

**EXHIBIT 45**

**Excerpts from Deposition of Keith  
R. McKennon**

**8/30/1994**

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**SILICONE IMPLANT FILE    Keith R. McKennon    8/30/94**

**PAGE 1 TO PAGE 312**

**Charlotte Smith Reporting, Inc.-Houston**

**(713) 523-5400**

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**CONDENSED TRANSCRIPT AND CONCORDANCE  
PREPARED BY:**

*Charlotte Smith Reporting, Inc.  
3730 Kirby Drive, Suite 909  
Houston, TX 77098  
Phone: (713)523-5400  
FAX: (713)523-6962*

Page 1

1 CAUSE NO. 92-16650  
 2 IN RE: \* IN THE DISTRICT COURT OF  
 3 \*  
 4 MASTER SILICONE IMPLANT FILE \* HARRIS COUNTY, TEXAS  
 5 \*  
 6 \* 157TH JUDICIAL DISTRICT  
 7  
 8 UNITED STATES DISTRICT COURT  
 9 NORTHERN DISTRICT OF ALABAMA  
 10 SOUTHERN DIVISION  
 11  
 12 IN RE: \* Master File No.  
 13 \* CV 92-P-10000-5  
 14  
 15 SILICONE BREAST IMPLANTS \*  
 16 PRODUCTS LIABILITY LITIGATION \* This Document Relates to:  
 17 (MDL-926) \* All Cases  
 18  
 19 IN THE UNITED STATES DISTRICT COURT FOR THE  
 20 DISTRICT OF MINNESOTA  
 21 THIRD DIVISION  
 22  
 23 IN RE: TMJ IMPLANTS PRODUCTS LIABILITY \*  
 24 LITIGATION \* 94-MD-1001  
 25  
 26 THIS DOCUMENT RELATES TO:  
 27 ALL ACTIONS  
 28  
 29 VOLUME 1 OF TWO VOLUMES  
 30  
 31 VIDEOTAPED DEPOSITION OF  
 32  
 33 KEITH R. MCKENNON  
 34  
 35 On August 30 and 31, 1994, the videotaped  
 36 deposition of the Witness in the above-styled causes  
 37 was taken at the instance of the Plaintiffs at the  
 38 offices of Kirkland & Ellis; 200 East Randolph Drive,  
 39 54th Floor; Chicago, Illinois, pursuant to  
 40 Stipulations of Counsel contained herein.

Page 2

1 These counsel present, representing their  
 2 respective client or clients in the cause of action  
 3 or causes of action in which he/she has filed an  
 4 answer, were as follows:  
 5  
 6 MR. JOHN M. O'QUINN  
 7 MS. JENNIFER ADAMS  
 8 O'Quinn, Korunsky, McAninch & Lammack  
 9 440 Louisiana Street, Suite 2300  
 10 The Lyric Centre Building  
 11 Houston, Texas 77002  
 12  
 13 Counsel for Plaintiffs,  
 14  
 15 MR. EDWARD F. BLIZZARD  
 16 Williams, Blizzard & McCarthy  
 17 440 Louisiana Street, Suite 1710  
 18 The Lyric Centre Building  
 19 Houston, Texas 77002-1824  
 20  
 21 Counsel for Plaintiffs  
 22  
 23 MR. STANLEY CHESLEY  
 24 Waite, Schneider, Bayless & Chesley  
 25 1513 Central Trust Tower  
 26 Cincinnati, Ohio 45202  
 27  
 28 Counsel for Plaintiffs  
 29  
 30 MR. JOHN JOSE  
 31 MR. MICHAEL J. HENRY  
 32 MR. RICKY BRANTLEY  
 33 Jose, Henry & Brantley  
 34 1300 Oil & Gas Building  
 35 300 N. Seventh Street  
 36 Fort Worth, Texas 76102  
 37  
 38 Counsel for Plaintiffs  
 39  
 40 MR. RALPH KNOWLES  
 41 MS. LESLIE J. BRYAN  
 42 Deffermyre, Shields, Canfield & Knowles  
 43 1600 The Peachtree  
 44 1325 Peachtree Street  
 45 Atlanta, Georgia 30309  
 46  
 47 Counsel for Plaintiffs

Page 3

1 MR. JUSTIN PRESAL  
 2 Fisher, Gallagher & Lewis  
 3 First Interstate Bank Plaza, 70th Floor  
 4 1000 Louisiana  
 5 Houston, Texas 77002  
 6  
 7 Counsel for Plaintiffs  
 8  
 9 MR. NYLES H. MALJAN  
 10 Kohn, Mast & Graf  
 11 1101 Market Street, Suite 2400  
 12 Philadelphia, Pennsylvania 19107-2924  
 13  
 14 Counsel for TMJ Plaintiffs  
 15  
 16 MS. PAMELA S. HOERSTER  
 17 Reynolds & Sydnor  
 18 One Riverway, Suite 1950  
 19 Houston, Texas 77056  
 20  
 21 Counsel for Plaintiffs  
 22  
 23 MR. ERIC J. O'BELL  
 24 Fayerd, Harris & Honeycutt  
 25 519 Florida Avenue  
 26 Beeham Springs, Louisiana 70126  
 27  
 28 Counsel for Plaintiffs  
 29  
 30 MR. MICHAEL P. MCGARTLAND  
 31 Chappell & Handy  
 32 1800 City Center Tower II  
 33 301 Commerce Street  
 34 Fort Worth, Texas 76102-4118  
 35  
 36 Counsel for Plaintiffs  
 37  
 38 MR. DAVID BERNICK  
 39 Kirkland & Ellis  
 40 200 East Randolph Drive  
 41 Chicago, Illinois  
 42  
 43 Counsel for Defendants,  
 44 DOW CORNING CORPORATION and  
 45 DOW CORNING WRIGHT CORPORATION

Page 4

1 MR. EUGENE A. SCHOON  
 2 Sidley & Austin  
 3 One First National Plaza  
 4 Chicago, Illinois 60603  
 5  
 6 Counsel for Defendant,  
 7 E. I. DU PONT DE NEMOURS & CO., INC.  
 8  
 9 MR. HERBERT ZARDY  
 10 MS. ROSARIA VIVO OMEN  
 11 Mayer, Brown & Platt  
 12 190 South LaSalle Street  
 13 Chicago, Illinois 60605  
 14  
 15 Counsel for Defendant,  
 16 THE DOW CHEMICAL COMPANY  
 17  
 18 MS. DEBRA M. BYRNES  
 19 McKenna, Storer, Rowe, White & Farrug  
 20 200 North La Salle Street  
 21 Chicago, Illinois 60601-1083  
 22  
 23 Counsel for Defendants,  
 24 BRISTOL-MYERS SQUIBB  
 25 COMPANY, MEDICAL ENGINEERING  
 26 CORPORATION, and SURGITEX, INC.  
 27  
 28 MR. MICHAEL V. KELL  
 29 Kell & Lynch  
 30 300 N. Woodward Avenue, Suite 212  
 31 Birmingham, Michigan 48009  
 32  
 33 Counsel for Defendants,  
 34 DOW CORNING CORPORATION and  
 35 DOW CORNING WRIGHT CORPORATION  
 36  
 37 MR. T. SCOTT ALLEN  
 38 MS. DEBBIE L. SALES  
 39 Cruse, Scott, Henderson & Allen  
 40 909 Fannin Street, Suite 1850  
 41 Houston, Texas 77010-1007  
 42  
 43 Counsel for Defendants/Surgeons

1 A Because I think by and large when somebody  
 2 writes another individual expressing a point of view,  
 3 they are writing somebody that they think has a  
 4 different point of view in order to convince them of  
 5 their point of view and the response would then  
 6 define the other point of view and the result of that  
 7 would be somewhere between the two points of view.  
 8 I think that's logical and most probable  
 9 and I concede what you say is possible, but you are  
 10 asking me for what I think the probability is and  
 11 that's what I said.

12 Q Any other reason other than the one you  
 13 have expressed why you reached that belief?

14 A No, sir.

15 Q Therefore, no one told you in the meeting  
 16 the contents of these disappeared written responses  
 17 so that that would help you get to that belief.  
 18 correct?

19 MR. BERNICK: I object to the  
 20 characterization.

21 Go ahead and answer.

22 A Nobody did, and it was my assumption that  
 23 those responses would do so.

24 Q What I am trying to find out among other  
 25 things in response to this question - and I will ask

1 it one more time - I am trying to find out: Can you  
 2 identify any person who told you what allegedly was  
 3 in these written responses?

4 A I cannot so identify.

5 Q Do you have any memory of anyone at the  
 6 meeting - you might not remember their name - but do  
 7 you have any memory of someone saying, "Here's what  
 8 was in one of those written responses"?

9 A I do not.

10 Q The people that make up the Management  
 11 Committee - I'm trying to find out what the  
 12 institutional memory of that group is.

13 Let ask it this way: How far back in time  
 14 would some of these people go in terms of their  
 15 institutional memory with Dow Corning? Back to the  
 16 Seventies?

17 A Many of Dow Corning's employees are very  
 18 long-term employees, and I would believe the answer  
 19 to that to be back to the Seventies.

20 Q All right.

21 THE WITNESS: I don't know what  
 22 protocol is here. I could do well  
 23 with just a little more water if there  
 24 is a way for that ---

25 MR. O'QUINN: (Interrupting) The

1 protocol is that this is not a torture  
 2 session. Hand me your glass.

3 MR. BERNICK: Let's take a  
 4 morning break here for a few minutes.

5 Are you at a good point?  
 6 MR. O'QUINN: Fine with me.

7 Let's take a break.

8

9 (AT THIS TIME A BRIEF RECESS WAS  
 10 TAKEN, AND THE PROCEEDINGS THEREAFTER  
 11 RESUMED AS FOLLOWS:)

12

13 (By Mr. O'Quinn)

14 Q Back to Exhibit 1.

15 A Exhibit 1, yes, sir.

16 Q I need to go back to Paragraph 1 again.  
 17 I will ask you to make sure I understand  
 18 this: Are you able to identify in any way any of the  
 19 memos you are referencing there in Exhibit 1 as "The  
 20 10 or so most painful"? Can you identify any ---

21 A (Interrupting) Paragraph 1? I'm sorry. I  
 22 was back to: "Hello."

23 You mean Paragraph 1 on Page 2?

24 Q Yes, sir.

25 A The numbered Paragraph 1?

1 Q Yes, sir. Can you identify in any way -  
 2 either by description or author or any way - any one  
 3 of these memos referenced there in Paragraph No. 1?

4 A I'm sorry. I cannot. I can't remember  
 5 which ones they were.

6 Q Okay. Now, would you - I'm going to  
 7 direct your attention now to a statement a little  
 8 above that on the same page where you say: "I also  
 9 believe there may be other actions Dow Corning can  
 10 take on behalf of implant users, and I will be  
 11 discussing these with my Dow Corning colleagues over  
 12 the next few days" - Do you see those words?

13 A I do.

14 Q Okay. Expand on that. For example, No. 1,  
 15 tell me at that point in time what were the other  
 16 actions that you believe Dow Corning could take on  
 17 behalf of the women? I assume by "implant users,"  
 18 you meant the women who had the implants.

19 A Yeah. I had a specific concern which  
 20 prompted this comment and this first page about that  
 21 group of women who for a legitimate medical reason  
 22 might need to have an implant removed or implants  
 23 removed and simply didn't have the financial  
 24 resources or the insurance resources to do so because  
 25 it seemed to me that was the one group of women in

1 this whole controversy who were left without a choice  
 2 about what they did. I didn't feel good about that,  
 3 frankly; but I didn't want to on my first day get  
 4 into the depth of that without understanding that and  
 5 expressing those feelings.

6 So, that's what prompted this comment.  
 7 Q Any other actions you were thinking about  
 8 at that time on behalf of the women?

9 A Gee, it was my first day; and that's as far  
 10 as my thought process had gone.

11 Q And with regard to the next part of that  
 12 sentence where you said you were going to discuss  
 13 these with my Dow Corning colleagues and expect to  
 14 discuss them publicly soon thereafter, did you do so;  
 15 and, if so, what were the results of that?

16 A Yes and yes. And that resulted in a Dow  
 17 Corning program specifically for the women I just  
 18 described.

19 Q Over the course of the next few days as you  
 20 discussed it, did you-all come up with any other  
 21 actions that Dow Corning should consider undertaking  
 22 on behalf of the women?

23 A Yeah. I believed and believe that Dow  
 24 Corning had and has a continuing obligation to do  
 25 Research & Development, to continue to develop the

1 science to take advantage of emerging information  
 2 from the scientific community, to support that  
 3 research where it is practical and possible.

4 Q All right.

5 A And I believe that's important for women  
 6 with implants.

7 Q All right.

8 A So, yes.

9 Q Okay. Anything in addition to those two  
 10 items?

11 A Those are the primary two that I think of  
 12 now.

13 Q I broaden this not only to what you were  
 14 thinking about on February 11th, but even after you  
 15 discussed actions that might be taken with your  
 16 colleagues at Dow Corning. Can you recall anything  
 17 of significance beyond the two items you have  
 18 mentioned?

19 A Those are the two ---

20 MR. BERNICK: (Interrupting) On  
 21 behalf of women?

22 MR. O'QUINN: Yes, on behalf of  
 23 women, right.

24 A Those are the two major items that I now  
 25 remember. I thought both of those were very

1 important, and I pushed them pretty hard.  
 2 (By Mr. O'Quinn)  
 3 Q All right. What, if anything, was done  
 4 with regard to the second item - the continuing  
 5 obligation to do research. I assume you are talking  
 6 about research at least in part that would concern  
 7 safety, right?  
 8 A Sure. I made that commitment publicly  
 9 shortly after this.  
 10 Q All right.  
 11 A I believe either at the FDA hearings or at  
 12 a subsequent press conference --  
 13 Q (Interrupting) So, my question is --  
 14 A (Interrupting) -- committing us to a  
 15 significant amount of research investments,  
 16 specifically to support that program.  
 17 Q Now, I want to focus on research that would  
 18 have something to do with safety or risk or things  
 19 like that.  
 20 A Okay.  
 21 Q What, if anything, did Dow Corning do in  
 22 that regard after you made this statement here?  
 23 A I pushed hard to get the commitment made,  
 24 which we did, in fact, make and continue to make --  
 25 Q (Interrupting) Who did you get the

1 commitment from?  
 2 MR. BERNICK: Hang on.  
 3 Were you done, Keith?  
 4 THE WITNESS: Actually I wasn't  
 5 quite done.  
 6 Q Well --  
 7 MR. BERNICK: (Interrupting) You  
 8 asked him what he did; and you've got  
 9 to kind of, you know, just hang on for  
 10 just a second. We'll get to the end  
 11 of the answer. They're not that long.  
 12 Q Okay. You pushed to get the commitment.  
 13 What else?  
 14 A I --  
 15 Q (Interrupting) We'll come back to who you  
 16 got it from. I'll try to remember that.  
 17 MR. O'QUINN: Somebody help me  
 18 remember that, now.  
 19 THE WITNESS: Fine, fine. I'll  
 20 help you if I can remember.  
 21 MR. BERNICK: Jennifer will help  
 22 you.  
 23 (By Mr. O'Quinn)  
 24 Q What else did you do?  
 25 A I announced that commitment.

1 Q All right.  
 2 A And I invited - what will I say - the  
 3 scientific community to recommend ways that money  
 4 could best be spent. And it is now being spent in  
 5 support of programs, many of which are epidemiology  
 6 studies, to determine, in fact, whether any causal  
 7 relationship of any kind, in fact, exists.  
 8 Q With regard to this particular program  
 9 after you got the commitment - I assume that's a  
 10 financial commitment, right?  
 11 A Yeah. The commitment I sought was from my  
 12 Dow Corning colleagues because I wanted everybody in  
 13 the outfit on board and fully supportive of this;  
 14 and, so, it was both financial and .  
 15 Q Otherwise?  
 16 A Personal, intellectual, emotional, or  
 17 however you want to describe it. I wanted all of us  
 18 very anxious to do that.  
 19 Q The financial component of the commitment  
 20 ended up being what?  
 21 A We committed to spend a minimum of  
 22 \$10 million and have spent more than that - I believe  
 23 more than that to date with a commitment that at  
 24 least is double that.  
 25 Q What do you believe has been spent to date -

1 double 10 million?  
 2 A No. I think 10-ish, but I'm away from it  
 3 now and I don't know exactly the amount.  
 4 Q The commitment, as you recall it, was  
 5 10 million; and you believe that's been spent by now?  
 6 A I do believe that.  
 7 MR. BERNICK: The original  
 8 commitment. I think he then said that  
 9 the commitment has also been changed.  
 10 Q What was the original commitment, and what  
 11 was the --  
 12 A (Interrupting) 10 million was the original  
 13 commitment.  
 14 Q What was the final commitment?  
 15 A I believe we have now said at least 20, but  
 16 it is not a commitment that I made. So, I am not the  
 17 best source.  
 18 Q Who made the commitment - the one you are  
 19 not the best source of?  
 20 A I'm sure it was Mr. Hazelton, who is the  
 21 current chief executive officer.  
 22 Q He took over after you left?  
 23 A He did.  
 24 Q What was his job before you left?  
 25 A President of Dow Corning Europe.

1 Q Once the commitment was obtained, who  
 2 became in charge of implementing that commitment?  
 3 A A major part of it was the responsibility  
 4 of a Dr. Ralph Cook.  
 5 Q Ralph Cook has what job inside what  
 6 company?  
 7 A Dr. Ralph Cook was at the time the head of  
 8 the - I don't know, I may not have the title exactly  
 9 right - but the head of the Epidemiology Group at Dow  
 10 Corning.  
 11 Q To the best of your memory, approximately  
 12 how far back does Cook's involvement with Dow Corning  
 13 go?  
 14 A He joined Dow Corning early in 1992, but I  
 15 can't remember the exact time.  
 16 Q Did anyone have the job of epidemiology  
 17 prior to Ralph Cook joining?  
 18 A We did. We did have epidemiologists on the  
 19 staff.  
 20 Q All right.  
 21 A Yes, sir.  
 22 Q How far back does that job function go?  
 23 A I don't know. It predates my knowledge of  
 24 Dow Corning.  
 25 Q When I asked you who you put in charge of

1 implementing this commitment, you said, "Ralph Cook."  
 2 And you seemed to say that kind of primarily. Was  
 3 there someone else involved?  
 4 A Well, we actually had three people involved  
 5 in that. Dr. LeVier, who I mentioned earlier, had  
 6 some involvement and a Dr. Harrison, who was the  
 7 company's chief medical officer, as well.  
 8 Q How long had LeVier been a part of Dow  
 9 Corning?  
 10 A I don't know, but quite a long time. He  
 11 was a long-time employee.  
 12 Q How about Harrison?  
 13 A He was there when I got there, but I don't  
 14 believe he had been there a long time. So, sometime  
 15 in '90, '91; and you got me.  
 16 Q Based on your answer so far, would it be  
 17 fair to say that you turned the responsibility for  
 18 implementing this commitment over to Cook --  
 19 A (Interrupting) To that group of three.  
 20 Q Those three people?  
 21 A It would be fair.  
 22 Q Okay. Let me ask it this way: As part of  
 23 this commitment to do research, was any of that  
 24 research to be basic testing of the implants or the  
 25 materials of the implants in animals or in any

1 (By Mr. O'Quinn)  
 2 Q I'm handing you Exhibit 2 (Tendering). Do  
 3 you recognize that to be - you can look at my copy  
 4 for a second - the text of your remarks to the FDA in  
 5 the latter part of February of 1992?  
 6 A (Reviewing document) I do.  
 7 Q Who wrote this?  
 8 A I wrote these remarks.  
 9 Q These are your words and your thoughts?  
 10 A These are my words and my thoughts.  
 11 Q Who helped you write it?  
 12 A I wrote this myself.  
 13 Q Would you take a look at the portion of the  
 14 sentence in the last paragraph, and I'll read it to  
 15 you.  
 16 MR. BERNICK: First page?  
 17 MR. O'QUINN: Yes.  
 18 (By Mr. O'Quinn)  
 19 Q "I believe my, and Dow Corning's,  
 20 overriding responsibility in this issue is to women  
 21 who are using our implant devices."  
 22 That is one of the things you told the FDA,  
 23 right?  
 24 A That's absolutely correct.  
 25 Q I assume by that, you meant you were

1 talking about the women who had already used the  
 2 devices; or are you talking about the women who were  
 3 going to be using the devices?  
 4 A Both.  
 5 Q At this point in time, it was still a  
 6 thought in your mind that you-all might start selling  
 7 them again?  
 8 A I hadn't reached the decision at that point  
 9 in time.  
 10 Q With regard to the ones who were already  
 11 using the devices, had them in their bodies, what  
 12 things, if any, did Dow Corning do to discharge this  
 13 responsibility under your watch?  
 14 A Yeah. We, as I have testified earlier in  
 15 this deposition, engaged on a very active research  
 16 program which continues to this day.  
 17 We initiated a program that I have also  
 18 described earlier in this deposition for women that I  
 19 believed might not be in the position to choose.  
 20 I worked very hard to communicate openly  
 21 with the public, with the media, with media sources.  
 22 We worked very hard to establish and maintain  
 23 effective communication relationships with the Food  
 24 and Drug Administration and, for that matter, with  
 25 many of our critics. I personally have spent time

1 talking with people on the other side, if you will,  
 2 of this issue and encouraged others to do that, as  
 3 well.  
 4 Those are the kind of things.  
 5 Q Did Dow Corning do anything to warn the  
 6 women that had implants in them that there was a  
 7 health issue about continuing to leave those implants  
 8 inside their bodies?  
 9 A Sir, with all respect, this was a raging  
 10 public controversy on the front page of, I think,  
 11 every newspaper in the United States. I think the  
 12 controversy at least was pretty well known.  
 13 Q I'll ask my question again.  
 14 Did Dow Corning do anything to warn the  
 15 women that had these implants in their bodies about  
 16 the health risk of leaving them in their bodies?  
 17 MR. BERNICK: I'm going to object  
 18 at this point in terms of the time  
 19 frame, kinds of - I mean, there is a  
 20 whole history here.  
 21 MR. O'QUINN: On his watch.  
 22 MR. BERNICK: On his watch.  
 23 MR. O'QUINN: 15 months he was in  
 24 charge. Did they do one thing to warn  
 25 the women on that subject?

1 MR. BERNICK: Go ahead.  
 2 A Again, I mean, let me repeat for you. This  
 3 was a full-blown public controversy. I don't think  
 4 anybody could have not known about the controversy;  
 5 so, in terms of informing women about the  
 6 controversy, that was done beyond any power that I or  
 7 we or Dow Corning had to do it.  
 8 You must understand, though, that I  
 9 believed then and believe now that these devices did  
 10 not represent an unreasonable health risk and, in  
 11 fact, filled an important medical need. I'm ready to  
 12 stand on that. So, when you say to me, "How come you  
 13 guys weren't out there doing a whole lot of warning  
 14 people." I'm prepared to say to you in my judgment  
 15 then and in my judgment now that what I just said is  
 16 true. So ...  
 17 (By Mr. O'Quinn)  
 18 Q Then Dow Corning did not itself give any  
 19 such warnings to women; is that correct?  
 20 MR. BERNICK: Again, I need to  
 21 object on the basis of time frame and  
 22 foundation.  
 23 Go ahead and answer if you can.  
 24 Q During the time you were the CEO, That's  
 25 the time period. Please answer my question.

1 A I believe the answer to your question, if I  
 2 understand it correctly, is no. I would just point  
 3 out so that there is no misunderstanding that the  
 4 Food and Drug Administration had already at this  
 5 point in time asked for a voluntary moratorium on  
 6 sale and use, which it later made permanent; so,  
 7 there was - I mean, all of that was well  
 8 disseminated and well known in the nightly news and  
 9 all the rest. It isn't quite clear to me what you  
 10 are after when you talk about disseminating.  
 11 Q I'll try one more time to be clear.  
 12 A Good. Good.  
 13 Q I'm not talking about what the FDA said,  
 14 I'm not talking about what the news media said.  
 15 A Fine.  
 16 Q I'm talking about what Dow Corning said.  
 17 A Dow Corning took no additional steps beyond  
 18 those that I have described.  
 19 Q All right. And in giving your rationale  
 20 for that, you made a couple of statements I need to  
 21 ask you about.  
 22 A Go for it.  
 23 Q You said in part the reason was that you  
 24 had decided there was an important medical need. Do  
 25 you remember you said that?

1 A I precisely do remember having said that.  
 2 Q Now, what is the important medical need to  
 3 a woman to have implants in her body?  
 4 A When I asked women at the time that very  
 5 question, I got two answers to that. One of them was  
 6 that reconstructive surgery patients found them  
 7 useful and very valuable in terms of that  
 8 reconstruction. The other answer I got from women in  
 9 this controversy - a great many, I should add - was  
 10 that "We think we have the right to make that choice  
 11 and we understand the trade-offs and that is our  
 12 choice to make. And for us, at least, they are an  
 13 important part of how we look and how we feel and  
 14 lots of other things and that has, for us, medical  
 15 consequences."  
 16 Q So, in your dictionary, the last thing you  
 17 described is an important medical need?  
 18 A I didn't - The combination of those  
 19 things, I considered to be an important medical need.  
 20 Q Let's put to the side just for a second so  
 21 that we can separate this out, the women who have had  
 22 breast cancer or for some reason they are using the  
 23 product. I'm not talking about those women. I'm  
 24 trying to see the way you use words and what they  
 25 mean to you.

## **EXHIBIT 46**

**Letter from claimant [redacted]  
dated 2/22/2005 submitted in  
response to SF-DCT letter stating  
that claimant was ineligible  
because of a release**

**TO: HONORABLE JUDGE DENISE PAGE HOOD**

**FROM:— REDACTED** -T

**DATED: FEBRUARY 22, 2005**

**Dear Judge Hood:**

**On approximately November of 1990 my wife had a mammogram. Two days later her Dr. Carol Martini called her with bad news. The mammogram showed a leakage on her left breast.**

**Dr. Martini then advised her to see Dr. Sharon Bushnell ASAP, a noted plastic surgeon in the area.**

**We immediately made an appointment with her the following week after Dr. Bushnell and a radiologist looked over the X-Rays they concluded it must be removed.**

**They told me the entire procedure would be approximately \$5,000., as it turned out it came to \$5,126.**

**I then called Dow Corning and explained my situation to them and also let them know that we were ingent, at the time and I had not worked for 15 years, due to my being 100% permanently and totally disabled service connected from the Korean War.**

**That was and still is my only income along with Social Security living month to month. They told me they would be happy to pay for the operation, if my wife, Sandra, signed a release. Within 2 weeks my wife received the release. I was concerned.**

**I immediately put a call into Judge Pointer, who at that time was in charge. Fortunately, or as it stands nor, unfortunately I was able to catch him in his chambers. I explained our situation to him and he told me in fact, very adamant about it. His words were, "Sign the release and get your wife's operation done.**

- 2 -

I then asked him if she signed the release would she still be eligible for the Class Action Suit and his answer was "Don't worry about it, it's no problem."

Several months ago we received a letter stating she was not eligible to receive restitution on her ruptured left breast, because she signed the release there no longer responsible.

This was quite a shock to both of us and after 14 years I did a little research.

I know it was a long shot, but I found out where Judge Pointer is and called him speaking with him on the phone, just 3 weeks ago. His answer was I can't say you and I can't say may after 13 to 14-years to try and remember this particular incident. I cannot blame him. I thanked him for his time.

It seems our only recourse is you Judge Hood, hopefully, you will understand how Dow took advantage.

I could go on and write 10 more pages of the way this entire situation has malfunctioned.

Yours In Truth  
Sincerely,

- - REDACTED -

- -

- REDACTED -

Enclosure

1. I submit two letters I wrote to the claim faculty haven't heard a word.
2. Letter of Acceptable.
3. Letter of Proof of Military.

**EXHIBIT 47**

**Letter from Dow Corning Wright to  
Dr. Lars Enevoldsen re claimant  
[redacted] dated 7/10/1992**

**DOW CORNING**  
**WRIGHT**  
P.O. BOX 100 • ARLINGTON, TN 38002

July 10, 1992

RECEIVED  
JUL 27 1992

LEGAL DEPARTMENT  
DOW CORNING CORPORATION

Lars Enevoldsen, M.D.  
1779 W. Yosemite Avenue  
Suite 104  
Manteca, California 95336

Re: Your Patient - [REDACTED]

Dear Dr. Enevoldsen:

This letter serves to confirm our conversation on June 17, 1992.

As we discussed, it is our company policy to assume financial responsibility for any reasonable, uninsured, out-of-pocket expenses related to the failure of our product due to its workmanship or materials. Reimbursement decisions are based upon evaluation of the removed, sterilized implant. Prior to making any claim payment, we would require Ms. [REDACTED] to sign a release.

In order to proceed, I will need to obtain a copy of Ms. [REDACTED] original and revision operative reports, and pertinent bills. I will also need to obtain her removed, sterilized implants for evaluation.

In an effort to expedite matters, I have enclosed an authorization for the release of Ms. [REDACTED] medical records. Please have Ms. [REDACTED] sign this release and return it me in the envelope provided. You stated you would retain a copy of the authorization to request the patient's medical records from her original surgeon. If I can be of assistance, please let me know.

If you have any questions concerning the above process, please feel free to call me at my toll-free number of 1-800-446-3845. Thanks for your patience!

Sincerely,



Rosalyn P. Wakefield  
Customer Relations Specialist

RPW:ai  
RW0259a

## **EXHIBIT 48**

**Letter from claimant [redacted]  
dated 5/11/2005 submitted in  
response to SF-DCT letter stating  
that claimant was ineligible  
because of a release**

May 11, 2005

Settlement Facility-Dow Corning Trust:  
P.O. Box 52429  
Houston, TX 77052

My name is Gracie.

My Dow Chemical implants were removed in 1992. RUPTURE. Without understanding what I was told to sign, I signed the document releasing Dow Chemical from all claims. Surgery would not be scheduled until all forms were completed, as part of the Removal Assistance Program. I was in fear of my life and wanted surgery as soon as possible. I signed. I was not aware, and it was not made clear to me that by doing so, it would bar me from participating in this, or any claim. I did not receive "one red cent". The \$7,500. went directly to the doctor. The doctor's address is on the form.

I did not receive the letter from the settlement facility in 2003 notifying me that I was not illegible to participate in the settlement, therefore, I have diligently complied with all requests. Filling out and returning every form, in a timely manner. I received a conformation card with claim # 0063852, (October 28, 1996). I have copies of all correspondence, medical and surgery dates, and certified mail receipts, verifying the Settlement Facility-Dow Corning received my information. I have a letter stating the receipt of a Participation form Proof of Manufacture, Rupture, Explant and Disease form. I was led to believe I was receiving compensation. I did everything I was asked. On August 17, 2004, I had not received a check. I emailed sfdct. The response was, "According to the information provided to us by Dow Corning, in the past you have signed a document that released Dow Corning from further liability, by signing this release, you are not eligible to participate in the settlement." Wow! What a shock. All these years and years of waiting. Now I am told I will not be included. Shame on you ! How can this happen? No. I will not allow myself to be treated in this manner. I object. I will continue to object.

My name is Gracie. I am a person.

A person deserving compensation for all the years of pain, worry and suffering.

I have been devastated by the notification of ineligibility to participate in the settlement. I am appalled Dow Chemical can turn away from me. I am still suffering. I am still in pain. I am scared.

PLEASE! PLEASE! Help me.

I am crushed by this. I feel I deserve to be compensated. The mental and physical pain are at times unbearable.

My name is Gracie.

I am a person. Not a number.

May 11, 2005 SID: 6181051

I had surgery, again, on November 2, 2004. After six months of sleepless nights, due to worry. Unending battery of tests. Numerous ultrasounds, and a MRI, I was once again on the operating table. General anesthetic. More risk to my frail and tired body. Two masses were removed. Silicone. Silicone. Silicone. I am still recovering. Still in pain. A continual state of worry. I this ever over? I deserve compensation. My family deserves compensation for all the years of standing by my side. Not only the monetary loss, but the mental strain is unmeasurable. Will I die before I see justice? I pray not.

My name is Gracie.  
I am in pain. I am always in pain.

Please include me in the settlement. I faith that you will make the only fair and humane decision and rule in my favor.

My name is Gracie. I am a person.  
I am not a number. I deserve to be recognized as a valid claim..  
I did not know what I was told to sign. My life was at stake.

-- REDACTED --

Signed under penalty of perjury  
With a heavy and broken heart

-- REDACTED --

07/12/45

Claim # 0063852

enclosures: 4  
cc: Deborah E Greenspan  
Claimant' Advisory Committee


## **EXHIBIT 49**

**Claim Report Form dated 6/17/1992 regarding a call with Dr. Lars Enevoldsen regarding claimant (name redacted). This document was produced by Dow Corning as part of its objection to the individual claim.**

Notice to  Date: 6-17-92

### CLAIM REPORT FORM

Report Made By: Doctor,  
Address: \_\_\_\_\_  
Phone: \_\_\_\_\_

Patient's Name:   
Address: \_\_\_\_\_  
Phone: \_\_\_\_\_

Doctor's Name: <sup>(revision)</sup> Lars Enevoldsen, MD  
Address: 1779 W. Yosemite Ave, Ste 104, Manteca, CA 95331  
Phone: 209-825-2025

Hospital (if any): \_\_\_\_\_

Product: Gel Mammary  
Size: \_\_\_\_\_  
Cat. No: \_\_\_\_\_  
Lot No: \_\_\_\_\_

Date of Original Surgery \_\_\_\_\_

Date of Re-Op/Occurrence \_\_\_\_\_

Description of Event: Alleges rupture & bleeding  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Device Return Requested:  Yes  No

Why? \_\_\_\_\_

Claim Report Made:  Yes; To: Gerry Hoas Date: 6-18-92  
 No; Why: \_\_\_\_\_

Comments: Wants reimb for removal & reimplanting  
(Add'l product info to be provided)

CALLER/WRITER INFORMATION RECORD

Name: Lars Enevoldsen, MD DATE: 6-17-92

Occupation: Doctor  
(patient, doctor, relative, other)

Address: 1779 W. Yosemite Ave, Ste 104,  
Merced, CA 95336

Telephone: 209-825-2025

Specific Concerns: Remid implant, one suspicious & one "bleeding badly"  
Pt is uninsured & wants to know what we can  
do to assist pt. Said pt was implanted prior to '86.  
Told him std claims process would probably best serve pt

Where did they hear about issue? \_\_\_\_\_  
(Doctor) (Media) (Other)

Caller requested:

- \_\_\_\_\_ Research (rat and human studies) \_\_\_\_\_ (specify study)
- \_\_\_\_\_ Reassurance because they are considering implant/support materials
- \_\_\_\_\_ Directions for returning implants because they are discontinuing procedure (hospital)
- \_\_\_\_\_ General information/brochures \_\_\_\_\_ (specify)
- \_\_\_\_\_ Other \_\_\_\_\_ (specify)

COMMENTS:

Pt. [REDACTED]

Cad # / Original, sees are being requested for  
Lot # / implanting surgeon

Told dr I would send Hr w/author for med recs.  
Said he would send author w/ his ops & implants.  
(pat calls) Should not have problem getting docs from original  
surgeon.

**EXHIBIT 50**

**Dow Corning Wright letter to Lars  
Enevoldsen, M.D. dated 10/5/1992**

**DOW CORNING**  
**WRIGHT**  
P.O. BOX 100 • ARLINGTON, TN 38002

October 5, 1992

Lars Enevoldsen, M.D.  
1779 W. Yosemite Avenue, Suite 104  
Manteca, CA 95336

Re: [REDACTED]

Dear Dr. Enevoldsen:

As we discussed, enclosed is a release for the amount of \$7,500.00 for Ms. [REDACTED] signature. Please have her sign the release in the presence of a witness and return it to me in the envelope provided. Once I receive the signed release, I will have our check issued for \$7,500.00 made payable to Ms. [REDACTED]

Should you have any questions, please do not hesitate to call me at my toll-free telephone number of 1-800-238-7188. Thank you for your cooperation.

Sincerely,



Rosalyn P. Wakefield  
Customer Relations Specialist

RPW:sjb

Enclosures

RPWA0030



**EXHIBIT 51**

**DCC 242010177 - 242010180**

## PREFACE

Following a request from the Corporate Legal Department and the Mammary Implant Issue Management Team, this two volume historical Chronology Of The SILASTIC(R) Brand Mammary Prostheses & Tissue Expanders has been assembled under Attorney/Client Privilege.

This document has been prepared by the Director of the Dow Corning Service To Medical Research(R), Arthur H. Rathjen. Information has been gathered from the scientific and medical literature and from various individuals and departments within Dow Corning Corporation and Dow Corning Wright, Arlington, Tennessee.

Today's scientific literature referencing silicone in medicine include textbooks that describe, in infinite detail, many polymeric materials currently being used in surgery, general medicine and pharmacology.<sup>1-7</sup> When added to the medical journals published around the world, the resource for references is almost beyond comprehension.

There appears to be a difference of opinion as to the first reported use of silicone as a medical material. An artificial urethra was reported in 1950.<sup>8</sup> In the early 1950s John Holter from Bridgeport, Pennsylvania contacted Dow Corning for help in supplying silicone rubber tubing for a newly developed hydrocephalus shunt.<sup>6</sup>

It appears that dentistry might take credit for the first reported application using silicone. In 1941, Dr. L.I. Grossman from the University of Pennsylvania School of Dentistry published on his experience with an antibiotic silicone paste for root-canal therapy.<sup>9</sup> "A low viscosity silicone fluid was used as the carrier of the reagents. The low volatility of the silicone oil, its physiological inertness, and its lack of water solubility are factors that were useful in this application."<sup>3</sup>

It was, however, the decades of the 1950s that witnessed the increased flood of medical requests for Dow Corning silicones. By the mid 50s the demand for silicone in its varied polymeric states became so great that Mel Hunter Ph.D., Director of Research asked Dr. Rob Roy McGregor from the Mellon Institute in Pittsburgh to join Dow Corning in Midland and handle this new phase of silicone applications. Silas Braley, also from Mellon, joined Dow Corning and McGregor to further investigate the medical usage. By 1959 the magnitude of requests became so great that Dow Corning formed the Center for Aid to Medical Research. McGregor was appointed Director and Braley, Executive Secretary. Dr. Ethyl Mullison, a Midland resident joined the center soon after the start-up.

DCC-242010177

★

"While the company had not intended to get into the medical products field, and could not foresee a rosy future for it, Dow Corning felt an obligation to continue what it perceived as an important contribution to medical science."<sup>5</sup>

So it is that in 1991, thirty-three years later, Dow Corning finds itself as the internationally recognized leader in medical products made from silicones.

In 1960, an already world renowned surgeon, Thomas D. Cronin from Baylor in Houston, working with one of his residents, Frank J. Gerow approached the Dow Corning Center for Aid to Medical Research inquiring about the use of silicone to design a breast augmentation device.

During the 1950s augmentation of the female breast was attracting interest among the plastic surgery community. The early implants (50s) were sponges of various materials, but they were very liable to infection and extrusion and even if retained became hard and shrunken because of the ingrowth of fibrous tissue. Some surgeons attempted to overcome this problem of fibrosis and shrinkage by enclosing the sponges in polyethylene. Edgerton and Arons reported their experiences in the medical literature.<sup>10,11</sup>

For two years Dow Corning's Center for Aid to Medical Research worked on developing a silicone elastomeric envelope filled with a silicone gel. In March, 1962 a gel filled prosthesis, with a backing of Dacron-mesh for fixation, was implanted in a post subcutaneous mastectomy patient.<sup>12</sup>

In 1963 Edwards reported on his experience using a silicone foam prosthesis covered with an impervious layer of silicone paste to seal it, and bonded to this was a layer of Teflon felt for fixation.<sup>13</sup> This served fairly well until the development of Dr. Cronin's silicone gel filled implant.

At about the same time (early 60s), Drs. Herb Conway and Dicron Goulian at the Cornell Medical School in New York City reported on their experience using Dow Corning R.T.V. for breast augmentation, but this also did not survive the silicone gel type implant developed by Cronin and Dow Corning.<sup>14</sup>

In 1963, Dow Corning completed the medical products plant in Hemlock, Michigan and commercialization of the SILASTIC(R)<sup>Brand</sup> Mammary Prosthesis was transferred from the research laboratories in Midland to this new manufacturing facility.

★

DCC-242010178

The two volume "Chronology of the SILASTIC(R)<sup>Grand</sup> Mammary Prostheses & Tissue Expanders" contains copies of mailing pieces, package enclosures, advertising copy and a year by year record of product design and material modifications.

Aves Advertising from Grand Rapids, Michigan began working for Dow Corning Medical in 1971. They have supplied me with originals or copies of everything they prepared during their 20 year association. From Dow Corning Wright in Arlington, Tennessee I have included copies of all breast implant literature beginning in 1986 when Dow Corning Wright started to prepare their own advertising and direct communications to the plastic surgery community.

Arthur H. Rathjen,  
Director  
Dow Corning Corporation  
Service To Medical Research  
Midland, Michigan 48686

September 11, 1991

DCC-242010179

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## REFERENCES

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DCC-242010180

**EXHIBIT 52**

**DCC KKA 033898 - 033901**

*Handwritten initials*

November 1, 1991

TO: IMPLANT ISSUE MANAGEMENT TEAM

Kerm Campbell	Barie Carmichael
Jim Jenkins	Bob LeVier
Forrest Stark	Harvey Steinberg
Gary Anderson	Darr Hayes
Burnett Kelly	Bob Rylee
Jim Clary	Greg Thiess
Bob Grupp	

FROM: FAYE GORMAN

SUBJECT: SUMMARY OF CONGRESSIONAL ACTIVITY ON  
IMPLANTS -- REPORT #2

Below is a list of the Congressional contacts that have been made since my October 18th report. For more detailed information about all the visits made to-date, you can refer to the attached information.

In summary, 27 visits have been made since the October 18th report, bringing our total to 34 visits with Members of Congress and/or their staffs. Our efforts are continuing.

Gold and Liebengood, a lobbying firm affiliated with Burson-Marsteller, has been excellent to work with and they have provided us with access to numerous of these offices. (Our thanks to Marty Gold, Bill Ratchford, Chuck Merin and Patti Jarvis at Gold and Liebengood.)

Attached are copies of the letters we've received to-date as well as copies of some of the letters sent to constituents by Members of Congress on the issue in response to a contact or letter.

-----

Congressman Carl Pursell (D-MI) Follow-up needed  
 Senator Mitch McConnell (R-KY) Sent letter to FDA  
 Congressman Robert Torricelli (D-NJ) - Circulating an excellent "Dear Colleague" letter to all House members soliciting signators -- 14 to-date  
 Congresswoman Jolene Unsoeld - Signed Women's Caucus letter to FDA  
 Congressman John Conyers (D-MI) - Will not be active on the issue  
 Senator Dave Durenberger (R-MN) - Continuing to study the issue  
 Senator Jim Jeffords (R-VT) = Needs constituent follow-up  
 Majority Leader George Mitchell (D-ME) - Studying the issue  
 Congressman Edolphus Towns (D-NY) Will not be active

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DCC-KK A033898

Page Two

Congressman Joe Skeen (R-NM) - Probably will not be active on the issue  
Congressman Dick Armey (R-TX) - Letter to FDA probable  
Congressman Norm Lent (R-NY) - Probably won't be active  
Senator Chris Dodd (D-CT) - Needs to hear from pro constituents  
Congresswoman Olympia Snowe (R-ME) - Signed onto Women's Caucus letter to FDA  
Congressman Bill Zeliff (R-NH) - Offered to try to get all Members of the Freshman Class to sign onto a letter  
Congresswoman Rosa DeLauro (D-CT) - Needs to hear from constituents  
Congressman Dennis Eckart (D-OH) - Letter probable  
Senator Tom Harkin (D-IA) - Won't be involved on issue  
Senator Claiborne Pell (D-RI) - Won't be involved on issue  
Congressman Don Payne (D-NJ) - Won't be involved on issue  
Congressman Bill Richardson (D-NM) - Opposed to manufacturers position; may try to get into the press  
Congressman Peter Kostmeyer (D-PA) - Opposed to manufacturers position; may try to get into the press  
Congressman Mike Synar (D-OK) - Won't take any action on issue  
Congressman Dan Schaefer (D-CO) - Agreed to send a letter to FDA  
Congressman Bill Dannemeyer (R-CA) - Already sent a letter to FDA along with two others from CA delegation  
Senator Strom Thurmond (R-SC) - Looking at the issue; needs follow-up

-----

If you have any questions on any of our contacts, please let me know.

Best regards,



ODC115861 4

DCC-KK A033899

Page Two

Mtg. with Craven Crowell, Senator Sasser's AA

Spokespersons: Jeff Dixon, Faye Gorman, Joy Murray, Gene Jakubczak

Excellent meeting; obvious that he'd done his homework on the issue. Committed to write a letter to FDA from the Senator and to making a call to Dr. Jim Benson (we provided his name when asked). Key point that made a difference appeared to be the 600 jobs. Plastic surgeons were also in today.

Mtg. with Charlotte Hayes, Senator Gore's AA

Spokespersons: Jeff Dixon, Faye Gorman, Joy Murray, Gene Jakubczak

Their LD attended the briefing at DCW several weeks ago but handed the issue over to Charlotte. Seems he felt uncomfortable with the issue. She'd also obviously done her homework and was a very sharp lady. Committed to briefing the Senator and the LD on the issue. A letter to the FDA was a definite possibility but she couldn't make a final commitment.

OCTOBER 9TH

Mtg. with Scott Frey, Congresswoman Mary Rose Oaker's

Spokespersons: Jeff Dixon, Faye Gorman

Had a chance to tell the Congresswoman on her way out what issue we were there about and she expressed her concern about the issue. Good meeting with Scott. Seemed to feel that they would write a letter to FDA pushing for reasonableness on the issue not a ban. Mentioned that the best "in" to members of the Women's Caucus was through the breast cancer support groups. He mentioned that Y'Me was coming in to meeting with him that afternoon at 3 p.m. FOLLOW-UP: Oaker may be willing to hold a hearing on the issue for the Congressional Women's Caucus.

Mtg. with Vicki Otten, Senator Simon's AA

Spokespersons: Faye Gorman, Jeff Dixon

Another staff member informed us that she was seeing two plastic surgeons later that day. Seemed receptive to the issue. Said Mrs. Simon was very interested in breast cancer issues. Probably needs a follow-up call.

Mtg. with Ed McDonald and Blaine Merritt, Congressman Coble's AA and LA

Spokespersons: Faye Gorman, Jeff Dixon

Listened intently and asked a lot of questions. We were the first ones they'd heard from on the issue. Seemed to be willing to seriously consider sending FDA a letter. Needs a phone call follow-up. FOLLOW-UP: On 10/16, Coble agreed to send a letter to FDA this week; heard from a Dr. in district.

QDC115863

DCC-KK A033901

**EXHIBIT 53**

**Dow Corning letter to Dr. John Dean  
dated 9/4/1992 re Bonnie Boyette**

**DOW CORNING**  
**WRIGHT**

P.O. BOX 100 • ARLINGTON, TN 38002

September 4, 1992

VIA FACSIMILE

John Dean, M. D.  
Attn: Michelle  
16777 Medical Center Drive  
Baton Rouge, LA 70816

I have spoken with Ms. Boyette and she asked that I fax this letter to confirm the options we have available for patients. We would like to assure you that Dow Corning is concerned with patients who use our products and we do stand behind them.

Our first option is our Breast Implant Removal Assistance Program which provides up to \$1,200.00 towards the cost of the removal if it is medically necessary and the patient is financially unable to pay. There is no release required. To apply for this assistance, please call 1-800-442-5442. Enclosed is a copy of the information sheet for this program.

The second option is to file a claim with my office. This payment policy is based upon an examination by our laboratory of the removed implants. If it appears that the implant failed as a result of our materials or workmanship, we will assume financial responsibility for the reasonable, uninsured, out-of-pocket expenses incurred by the revision surgery. Prior to making any claim payment, we would require Ms. Boyette to sign a release. Our toll-free number is 1-800-446-3845.

If she wishes to initiate a claim, we will need to obtain the removed sterilized implant, original and revision operative reports, and documentation of the out-of-pocket expenses. I have provided a medical authorization for Ms. Boyette to sign allowing us to obtain the medical records.

Should Ms. Boyette have questions or concerns about her implants, our Implant Information Center can be reached at 1-800-442-5442. They can supply her with a Patient Information Packet.

Due to the large number of telephone calls we are receiving, I know it can be difficult and frustrating trying to reach us. We do apologize and want to assure you that we are concerned about Ms. Boyette's well-being and will make every effort to respond to you both as quickly as possible.

Please do not hesitate to call me should you have any questions. I can be reached at 1-800-446-3845.

Sincerely,



Patricia A. Barnes  
Customer Relations Specialist

PAB:jk  
PAB0451  
Enclosure

**EXHIBIT 54**

**Dow Corning Wright letter to Dr.  
Lars Enevoldsen dated 11/1/1992**

**DOW CORNING**  
**WRIGHT**  
P.O. BOX 100 • ARLINGTON, TN 38002

November 2, 1992

NOV 09 1992  
LEGAL DEPARTMENT

Lars Enevoldsen, M.D.  
1779 W. Yosemite Avenue, Suite 104  
Manteca, CA 95336


Re: Gracie Harper

Dear Dr. Enevoldsen:

Enclosed please find Dow Corning Wright's check in the amount of \$7,500.00 in settlement of Gracie Harper's claim.

We appreciate being given the opportunity to stand behind our products. If we can be of any further service, please let us know.

Sincerely,

  
Rosalyn P. Wakefield  
Customer Relations Specialist

RPW:sjb

Enclosure

RPWA0023