinion. They are issues of how you analyze data
19 statistically correctly. It has to be done correctly
20 but it also has to be explained in ways that patients
21 really can understand. **

22 I also think it's terribly important that

1 because there are some negative consequences of these
2 kinds of surgeries that are incontrovertible. I'm
3 talking about some cosmetic problems of clearly that
4 there are some women, we don't know the numbers, who
5 end up looking a lot worse when their surgery is
6 over. I don't mean immediately after but down the
7 road look a lot worse than when they started.

8 I think there should be photographs in any
9 kind of informed consent document. A video tape would
10 be nice, too, but I think a booklet that is clear,
11 easy to understand, with photographs not just of what
12 can look good but of what some of the negative
13 consequences can be. I think that is very important.

14 I think it's also very important that you
15 all understand and that the patients understand that
16 to some extent implant surgery, any kind of implant
17 surgery makes changes that are permanent. If a women
18 gets breast implants tomorrow and she wants them taken
19 out later, her breasts will have already changed. You
20 can't just put them in and take them out and expect to
21 look the same afterwards. ~~Eve~~ If you have no problems
22 you're not going to look the same.

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1 Women have to understand that and it's
2 particularly hard, I think, when you're 18 and
3 thinking about it. They have to understand the
4 irrevocable nature of surgery, that certain changes
5 are going to be made and you can't change back again.
6 Even if you think there are -- even if you think the
7 risks are not great, there still are risks and they
8 have to understand what those risks are and they have
9 to understand that you can never go back to exactly
10 where you were to begin with.

11 I've talked to many women who had
12 augmentation who started out with small breasts and by
13 the time their implants were taken out for the second
14 or third set, they ended up with almost no breast
15 tissue at all.

16 The last thing I want to focus on, which I
17 mentioned in earlier testimony, has to do with what do
18 we know or what don't we know about systemic disease.
19 I agree that there is no conclusive evidence that
20 breast implants cause systemic disease, but I don't
21 agree with the statements that there is evidence that
22 they don't cause systemic disease. I was disappointed

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1 and surprised that it seemed that one of the
2 assumptions of this panel to start with was that we
3 are not going to talk about systemic disease because
4 we don't think that breast implants cause systemic
5 disease.

6 As I mentioned in the handout that I gave
7 you what seems like a year ago but might have been a
8 day or two ago, if you look at all the major studies
9 of connective tissue disease, all the epi studies, the
10 ones that are talked about by the Institute of
11 Medicine and they are talked about by Marcia Angel and
12 they are talked about by all the experts on this,
13 there are 17 studies that are most widely quoted and
14 only one of them separately analyzes women with saline
15 implants. Only one.

16 By the way, that's also the only study that
17 looks at mastectomy patients with saline implants
18 separately. We have almost no information about
19 reconstruction patients and we have no separate
20 analysis of saline implants. Let me say what that
21 means. That means that many of the studies have no
22 women with saline implants.

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1 The other studies have mostly women with
2 silicone gel implants and a very small number with
3 saline implants. Guess what? When they analyze them,
4 this is what they do. First they analyze them all
5 together and so you have saline implants, maybe 5 or
6 10 percent of the population, clearly not much
7 information, and then they analyze them separately
8 looking only at silicone gel. Those are what the
9 analyses are. There are no analyses of the saline
10 except in one study.

11 I also mentioned before, and I want to
12 reiterate, the NIH is doing studies. NCI is actually
13 doing studies on systemic disease. They are doing a
14 study of 13,000 implant patients. That does include
15 saline, although again it's a minority. They are
16 looking at breast cancer, other cancers, and
17 connective tissue disease. FDA needs to look at those
18 studies. They are not published yet.

19 There is a scientific advisory committee.
20 I happen to be on it so I can tell you that some of
21 those data are written up but they are not published
22 yet but I'm assuming that they would be available to

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1 FDA since they are coauthored by an FDA employee.

2 In closing, since I'm seeing the red light,
3 I just want to say that I think it's terribly
4 important that in informed consent women be told what
5 is known and what is not known. That's what I spend
6 all my time doing. It's not enough just to say we
7 don't have evidence of something.

8 If there is no research on it, or course
9 there is no evidence on it. We can't say it's there
10 but we can't say it's not there. Specifically with
11 systemic diseases but also even with the prevalence
12 and incidence of some of these local complications.

13 DR. WHALEN: Dr. Burkhardt.

14 DR. BURKHARDT: I have a question. Thank
15 you very much. I enjoyed that. What kind of study
16 would you use to convince yourself personally that
17 breast implants, either gel or saline, do not cause
18 systemic illness? What kind of study would be
19 acceptable to you?

20 DR. ZUCKERMAN: Of course, we would all
21 prefer perspective study bttt there are problems with
22 perspective studies. I mean, it would be really nice

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1 to start out with the women who just got implants
2 recently and follow them for as many years as
3 possible. The disadvantage, of course, is it takes
4 longer and --

5 DR. BURKHARDT: And if they get ill, how
6 would you know that was or was not related to their
7 implants?

8 DR. ZUCKERMAN: Well, that's the nature of
9 research. You have a control group.

10 DR. BURKHARDT: I guess that's what I'm
11 asking you because it's been done with control groups,
12 as you know.

13 DR. ZUCKERMAN: You would have to have -- I
14 mean, obviously this is not a double-blind study. We
15 know that. There are a couple of things you could do.
16 First of all, you could have comparison samples of
17 women of the same age and health status, and probably
18 socioeconomic status and whatever else you think
19 influences health, and follow those women over time as
20 well.

21 One of the terribly important things that
22 seems to be missing from all the manufactures studies

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1 is that you would have the person determining their
2 health status not be their practicing physician, not
3 be their plastic surgeon.

4 DR. BURKHARDT: Who would you recommend?

5 DR. ZUCKERMAN: Any other doctor who has no
6 conflict of interest financially. I mean, somebody
7 who would be paid to do that as part of the study. If
8 you were doing retrospective studies, which I think is
9 obviously a quicker way to do things, and that is what
10 was done with the NCI study, then you do to some
11 extent what NCI did which is you identify patients.

12 They identified the patients through the
13 doctors, not through the lawyers as some people have
14 charged. You identify the patients through the
15 doctors. You get the records for all the patients
16 they have seen. You have to do very aggressive
17 follow-up to find out where they are now because who
18 knows whether the doctor has seen them in the last few
19 years.

20 You have follow-up done through medical
21 exams -- through medical exams by doctors who are not
22 -- they can't be blind, I don't think, but they can be

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1 at least not paid by anybody, not have any kind of
2 financial conflict of interest of finding or not
3 finding whether a women has a particular illness.

4 The other thing that I would really like to
5 see is that those medical exams cover a wide variety
6 of diagnoses and symptoms and not just rare disease
7 like scleroderma.

8 DR. BURKHARDT: Thank you.

9 DR. WHALEN: Ms. Brinkman.

10 MS. BRINKMAN: Dr. Zuckerman, you have given
11 us a lot of information on what you feel needs to be
12 in a product. We're talking about informed consent.
13 I think that developing the product will be relatively
14 easy compared to developing the process. What are
15 some of your thoughts and recommendations on the
16 process?

17 DR. ZUCKERMAN: I'm glad you asked that
18 because I had meant to talk about it and I forgot. I
19 ran out of time anyway. I actually just very recently
20 was talking to Joan Pitkin who is a state legislature
21 in Maryland. She was instrumental. I had never met
22 her before. We had talked on the phone years ago.

1 She was instrumental in passing an informed consent
2 law on breast implants in Maryland. I asked her what
3 she thought.

4 I saw her just a few months ago and she said
5 it was a total waste of time. She said that the law
6 passed but the doctors didn't use the brochure. They
7 developed a very good brochure. She said, "I've
8 actually never seen it." She said the problem was the
9 doctors wouldn't distribute it and even if they did
10 distribute it, she wasn't at all sure what they were
11 saying that would negate what was in it.

12 Let me also say in informed consent issues
13 with breast cancer patients there was a study recently
14 that was published, I think in the New England Journal
15 but I'm not sure, that talked about informed consent
16 laws that women newly diagnosed with breast cancer be
17 given a pamphlet about lumpectomy and mastectomy and
18 what other options they have.

19 What they found in the study was that there
20 was an initial increase in women getting lumpectomies
21 which decreased quite rapidly and a year or so later
22 the numbers were exactly the same as before so there

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1 was a sense that they had in that research that the
2 doctors were basically initially being a little bit
3 more careful and cautious about providing all the
4 information but that ultimately women are making
5 decisions based on what their doctors tell them.

6 I'm not sure I'm answering your question.
7 I'm agreeing with you how difficult it is. That's one
8 of the reasons why I think a picture is worth -- not
9 to be trite here -- a picture is worth a thousand
10 words.

11 If you have a booklet that has some woman
12 who has serious breast deformities as a result of her
13 implants, even though it should be explained that this
14 may not be a common occurrence, I think that goes a
15 long way in protecting women to at least get them
16 engaged in this process and to get them to understand
17 that there are real risks involved that I think no
18 amount of words written on a page is going to convey.

19 I also, of course, would like to see some
20 kind of monitoring by some outside group in terms of
21 what the doctors actually are saying. If you ask the
22 patients they will tell you -- oh, let me just say, I

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1 met with some breast cancer activists a couple of
2 weeks ago. These were women who were not particularly
3 interested in the implant issue.

4 I was just talking to them about their
5 experiences and every single one of them thought that
6 saline breast implants were FDA approved and perfectly
7 safe. Not only that, but -- I mean, these are
8 activists. These were people who had come to
9 Washington for a federally funded couple-of-day
10 conference. These are not your typical people so they
11 knew a lot. Several of them had saline implants.
12 They were just shocked to learn they had never been
13 FDA approved.

14 They had been told from the get go that
15 these were approved and perfectly safety. Again, that
16 gets into this issue. It's not just the women who are
17 now unhappy saying, "Oh, nobody ever told me." That's
18 my point here. It's all the women that I've talked to
19 whether they were happy or unhappy and they are
20 telling me the same thing.

21 DR. WHALEN: Thank you.

22 Next we'll hear from Ann Stansell from the

1 United Silicone Survivors -- I'm sorry. I'm sorry.
2 Martha Murdock is next, National Silicone/Saline
3 Implant Foundation.

4 MS. MURDOCK: My name is Martha Murdock and
5 I am the founder of the National Silicone/Saline
6 Implant Foundation. We support survivors of medical
7 implant devices. I am not compensated or retained by
8 industry or anyone else. I did pay my own way to this
9 meeting. I am in litigation with one of the
10 manufacturers.

11 That's all I have to tell you about me, that
12 I'm from Texas. I guess you can tell that.

13 Society force feeds both females and males
14 a definition of a beautiful body. Beautiful young
15 women grace the covers of magazines that line the
16 supermarket checkout standards and these images serve
17 as the source of shame for those staring down at a bag
18 of cookies sitting right there front and center in the
19 grocery cart.

20 On the other hand, consider what you see is
21 not what you always get when you're looking at the
22 fronts of those magazines. Advertisers paint a

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1 prettier picture than reality often times guarantees.

2 Ladies and gentlemen, your body is unique.

3 It will carry you through every season of life so why

4 not take care of it? Taking care of your body is

5 similar to taking care of your car. For your car to

6 run properly you must put gas in the tank and oil in

7 the engine. The same is true for your body.

8 I for one am tired of having my body used as

9 a guinea pig because that's exactly what they have

10 done. They have used the women to do their

11 experiments on. I don't know why they don't use the

12 women to do the research on.

13 I would like to discuss some informed

14 consent issues to be considered. The manufacturers of

15 saline breast implants claim that women who get saline

16 breast implants get informed consent prior to their

17 surgical procedure. How can a woman truly give

18 informed consent if she is not provided with all the

19 information that the manufacturers knew about their

20 products? The manufacturers cannot do this because

21 they continue to deny all they know.

22 Rarely ever does a surgeon tell a patient

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1 these medical devices have never been approved by the
2 FDA. There are numerous reports of silicone shells
3 filled with medicogrates, isotonic saline causing
4 autoimmune and other diseases. All implants leak
5 because the silicone shells are porous.

6 The silicone shell will slough off silicone
7 particles which may migrate throughout the body and
8 lodge in your major organs. The implant manufacturer
9 who previously advertised implants would last a
10 lifetime actually knew at that time they would fall
11 apart in five years. The manufacturers of saline-
12 filled breast implants still have never tested their
13 products to determine if there would be long-term
14 health risks prior to putting their new implants on
15 the market.

16 Any patients nightmare is just beginning
17 when they decide to take the chance of having saline
18 implants in their body. Within a short time of
19 receiving implants, a formerly healthy individual may
20 begin to have strange and unexplained medical
21 problems. One day that patient's doctor writes in
22 this patient's report that the patient has many

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1 illnesses. He also makes a note that this patient has
2 saline implants.

3 The result of that, bingo. No more life
4 insurance. No more health insurance. No more
5 insurance ever. No one told that patient that within
6 two years they would never be able to get any kind of
7 life or medical insurance. I worked in the industry
8 and as an assistant to the group actuary and I know
9 they have the statistics. Why do not the other
10 manufacturers and industry representatives?

11 Manufacturers of saline-filled breast
12 implants claim that patients who get saline implants
13 are provided package inserts prior to their surgical
14 procedures. I personally never saw one. I can't find
15 a friend that ever saw one of any kind. Furthermore,
16 how can a patient truly give informed consent if they
17 are not provided with all the information the
18 manufacturer knows about these products.

19 Do those patients have the right to receive
20 this information? My answer is absolutely yes. Do
21 they have the right to destroy their body in making
22 their decision? I guess they do. I wouldn't.

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1 If any patient is told the truth that saline
2 implants were never tested and determined to be safe
3 for long-term human implantation, the implants would
4 leak saline into your body from the implant shell and
5 could travel to all your major organs and on and on
6 the same thing, but they don't tell their patients
7 these things.

8 What is wrong with hundreds of thousands of
9 women whose only common denominator is a silicone
10 envelope filled with a saline solution as an implant?
11 On one hand the manufacturers claim saline breast
12 implants are safe and do not cause health problems.
13 They claim these women have illnesses that don't exist
14 diagnosed by greedy doctors taking advantage of a
15 valid concern that this untested product might be the
16 cause, or at least a contributor to the medical
17 problems the women are experiencing.

18 Could thousands of doctors treating hundreds
19 of thousands of women for the same illness or the same
20 symptoms or similar problems be that wrong? Could
21 laboratories all over the country testing and
22 evaluating the blood and specimens from these women be

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1 manipulating and orchestrating the test results so it
2 appears these women have illnesses that don't exist?
3 Or is it more likely than not the breast implant
4 manufacturers have another reason to promote the
5 fallacy of the illness that doesn't exist?

6 Reasonable minds would wonder. If a
7 silicone shell filled with isotonic saline breast
8 implants are truly safe and do not cause health
9 problems, why is the same insurance company insuring
10 the saline implant manufacturers and then refusing to
11 pay health claims of women with breast implants? If
12 saline implants are safe, why did the manufacturers
13 only begin testing once the silicone implants were
14 pulled off the market and restrained to only a few?

15 Do the insurance companies know something
16 that we don't know? You bet they do. They have all
17 the information in one form or another. If the
18 members of this committee are sincerely looking for
19 the truth, ask yourself how can so many women have an
20 illness that doesn't exist which can be diagnosed,
21 quantified, qualified, by scientists, epidemiologists,
22 and researchers, not to mention the treating

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1 physicians for these scores of women.

2 The truth will never be found through
3 research funded by the very manufacturers whose
4 product has caused this illness that doesn't exist.
5 Stated failure rates for these products that I have
6 heard this week I find to be totally unacceptable for
7 myself, my daughter, my granddaughter, or anyone else
8 I know.

9 In closing I would like to mention the
10 saline inflatable penile prosthesis. Given the panels
11 views of buyer beware policy associated with your
12 views so far as what I basically heard, would you be
13 prepared to use the same approval with conditions for
14 saline inflatable penile prosthesis? I seriously
15 doubt it. The failure rate tables must be available
16 for all breast implant and penile implant recipients
17 in their informed consent information.

18 I thank you so much for your time and I'm
19 sorry I'm hoarse. Do you have any questions of me?

20 DR. WHALEN: Thank you, ma'am.

21 Now next indeed we do have Ms. Anne Stansell
22 from the United Silicone Survivors of the World.

1 MS. STANSELL: My name is Anne Stansell.
2 I'm from New Mexico. It's unbelievable that I am here
3 today to talk to you about something that should have
4 been taken care of 30 years ago.

5 DR. WHALEN: Ma'am --

6 MS. STANSELL: I have no financial ties to
7 any other matter in this other than we have a
8 contract. We the people of the United States pay our
9 taxes in part so the Government will provide certain
10 protections. We trust in these protections.

11 When I got the news I had breast cancer, I
12 was devastated. I had to put my trust in a borage of
13 doctors. After the mastectomies the surgeon said,
14 "You need breast implants." The oncologist, the
15 psychologist, the radiologist, the plastic surgeon all
16 said get implants and they are perfectly safe.

17 I felt as if they had just saved my life by
18 removing the cancer so I trusted them. I knew they
19 had to answer to my Government and we have a contract.
20 So I trusted that the use of breast implants for
21 American women was being supervised. At first a
22 breast implant seemed okay just like you were told

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1 yesterday and the day before. I was satisfied for the
2 first two or three years. It helped me be in denial
3 about having my life threatened. Several women
4 testified to that here the last few days and even one
5 today.

6 One doctor hit the nail right on the head.
7 Soon I realized these lumps on my chest were not
8 breasts. They did not even resemble breasts anymore.
9 One was hard as a baseball. The other shifted up to
10 my shoulder. I looked ridiculous. I realized I was
11 in constant pain. I had been ignoring the pain. As
12 it became more severe I had to face it.

13 Then when I got sick after having implants,
14 I started to check into whom I had so blindly trusted.
15 I checked with the cancer organizations. They knew of
16 no research on mastectomy patients and breast
17 implants. I checked into the medical organizations.
18 They could provide no evidence of research that had
19 been done on mastectomy patients and breast implants.

20 Then I checked with my Government, the
21 department that oversees our medical needs, the FDA.
22 I was appalled to learn there was and still is no

1 research on mastectomy patients and breast implants.
2 We have survived breast cancer. Will we survive
3 implants? We don't know. You don't know. Cancer
4 survivors with implants now face a lifetime of surgery
5 and pain. What good is it to survive cancer then?

6 Yesterday I heard McGhan quote a 95 percent
7 complication rate for reconstruction patients. 95
8 percent and you recommended approval. 95 percent
9 complication rate was not shown on the slick slides
10 that we've seen today. 95 percent complication rate
11 means a lifetime of surgery every five years per
12 breast. that is not statistically acceptable.

13 Even toasters come with a better guarantee.
14 I would not buy a toaster that came with an expected
15 failure rate of 90 percent. Would you? Toasters come
16 with a registration card. If something should be
17 found defective with the appliance, there is a recall.
18 If toasters can be tracked, why can't women's breast
19 implants?

20 When you see those clean colorful bargraphs
21 on the screen they sure**look pretty, but those
22 represent real lives, real women with real families.

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1 Most insurance companies accept women five years after
2 breast cancer treatment if there is no recurrence.
3 Insurance companies will not accept us if we have now
4 or ever have had breast implants. This was not
5 mentioned on the pretty bargraphs either.

6 The manufacturers talked of deflation and
7 deflation rates. Sounds rather harmless. Not once
8 did I hear rupture. When a breast implant deflates,
9 it ruptures. The word rupture brings to mind the
10 violation occurring in our tender chest.

11 Tell me what would happen to a physician who
12 puts a saline IV into a patient's body with an
13 expiration date of seven years ago? Isn't that, in
14 fact, what happens when a seven-year-old implant
15 ruptures?

16 Dr. Goldberg's research proves the rupture
17 rate and we are providing the evidence that breast
18 implants are not safe and effective. We are Dr.
19 Goldberg's lab rats. We trusted the FDA to have these
20 facts before you so negligently committed all of us to
21 a lifetime of illness and suffering.

22 We have a contract. You, the Government,

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1 and we, the people -- we the women. We have come here
2 to let you know that this generation has been
3 betrayed. Stop. Don't betray the next generations as
4 well. But we already have that contract. What kind
5 of sick process is this anyway where women from all
6 over the country have to travel here all this way to
7 bear our souls and chests to you?

8 Is it not enough that we have already lost
9 our breasts, one of the most nurturing aspects of
10 womanhood, the very parts necessary to raise the
11 continuation of we the people. We have a contract.
12 You must fulfill it. You must do your part.

13 I would like to give the remaining three and
14 a half minutes to Marlene Keeley.

15 MS. KEELING: One informed consent by the
16 manufacturer states, "Neither Mentor nor FDA know of
17 any reason why existing coverage policy should not
18 continue." I have a copy of an insurance underwriters
19 guide which states if a women applies for health
20 insurance and she has breast implants, the standard
21 response is to deny her coverage. American women
22 deserve the truth. Truthful information from the FDA,

1 the chemical companies, the manufacturers of implants,
2 and the medical community.

3 May I remind this committee the Nuremberg
4 Code states the following. "(1) The voluntary consent
5 of the human subject is absolutely essential. The
6 person involved should have free power of choice
7 without any element of fraud, deceit, overreaching, or
8 other ulterior form of constraint or coercion and
9 should have sufficient knowledge and comprehension of
10 the elements involved to be enabled to make an
11 enlightened decision.

12 (2) No experiment should be conducted where
13 there is an a priori reason to believe that death or
14 disabling injury will occur except perhaps in those
15 experiments where the experimental physician also
16 serves the subjects.

17 (3) During the course of the experiment the
18 scientist in charge must be prepared to terminate the
19 experiment at any stage if he has probable cause to
20 believe in the exercise of good faith, superior skill,
21 and careful judgment required of him that a
22 continuation of the experiment is likely to result in

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1 injury, disability, or death of the experimental
2 subject. Once implanted, it is impossible for a woman
3 to terminate the experiment because the degrading
4 chemicals from the shell and the gel that spreads to
5 all parts of her body may never be removed. Thank
6 you.

7 DR. WHALEN: Would you entertain a question,
8 ma'am?

9 DR. BURKHARDT: May I ask a question?

10 MS. KEELING: Yes.

11 DR. BURKHARDT: I'm intrigued by the
12 underwriter's guide to which you referred. Do you
13 have a copy of that?

14 MS. KEELING: I'm sorry. I meant to bring
15 it with me. I'll be glad if you have a card to --

16 DR. BURKHARDT: From what company did you
17 get it?

18 MS. KEELING: I'll have to check on that for
19 you.

20 DR. BURKHARDT: Thank you.

21 DR. WHALEN: Thank you.

22 Next scheduled speaker is Amy Allina of the

1 National Women's Health Network.

2 MS. ALLINA: Hello. My name is Amy Allina.
3 I'm the Program and Policy Director of the National
4 Women's Health Network. You heard comments Wednesday
5 and Thursday from my colleague, Cynthia Pearson, and
6 I'm here today to talk about the issue of patient
7 information.

8 The network is an independent member
9 supported organization dedicated to safeguarding
10 women's health rights and interests. We accept no
11 money from pharmaceutical companies, medical device
12 manufacturers, or trial lawyers. I'm not a party to
13 any implant lawsuits and I do not derive any income
14 from implant surgery.

15 Throughout the three days of this meeting
16 the question of whether or not saline-filled breast
17 implants should be found to be safe and effective has
18 been repeatedly presented by implant advocates as a
19 matter of choice. Women, they say, should be able to
20 choose whether or not to take whatever risks are
21 associated with implantation of these devices.

22 The National Women's Health Network was

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1 founded on the principal that with accurate and
2 complete information women can make good health
3 decisions for themselves.

4 Our concern about saline-filled breast
5 implants is the data that women need to make fully
6 informed decisions about this healthcare choice are
7 not available.

8 That said, we believe that all the data that
9 are available about complication rates over time
10 should be included in the patient information given to
11 women receiving implants. This means that the patient
12 information should include the total complication rate
13 and a full explanation of the kinds of complications
14 that might occur including infection, breakage, and
15 contracture.

16 In addition to the total complication rate,
17 it should also include a breakdown showing the
18 different complication rates for augmentation patients
19 and reconstruction patients. The data should be
20 presented in a way that is easy to read and understand
21 for consumers. We agree that they should be
22 illustrated by photographs of the outcomes described.

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1 We also feel that any benefit information
2 included must also be supported by data. Patients
3 should be told that the FDA encourages them to consult
4 a different physician if their doctor's oral
5 communication negates the written information that
6 they receive.

7 Finally, we urge the panel to recommend that
8 the patient information should include a statement
9 explaining that the expert panel which approved these
10 products did so in spite of the fact that it believed
11 further research was needed to determine the long-term
12 safety of these devices.

13 Women receiving saline-filled breast
14 implants need to know that experts believe there is
15 not enough data to definitively say what happens to
16 implants and implant users beyond five years after
17 implantation. There should also be a statement
18 informing women that the safety of breastfeeding
19 following implant surgery has not been adequately
20 studied.

21 To make a fully informed choice women must
22 be provided with data about what is known as well as

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1 information about what is not known. Since the panel
2 has recommended approval of these devices, even while
3 acknowledging the lack of long-term safety data, we
4 ask you to be ensure that women choosing implants have
5 the opportunity to make that choice with the full
6 information that was available to you when you made
7 yours and with the awareness that you, the experts,
8 found the long-term safety data to be lacking. Thank
9 you.

10 DR. WHALEN: Thank you.

11 Next we'll hear from the organization NABCO.
12 I understand the speaker will be Rosemary Locke.

13 MS. LOCKE: Good morning. My name is
14 Rosemary Locke and to answer your question I have no
15 financial motives. I'm not involved in a lawsuit. I
16 receive no compensation. However, as both Jill and I
17 stated on Monday, our organizations do receive some
18 funding from pharmaceuticals and in the past from some
19 manufacturers of devices that are no longer available
20 on the market.

21 DR. WHALEN: I think it was Wednesday but I
22 don't blame you for thinking it was Monday.

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1 MS. LOCKE: First of all, I want to thank
2 the panel for its very thoughtful understanding of
3 some complex issues. I had the pleasure of serving
4 with Nancy Dubler on the last panel. This issue of
5 informed consent and labeling is tough. I have found
6 myself over the years in agreement often with those
7 who are in opposition for breast implants, though my
8 organization and a number of breast cancer
9 organizations are in favor of choice.

10 Before I make the comments about labeling,
11 and that's really why I'm here, on labeling and
12 informed consent, I do want to point out that the
13 breast cancer organizations, the main large ones, got
14 together and sought funding from the IOM to review the
15 studies on gel breast implants because it was so
16 contentious and we felt we had to go to an unbiased
17 source.

18 Now, with that these are my comments on
19 informed consent labeling. There should be general
20 information about all reconstruction options and
21 devices. Along with that I would like to see the
22 information that is given in the clinical trials, for

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1 example, with gel trial for patients. Much of that
2 information should be included for women considering
3 breast implants.

4 Women considering breast implants may have
5 varying communication styles so that while one person
6 might be inclined to request additional information
7 including the package insert, another would leave the
8 doctor's office with only the information given to
9 her. These differences must be accounted for in a
10 more standardized approach to disseminating
11 information and tools to help gain a deeper
12 understanding.

13 Now, I know in the instructions there was
14 talk about focus testing. I think that is crucial.
15 I would like to see experienced advocates included
16 with novices who would be coming like a newly
17 diagnosed patient so that you could see how people
18 really receive and retain information. Those of us
19 who have worked in counseling patients know that you
20 can tell someone something numerous times but are they
21 hearing and truly incorporating that information in
22 how they are processing and coming to a decision.

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1 Now, I think that all of the information put
2 out by the manufacturers and FDA have to reflect the
3 IOM review. The IOM deals with what we now know, what
4 we don't know, and the remaining concerns. I think it
5 has to be updated.

6 I would also like to see something put in
7 there about the technique and experience of the
8 surgeon. As many of you addressed, it's not simply a
9 matter of the device. You need to elaborate on the
10 risk and cost implication of revision and replacement
11 surgery. Who pays for this?

12 We need to know more about the life
13 expectancy of the implants. Since we don't know all
14 that much, you have to acknowledge that they have to
15 be replaced periodically and that there will be a need
16 for an ongoing relationship with the plastic surgeon.

17 It is especially important for young women
18 to know this issue of failure rate or the unknowns
19 about failure rates. Again, I'm speaking of breast
20 reconstruction primarily. A woman's age and the
21 uncertainty of these devices over a long period of
22 time might significantly influence her choice of

1 reconstruction. And considerations for current
2 insurability and the financial implications of
3 selecting a device.

4 While both Y-ME and NABCO choose only to
5 focus on reconstruction, for those women who do
6 consider these devices for augmentation, a great deal
7 of information should be given to them about the
8 nuances of placement of that implant in relationship
9 to what is optimal for screening mammography.

10 Certainly there should be duplicate copies
11 of the package insert with the specific model and type
12 so that the patient has one and the doctor has one.
13 I didn't quite understand when the manufacturers
14 presented today why it was the patient's obligation to
15 jot down the model and the type. It seems like that
16 should be somewhat routine coming with that particular
17 model.

18 While I didn't stay for all of the PIP
19 discussions yesterday, the idea of having kind of a
20 bar code or something on an implant so that if it's
21 taken out, you know exactly what model and batch it
22 came from might not be something to be dismissed. It

1 might be a good idea.

2 Clearly the description of the operation --
3 Sybil and I have been in agreement on the need for a
4 registry so I would like to follow up on the
5 manufacturer's suggestion and a card in there for
6 having patients in a registry because that would help
7 solve a lot of these unknowns we have about long-term
8 studies.

9 I do want to compliment the FDA in its
10 instructions, however, for pointing out to the
11 manufacturers that if you over warn about devices, it
12 dilutes the strength of the most frequent and serious
13 risks. I think you have to be very careful in
14 devising this information and the labeling so that
15 people really understand the magnitude of the problems
16 as the frequency and the seriousness of those.

17 One comment on the retrospective studies
18 that Diana spoke to you about and many of her remarks
19 were very thoughtful as they always are. One of the
20 problems with the retrospective study that she has
21 brought up several times, 'we fear there's the self-
22 selection bias because those augmentation patients who

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1 they try to bring in to that study could choose to
2 participate or could choose not to participate. It is
3 our sense that a lot of people who are happy with
4 their implants for augmentation probably don't want to
5 come forward and make a point about it.

6 There is another problem with a
7 retrospective study like that as far as giving usable
8 advice now. There were so many manufacturers and so
9 many models involved in those earlier years that it's
10 somewhat meaningless information to give to women who
11 are trying to select an implant now. From that point
12 of view I don't find it terribly helpful.

13 Now, in closing I would say that Y-ME, and
14 I'm sure other consumer groups, would welcome the
15 opportunity to work with the FDA to try to develop a
16 more uniform informed consent document that would help
17 women truly understand the risks and the benefits of
18 these devices and take away some of this terrible
19 sense of betrayal that some women feel and rightly
20 felt in the earlier years when they did not have
21 adequate informed consent.**

22 Thank you. Do you have any questions?

1 DR. BURKHARDT: I have a question. We've
2 had so many studies to deal with. Can you tell us to
3 which study you were referring in your comments about
4 patient selection?

5 MS. LOCKE: Well, it's the one currently
6 going on at NCI with one FDA official who is here now.
7 Do you want me to name names?

8 DR. BURKHARDT: I don't know. I mean, is it
9 a published study?

10 MS. LOCKE: No, it's not published.

11 DR. BURKHARDT: So we really don't have
12 access to it then?

13 MS. LOCKE: No, we don't. But my point --

14 DR. BURKHARDT: No, that answers my
15 question.

16 MS. LOCKE: Okay. But my point really was
17 more of a generic nature with the retrospective
18 studies where you have a patient. Patients can choose
19 or not choose to participate in the study. Because of
20 that you've already got a self-selection bias.

21 DR. BURKHARDT: I understand.

22 MS. LOCKE: Thank you.

1 DR. WHALEN: Thank you.

2 Next we'll hear from Christine Williams on
3 behalf of the American Cancer Society. Maybe we
4 won't. We'll hear from Jama K. Russano from Children
5 Afflicted by Toxic Substances. Strike two. That was
6 the list of the scheduled speakers that we had.

7 Before we proceed on to Mr. Rhodes
8 presentation to us, the open panel discussion was
9 scheduled to begin after lunch. We were going to be
10 addressed with comments like two of the panel members
11 for this process and Ms. Dubler may not be able to be
12 here due to time constraints. I would ask that she
13 address the panel with her remarks at this time.

14 Ms. Dubler.

15 MS. DUBLER: First I'd like to thank all of
16 the people who spoke this morning for presenting to us
17 a different quality of data than we generally receive.
18 That is qualitative data. There are two sorts of data
19 that medicine now looks at. It looks pretty
20 exclusively to quantitative data but testimony over
21 time I think has its own importance.

22 I would like to take a few minutes to really

1 reflect upon this process of informed consent that we
2 are all trying so hard to get to work and suggest to
3 you that there are structural reasons why it's not
4 working. I'm not exactly sure how to solve them.

5 Informed consent is a concept that's been
6 around for a while, although it's interesting that it
7 wasn't called that until a California case in 1957 so
8 it's relatively recent doctrine. It was developed in
9 the context of the doctor/patient relationship as a
10 way of redressing an imbalance of power within that
11 relationship.

12 It became important at the time of the
13 rights movements; the women's rights, the patient's
14 rights, etcetera. It was developed really and
15 elaborated as a way of redressing a situation in which
16 by in large doctors made decisions. They had the
17 skill and the wisdom and the experience. It was the
18 time of hegemony of paternalism as a mode of
19 operation. Doctors told patients what would happen.

20 Informed consent was there as a way of
21 redressing that and saying; well, it's really what's
22 important to the patient in the context of this

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1 illness that should determine what should happen and
2 that a patient's values and personal idiosyncratic
3 choices are as important as the things that the doctor
4 thinks is important. So the skill and wisdom and
5 options and explanations that the doctor could provide
6 were to be used by the patient to make a choice.

7 Now, this notion of patient choosing is an
8 old one. The best quote I know, there is a wonderful
9 New York State case from 1914, Schloendorff v. Society
10 of New York Hospital where the court says every human
11 being of adult years and sound mind shall have the
12 right to determine what shall be done with his own
13 body.

14 So informed consent is a doctrine that
15 developed in the following way. First of all, it
16 requires a "decisionally capable patient." That is,
17 in common parlance an adult patient, not a child, who
18 isn't retarded and who's come to have the general
19 capacity to weigh and value what's important.

20 Now, I don't say wisdom. Some of us get
21 wisdom when we get older and some of us never gain
22 wisdom. Informed consent doesn't require wisdom and

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1 that's really important in the context of what we're
2 talking about.

3 I hear the people talking this morning who
4 want to get out there fists and say, "You silly woman.
5 Can't you read these data the way we do?" Well,
6 informed consent doesn't require that a woman be able
7 to evaluate data the way some of us would like her to.

8 It requires a decisionally capable person
9 who is able to articulate and identify personal
10 values, who is provided with sufficient information to
11 understand to the greatest degree possible for that
12 person what the issues are, and to make a personally
13 valid choice, and to communicate and act on that
14 choice.

15 That's the classic notion of informed
16 consent. I'm here to tell you since I work in the
17 trenches in the Bronx that it hardly ever operates the
18 way we would like to see it operate. If it ever works
19 at all, I would like to say it works well between two
20 white upperclass males in Scarsdale where they all
21 share the same values and the same economics and the
22 same life view, and it helps if they went to the same

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1 college together.

2 But once you introduce race and class and
3 power and economics and differentials and education,
4 it's a very hard doctrine to make work. That's the
5 context in which we are trying to make it work now.

6 One other comment about how it exist now.
7 It is largely not a doctrine for empowerment and
8 deciding. Over the last 15 to 20 years it's become a
9 risk management technique. Hospitals, institutions,
10 and physicians have said if we can get all these risks
11 on the table and we can document that the patient saw
12 them, then we are not liable if they happen. So that
13 violates everything that we really want out of an
14 ethical doctrine of informed consent, but it's now the
15 dominant mode of how the concept is used.

16 I like to say that it's what I call the
17 smorgasbord theory of consent. Physicians some of
18 whom are very angry about this doctrine and about
19 issues of liability put out their options. "Here is
20 a little cheese. Here's a little salami. Here's some
21 pickles. Okay, patient, 'you make your sandwich."
22 That's not really what the doctor/patient relationship

1 is. The doctor/patient relationship is one of advice
2 and trust, but informed consent has worked
3 unfortunately to undercut that.

4 So where does that leave us? I think it
5 leave us with having to develop something of a new
6 paradigm and the FDA having to really articulate what
7 that is and make it work. Because this dual
8 relationship that was the basis for informed consent,
9 the doctor and the patient, has changed. What we now
10 have are, as I analyze them in any ethical analysis,
11 I ask who are the parties, what are their interests,
12 are their interests in conflict, and how do we resolve
13 that conflict.

14 We have a lot of parties who are players
15 here. We have the sponsors and the manufacturers.
16 Their interest is in selling and advertising and
17 increasing the market for their devices. We have the
18 surgeons. Some of them are very well trained and very
19 adept and are probably very good at what they do and
20 some of them are not. There is a great reluctance
21 within the surgical community to become involved in
22 identifying who fits into which one of those pots.

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1 We have surgical organizations. We have
2 consumer organizations. We have patients. Something
3 we haven't heard a lot about at this meeting, but I
4 hear a lot about in my work, and those are the
5 partners of women who go for especially augmentation,
6 men who are their partners who have very heavy
7 commitments to this surgery. We haven't heard that
8 and there aren't data to support it, only my own
9 useless anecdotes.

10 So what do we do? Well, I would suggest
11 that there are three principles that should guide what
12 the FDA does. One is the notion of transparency.
13 That is, any data that exist should be given to the
14 woman, and it should be given to the woman in the best
15 form that the FDA can help the sponsor to put it in.
16 And those data should be very stark and very
17 informing. There is a 60 percent rate of complication
18 and resurgery over x number of years so any data that
19 are there should have to be in the sponsor's informing
20 material in a way that the FDA approves of.

21 Second is awareness, the second principle.
22 That is, within this very complex world of different

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1 players that the FDA should work to make an awareness
2 of the risks of continued surgery, capsular
3 contracture, whatever the major risks are, highlighted
4 to a woman, not set in the context of advertising and
5 promotional literature in the way that the company
6 thinks supports its interest, but that a way the FDA
7 supports the interest of informing the individual
8 patient.

9 Finally, I'm going to suggest, because I
10 think this really is a field of great conflict, that
11 we think about having some independent source of
12 information in the process. Let me give you an
13 example from the research world. Many of us who work
14 in research ethics have for a while written about the
15 problem of the researcher and the clinician being the
16 same person, the duel hat problem.

17 For example, my IRB in very complex
18 psychopharmacological protocols now require simply
19 that there be two people. The clinician and the
20 researcher be two different people. If you're going
21 to take someone off medication for schizophrenia,
22 you're going to leave that clinician to work with the

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1 patient.

2 I'm not sure that we can provide an
3 independent advocate for every woman and I'm not sure
4 that all women would want that. But I do think the
5 FDA in its materials can make very clear where the web
6 sites are, where you can get independent information,
7 and perhaps what the phone numbers would be, the 800
8 numbers of advocacy groups which we will very clearly
9 identify as groups that will argue against.

10 So transparency, awareness of risks, and the
11 availability of an independent source of information
12 would be the three principles that I think we would
13 add to the standard principles of informed consent
14 that deal with this very complex arena of players and
15 conflicting interest. Thank you.

16 DR. WHALEN: Thank you, Ms. Dubler.

17 Do any of the panel have questions or
18 comments on those remarks? Dr. Burkhardt.

19 DR. BURKHARDT: I do again. I would just
20 like to comment, Ms. Dubler, that many surgeons have
21 no reluctance whatsoever to comment on the lack of
22 qualifications of individuals who are doing this

1 procedure. The problem is that we have no authority
2 under the anti-trust statutes to control that activity
3 and I'm sure that you realize that. In many cases we
4 are indeed faced with an instance of caveat emptor
5 which we do not like but over which we have no control
6 as a professional.

7 The second issue that concerns me is the web
8 site suggestion. In general I have no problem at all
9 with access to information but my experience is that
10 the information that my patients are now getting on
11 the web site they regard as written on stone tablets
12 because it's on their monitor. In fact, if they can't
13 properly judge the information I give them as a
14 responsible surgeon, they sure can't judge the
15 accuracy of the information that they receive from
16 advocacy groups.

17 DR. WHALEN: Any other questions?

18 MS. DUBLER: Can I answer?

19 DR. WHALEN: Oh, certainly. Feel free.

20 MS. DUBLER: Yes, but. The but is if our
21 goal is to raise an awareness that there are problems
22 that they better investigate further, I grant you

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1 there's no quality control over web information, but
2 at least we will feel we have done our best to give a
3 clear notion that there are two sides of the issue.

4 DR. BURKHARDT: I would like to ask you a
5 question. I am very interested in your presentation.
6 Do you feel that the -- I don't know what the
7 legalities are here but do you feel that the authority
8 of the FDA as the supervising agency here should
9 extend to the promotional material that is published
10 really by the companies?

11 What the companies do, of course, they want
12 to sell their stuff. I don't blame them. If I was in
13 the business, I would want to sell my stuff, too. So
14 they'll go through an advertising agency and they will
15 give them a certain basis on which to work with. One
16 of the things that I noticed, as I'm sure you did,
17 there weren't any ugly women in those photographs that
18 come through. Should we attempt to control that area
19 of commerce in the name of fair balance?

20 MS. DUBLER: Without question. Without
21 question. Can the FDA do that?

22 DR. WITTEN: Well, maybe I should clarify

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1 that. We do, in fact. Labeling broadly encompasses
2 for these PMAs. It broadly encompasses the material
3 that goes with the product and the material that is
4 meant to explain the product even if it's not
5 physically accompanying the product.

6 DR. WHALEN: Does it also encompass the
7 local physician's advertisement when it mentions the
8 product name?

9 DR. WITTEN: It doesn't encompass the
10 physician's advertisement.

11 DR. WHALEN: Is that the thing that you know
12 of in the FTC?

13 DR. WITTEN: I can't answer that.

14 DR. WHALEN: Dr. Blumenstein.

15 DR. BLUMENSTEIN: Could I ask a question
16 about that? Will the ability to, how should I say, be
17 involved in the advertisement part, does that change
18 with the status from an approved PMA to the previous
19 status whatever that was called?

20 DR. WITTEN: In terms of what we can -- what
21 we regulate it doesn't. What does change is the fact
22 that we need to see in advance for material that

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1 accompanies the PMA, that goes out with the PMA. We
2 approve all the labeling in advance. In other words,
3 we have authority over the material but we don't
4 preapprove it the way we do with the PMA.

5 With these products when and if we move to
6 approving the PMAs, we would work with the sponsors to
7 make sure that they label all the material that they
8 send out. All the promotional material be something
9 that is consistent with what we think it should be
10 based on the data that the sponsor provided. Also
11 we'll be looking at the kind of discussion that we had
12 today to see how we will incorporate those ideas into
13 what we tell them about their promotional material.
14 The answer is yes, we'll be looking at all the
15 material.

16 DR. BURKHARDT: Could I bring up to just
17 follow this issue a little bit, I served on the ethics
18 committee of our national organization for quite some
19 time and one of our provisions at the time I served
20 was that if a member of our society would advertise,
21 which is okay, and showed pictures of someone
22 purporting to represent the product or the service

1 advertised, that individual had to be a true patient
2 of the doctor who is advertising and not only had to
3 be a true patient but had to have had the procedure
4 that is being advertised.

5 We enforced that for quite a while. Then
6 one of the implant companies came out with an
7 interesting marketing program in which they now refund
8 us "monopoly" dollars in their advertising dollars
9 depending on our commercial relationship with them.
10 Those dollars are used to run advertisements that are
11 provided by the implant company but we run them in our
12 local newspapers and magazines and so forth with our
13 name on them.

14 The patients who are pictured in those
15 advertisements are very good looking as you might
16 imagine. They are not my patients so we've had to
17 completely readjust our own ethical standards based on
18 some of the commercial activity that is going on. I
19 just wonder if you think that the implant companies
20 should be permitted to continue to promote their
21 product directly to the patient?

22 MS. DUBLER: I have a prior comment which is

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1 you were forced to adjust your ethics to commercial
2 practice. Why? You could just as easily said it is
3 unethical for doctors to accept money to use these
4 advertisements.

5 DR. BURKHARDT: It's interesting because our
6 attorneys -- whenever there is a problem, there's
7 usually an attorney right in the middle of things.

8 DR. WHALEN: Who never solves anything.

9 DR. BURKHARDT: Our advice from our attorney
10 who oversaw the process is that that would be
11 restraint of trade.

12 MS. DUBLER: My LLB, a number of people have
13 asked me what it is. It's the law degree that you got
14 if you graduated from law school before 1968 which I
15 did.

16 DR. WHALEN: At the age of 6.

17 MS. DUBLER: It attests to my venerable age.
18 I don't have the skill to evaluate the wisdom of that
19 attorney's advice. I do think that organizations have
20 the right and the obligation to set their ethical
21 standards according to their patterns of professional
22 practice and their values rather than according to the

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1 vagaries of commercial behavior.

2 DR. BURKHARDT: I have no disagreement with
3 that.

4 DR. WHALEN: Dr. Blumenstein.

5 DR. BLUMENSTEIN: I feel like I'm stepping
6 out onto thin ice. I'm a numbers guy. We talked a
7 lot about numbers and I'm very interested in whatever
8 materials are produced having numbers that are, first
9 of all, accurate and, second, understandable and so
10 forth. I feel like I'm on solid ice there but now I'm
11 going to step on it.

12 I am a father of teenagers and I have not
13 had to face this yet but it is something that I expect
14 might happen, and that is body piercing and tattooing.
15 What I'm concerned about here more than anything else
16 with this informed consent process is the younger
17 people who are faced with this augmentation decision.

18 I'm wondering because there seems to be a
19 substantial difference just taking a real contrast
20 between the informed consent that such a person is
21 faced with. Maybe not conformed consent so much as it
22 is the process of making the decision, versus an older

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1 woman doing it or a patient seeking reconstruction or
2 whatever.

3 I'm wondering what -- I really have two
4 questions. Are there really substantive differences
5 between that extreme form of informed consent or that
6 process and all the other parts of it? I would like
7 for you to comment on that.

8 Then I'm wondering if there should be
9 something like a personal responsibility web site that
10 people should be referred to who are in that kind of
11 a position that talks about personal responsibility
12 and decisions regardless of whether it's tattooing,
13 body piercing, or whatever, along those lines.

14 MS. DUBLER: I'm not sure. I mean, I share
15 your concern. I'm not sure I have anything useful to
16 respond to it. We just published a book out of my
17 shop called The Adolescent Alone. For that we
18 reviewed over the last two years all of the literature
19 on developing capacity. The capacity literature says
20 from about 13 years on most children have the ability
21 to make decisions based on data.

22 However, as I'm sure you know, I pause at

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1 that point having raised kids. It takes my breath
2 away. There is also this notion that I'm sure you
3 know that probablistic thinking is the most abstract
4 kind of thinking and the last one to develop in this
5 range of skills of capacity that we have. We are
6 dealing largely with probablistic information.

7 I don't think there is any way to limit
8 these implants. Once someone reaches 18 and they are
9 legally able to make choices, I don't see how we can
10 effect it. Although I was very pleased to hear the
11 surgeon say this morning that he has a different
12 protocol for younger patients which, I hope, include
13 the early 20s.

14 I mean, they are going to piece their navals
15 and tongues and they are going to get breast implants.
16 It's all quite consequential and the breast implants
17 perhaps the most consequential. I don't know any way
18 that we can limit that decision-making ability.

19 DR. WHALEN: Dr. Bandeen-Roche.

20 DR. BANDEEN-ROCHE: I'm going to step on
21 even thinner ice but it's addressing Dr. Blumenstein's
22 comment about the process of giving information. We

1 had a comment this morning to the effect that we won't
2 know how to evaluate whether people really get it or
3 not, but there are formal methods imperfect as they
4 may be for evaluating.

5 I recognize them explicitly in FDAs
6 recommendations about how you draw up informed consent
7 making sure that people first recognize a risk and
8 then perceive the risk as real to themselves and
9 health seeking. There is a very standardized
10 literature on this imperfect as it may be.

11 I strongly hope that whatever materials are
12 developed will be rigorously investigated along these
13 lines with data on their effectiveness and people not
14 only having read it but actually comprehending. I
15 mean, the GRE test, you know, evaluates how well
16 people comprehend what they read and in some sense
17 internalize the meaning of risk, both probability of
18 risk but also loss. That is the other component of
19 risk even if something is very rare. If it carries a
20 high loss, then one should internalize that, too.

21 DR. WHALEN: Thank you. I'm going to
22 exercise the prerogative of the Chair since I think

1 there's some good healthy discussion going on and ask
2 Ms. Brinkman to go ahead and make her remarks at this
3 time.

4 MS. BRINKMAN: Thanks. I would like to
5 comment, though, in my 30 years since I was a very
6 small child developing and evaluating patient
7 education materials. There are very effective methods
8 for assessing effectiveness of the materials and we do
9 use them constantly in our settings.

10 As consumer representative I asked some time
11 ago when I knew that this panel was going to convene
12 to make myself available to consumer groups, to
13 professional groups that had interest in the subject
14 matter. It was a mixed blessing but I've learned a
15 lot.

16 I have had the opportunity to listen to
17 literally dozens of consumer groups and patients and
18 communicate with professional groups as well,
19 physician groups. I want to assure those consumer
20 groups that are here today that I have taken extensive
21 notes on all of your comments and will share them with
22 the FDA so that your suggestions for things that you

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1 would like to see included are relayed to the FDA.

2 Some consensus amongst consumer groups.
3 Certainly, as we all know, talk about improving our
4 informed consent both in content and process. We have
5 discussed adequate decision-making time, although I
6 don't know what that is and don't pretend to.

7 We've talked about improved access of
8 mediated materials which include the use of
9 multimedia, written materials, toll free numbers, web
10 sites, audio visuals, full disclosure of data
11 including information from the IOM report. Certainly
12 improve details of description of risks and benefits.

13 We talked about using photographs of desired
14 results and often times photographs of results that
15 are less than desirable. We talked about easy access
16 to additional resources such as creating a web site
17 with hyperlinks so that the most commonly looked
18 resources for someone who is considering some sort of
19 breast health issue, they may go to ACS or NCI or Y-ME
20 or whatever and have a hyperlink from their web sites
21 to an FDA web site that talks more extensively about
22 breast implants.

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1 We discussed a national registry of all
2 implant patients including a good suggestion, I
3 thought, was not only identifying office of the
4 manufacturer and the product number, but having on the
5 flip side of that for the patient instructions that
6 they could take to the mammography site with them
7 about how their implant and being able to assess the
8 mammography site's ability to use appropriate
9 techniques.

10 We discussed about patient costs, what are
11 they over a period of time, what is the availability
12 of insurance, and what does this do to one's ability
13 to get insurance.

14 We talked about duplication of package
15 inserts. We talked about standardized systems to help
16 collect more information about frequent causes of
17 complications and their medical management.

18 We talked about including in education
19 materials changes in physical properties including
20 implanted breasts such as match, shifts, healing
21 process, lactation, etcetera.

22 We talked about or had some discussion on

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1 professional responsibility and advertising and
2 looking at what age group do we advertise to and the
3 FDA's responsibility at least in the content of
4 advertising.

5 I took notes this morning. There are many
6 more suggestions. I will give them to the panel and
7 I'm not going to continue. Some of them are repeats.
8 One suggestion in particular came from a physician
9 group which I thought was interesting.

10 The physician was a board certified plastic
11 surgeon who said, "I would like to see a brief concise
12 physician training designed by physician experts that
13 was required before their ability to purchase any
14 products. This would include continuous update on
15 clinical trials and availability of patient education
16 resources, etcetera." His comments were that this has
17 been done for other devices and is mandatory for all
18 physicians who wish to purchase the devices.

19 I believe the challenge that lies ahead of
20 us is not only in developing an adequate product but
21 in providing an entrepreneurial nontraditional
22 approach to get information into the hands of

1 consumers. I also believe in my years in healthcare
2 that the physician/patient relationship is of utmost
3 importance. No one would certainly want to put their
4 life in the hands of someone that they did not trust.

5 I think we need to be realistic about the
6 nature of human relationships. We have highly skilled
7 physicians that do not have good communication skills.
8 We have some physicians that may not be good teachers.
9 We have some physicians that may be biased, as well as
10 some patients that are not good listeners. They are
11 selective listeners that have high anxiety especially
12 after breast cancer surgery that oft times clouds
13 their ability to be a good listener and absorb
14 information.

15 We have some patients who do not care to
16 learn at all. I think the one thing that we can all
17 agree upon is that the majority of physicians and
18 patients do want a positive relationship and good
19 communication.

20 I think we all agree upon the fact that
21 consumers today are more savvy and have increasing
22 access to multimedia. Interestingly enough successful

1 industry knows how to reach their customers and
2 measure outcomes of their effectiveness in both
3 content and process. Otherwise, they wouldn't be in
4 business. I think we in healthcare need to be able to
5 do likewise. Thank you.

6 DR. WHALEN: Thank you, Ms. Brinkman.

7 Are there any questions or comments?
8 Obviously as an educator you presented it so perfectly
9 that we don't need to ask any questions.

10 MS. BRINKMAN: Oh, yes. Well, it's not
11 anything you probably didn't know.

12 DR. WHALEN: I would then like to ask that
13 Mr. Stephen Rhodes do the FDA presentation at this
14 time.

15 DR. RHODES: Good afternoon. I am Stephen
16 Rhodes and I am the Chief of Plastic and
17 Reconstructive Surgery Devices here at the FDA. The
18 panel has heard from patients about the importance of
19 making an informed decision and breast implant
20 surgery. You have heard from the manufacturers about
21 their process and patient**information labeling for
22 women.

1 I'm going to summarize the agency's history
2 in assisting women to make informed decisions and will
3 ask you questions that will help us to assure that
4 patients get the right information in the most
5 appropriate format to make informed decisions.

6 The FDA has published two Federal Register
7 Notices on patient information for women considering
8 breast implant surgery. Due to the high number of
9 inquiries that the agency gets each year from patients
10 either with implants or considering implant surgery,
11 the agency has also published a breast implant
12 Consumer Handbook which is updated regularly.

13 I'll summarize briefly the kinds of
14 information that the agency has found of value to
15 include in the handbook. FDA has also developed draft
16 guidance for patient labeling for any type of medical
17 device and I will mention a few highlights that are
18 particularly relevant to women and saline-filled
19 breast implants.

20 Lastly, the FDA has drafted an outline of
21 patient informed decision information and we have
22 questions regarding the content of this draft.

1 In 1991 FDA published a Notice in the
2 Federal Register to promote the dissemination of
3 information on risks associated with saline-filled
4 breast implants. The Notice said that the FDA will
5 consider breast implants misbranded if their labeling
6 does not provide adequate written information to
7 patients on the risks associated with these devices.

8 The Notice said that such information should
9 be written so as to be easily comprehensible to most
10 patients prior to scheduling the implantation so that
11 patients have sufficient time to review the
12 information and discuss it with their physicians.

13 To satisfy these requirements the Notice
14 required that patient risk information must set out
15 the known, suspected, and potential risks associated
16 with the implantation of breast implants.

17 In addition to the general risk associated
18 with any surgical procedure such as infection, the
19 Notice stated that patients should receive information
20 on local complications such as capsular contracture,
21 rupture, and changes in nipple and breast sensation.

22 The Notice said that in addition to these

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1 numerous, patients should receive information about
2 the unanswered questions regarding the risk of longer
3 term systemic complications, autoimmune disease being
4 an example.

5 Then in 1994 FDA solicited comments from
6 health professional groups, consumer organizations,
7 and manufacturers of saline-filled implants on
8 updating the patient risk information. In 1995 FDA
9 published another Notice in the Federal Register
10 announcing the availability of a patient risk
11 information sheet entitled, "Information for Women
12 Considering Saline-Filled Breast Implant."

13 The manufacturers of these implants at the
14 time, McGhan Medical and Mentor Corporation, agreed to
15 send a Dear Doctor letter to their physician customers
16 to remind them of the importance of providing this
17 information to all perspective patients.

18 The Notice also ensured that all saline-
19 filled breast implants include the revised patient
20 risk sheet in their packaging. The updated sheet had
21 information of the most common risks such as
22 deflation, capsular contracture, and interference with

1 breast cancer detection.

2 The information sheet included discussion of
3 the known risks of saline breast implants such as
4 additional surgery and shifting of the implant and
5 unknown risks such as autoimmune disease, breast
6 feeding, and candor.

7 Additionally, in response to a large number
8 of patient inquiries that the FDA was receiving
9 directly, the agency developed a Consumer Handbook for
10 all types of breast implants, saline filled, gel
11 filled, and alternative fillers.

12 The handbook is available in hardcopy and on
13 the Internet. The handbook explains the availability
14 and regulatory status for breast implants. It is
15 information on both augmentation and reconstruction
16 surgery procedures and a summary of the risk benefit
17 factors to weigh when considering whether to have the
18 surgery. The handbook has a section on patient risks
19 similar to the risks in the patient information sheet.

20 The handbook also has information on special
21 medical and physical considerations that patients
22 should discuss with their physicians such as changes

1 in the physical properties of the breast, movement or
2 discomfort of the implant on lying down, and changes
3 in the appearance of the breast such as unevenness or
4 shifting.

5 It includes other considerations to discuss
6 with a physician such as if a woman smokes, drinks
7 alcohol, takes medications, past medical history, and
8 effects of chemotherapy on the implants.

9 The handbook has a section on how serious
10 problems are reported to the FDA and summarizes the
11 number of adverse reaction reports the agency has
12 received on breast implants. Although reporting by
13 physicians or other health professionals is preferred,
14 a woman may report any serious problem directly to the
15 FDA through the Medwatch Program.

16 The handbook also has a section on
17 Frequently Asked Questions such as what information
18 should a patient obtain for her records. As an
19 example, it suggests patient information sheet, the
20 manufacturer sticker, package insert, informed consent
21 form, and insurance coverage if a breast cancer
22 patient.

1 Patients want to know how long an implant
2 will last and how to properly examine her breasts. In
3 addition, women frequently ask whether regular
4 mammograms are needed and if there is a test to detect
5 silicone in the body or determine whether an
6 individual is sensitive to silicone. The handbook
7 also advises women what to do if they are asking
8 whether their implants should be removed.

9 The FDA has also developed guidance on
10 patient labeling in general for medical devices. It
11 is available on the Internet and has been provided to
12 the panel. The draft guidance discusses many of the
13 issues covered in the two Federal Register Notices on
14 patient labeling and in the template that I will
15 present next to you.

16 However, it also stresses other issues that
17 we consider important for patient labeling including
18 information on expectations of the surgery,
19 expectations of the device, and information about
20 alternatives to the device. The draft guidance
21 suggest a stematic and form^{al} pretesting of the target
22 audience's reaction to the patient labeling content

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1 and format by conducting individual indepth
2 interviews, focus group interviews, and self-
3 administered questionnaires.

4 You all were provided with copies of this
5 outline so I'll read it to you briefly. There is an
6 introduction section. Based on the information
7 currently available, FDA has distilled the information
8 to assist patients in making an informed decision into
9 this template. In addition to the public comments you
10 have heard today, I would like you to consider how to
11 best inform women.

12 After I go over this template, we'll ask you
13 five panel questions. the first section is just a
14 discussion of the purpose of the patient information,
15 brief background on breast surgery, and a brief
16 description of the implants.

17 The next section in the template is a
18 section on which patients are eligible for the implant
19 and describes the purpose of the device, a description
20 of each indication, all applicable contraindications,
21 and all applicable warnings and precautions.

22 The next section is a description of the

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1 actual surgery including description of the surgery
2 and alternative procedures, differences in procedures
3 for each indication, and the importance of a hearing
4 to postoperative care regimen.

5 It goes on to have a description of the
6 recovery period and signs of potential problems and
7 options if dissatisfied with the cosmetic outcome. It
8 has a section on the summary of clinical results which
9 would be a description of the studies conducted,
10 patients enrolled, summary of the complication safety
11 data as ratified by indication.

12 Then followed with a section on potential
13 risks including general risks associated with surgery,
14 specific risks associated with breast implants, and
15 epidemiology literature on the long-term risks such as
16 cancer and CTD.

17 Lastly, a section on additional information
18 which would be a discussion of a warranty, if
19 applicable; index/glossary for medical jargon; patient
20 assistance information including identification of the
21 Consumer Handbook and company contact information; and
22 the date of printing.

1 The next section is the actual questions for
2 the panel. Shall I go on to the questions or would
3 you like to have a discussion?

4 DR. WHALEN: If acceptable to you, we'll
5 just have a brief discussion now and then this
6 afternoon we'll have the questions formally.

7 Are there any questions or discussion
8 points? Dr. Blumenstein.

9 DR. BLUMENSTEIN: In your list of things
10 that are there, I didn't notice anything about
11 insurance information. Is that planned? Any comment
12 on that?

13 DR. RHODES: I have noted that as something
14 to consider adding based on the discussions I've
15 heard. We hadn't planned on including that
16 information but I think that is important information
17 that a patient should be aware of. I don't know how
18 much -- we probably would need to get some real data
19 on what the insurance options are.

20 DR. BURKHARDT: Is there a current time or
21 has there been over recent* history an FDA review of
22 the promotional materials that the companies have

1 used?

2 DR. RHODES: Well, we do review the
3 promotional materials.

4 DR. BURKHARDT: Obviously the premarket
5 approval hasn't gone through yet but have you been
6 reviewing these materials and censoring them if
7 necessary?

8 DR. RHODES: Well, I think Dr. Witten
9 alluded to the fact that there is a shift when a
10 company goes from a 510(K) marketing approval to a PMA
11 approval. I think that we have a little more impact
12 on the labeling for PMA. I think that we will be
13 looking at and talking with the companies about all
14 their labeling and advertising.

15 DR. BURKHARDT: How does the FDA make
16 judgments about the material that is used in
17 commercial advertising? What is the process?

18 DR. RHODES: We have actually a group at the
19 FDA, Policy and Advertising staff in our Office of
20 Compliance that looks at the way marketed products are
21 being labeled and advertised. They get input from us
22 on the kind of claims and the scientific nature. That

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1 is a separate harm of the agency that actually is
2 responsible for regulating advertising.

3 DR. BURKHARDT: Thank you.

4 DR. WITTEN: Can I just add to that? I'll
5 just add to that in terms of your recommendations for
6 us, any recommendations you have on any type of
7 information that goes to patients whether it's the
8 informed consent, in particular, or any other kind of
9 information that they would provide describing the
10 risks and benefits of the product would be important
11 for us to hear.

12 DR. WHALEN: Ms. Brinkman.

13 MS. BRINKMAN: Who actually write this
14 information and how are these individuals selected?

15 DR. RHODES: The patient labeling?

16 MS. BRINKMAN: Informed decision making.
17 Any of this.

18 DR. RHODES: Well, the handbook is written
19 by the FDA. The patient labeling is written with the
20 manufacturers so it's the FDA and the manufacturers
21 who are writing the labeling. The FDA has ultimate
22 authority over the labeling but we work together with

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