scar tissue surrounds the implant. Dow Corning, as a manufacturer, does not recommend this procedure be done. If there is enough pressure applied to break up the scar capsule, it can then be enough pressure to rupture the implant.

If you had cancer would you have one of these? Would you ever have an implant?

WOMAN: Did you talk about [mixed verbal]

PAULETTE: No that's when she came in. Again, just let me finish the cancer, turn it around, turn it back to them just as quickly as you can. How safe are these implants? Are [undiscernible]. Safe does not mean risk free. These are man made devices, man made devices are known to fail. Is there a medical devices? Medical devices have failure rates. Be very patient specific. I wouldn't advise you to say patient specific to them, no, what I would advise you to say is that a lot of this depends on your medical history, what do you do for a living? what do you do for recreation? how tall are you? what do you weigh? all of those things enter into the life of the implant and the safety of it. At that point I might ask her, have you ever read a package insert. If she says no [low verbal] which includes the package insert, which you may want to do.

How many of these implants are rupturing any way? This is very important, this has to be stated exactly like this and not deviate from this in any way ....

# IMPLANT HOTLINE PROGRAM TRAINING SESSION MARCH 25, 26, 27, 1992

### TAPE 6 SIDE B

)

WOMAN: ...a lot of variables depending on their life style and their health pattern that the doctor really needs.

PAULETTE: I think that people need to know that safe doesn't mean risk free. It does not mean that there are no risks involved at all. Of course there are. I believe that there is a 4% acceptable failure rate for medical devices.

WOMAN: I won't even write that down I don't to misquote it.

How many implants have ruptured?

PAULETTE: Based on our returns, the rate of rupture is one tenth of one percent.

WOMAN: Based on what?

PAULETTE: Our returns.

The thing I want you to understand about that and the reason that it has to be quoted specifically is that there probably are more ruptures out there, however, this is based on our returns. These are the hard facts that we have. Sometimes a rupture occurs and the doctor removes the implants and puts another set of implants in and never sends them back and we don't see it and we don't know about it. So it is based on our returns. We also know that are probably some silent ruptures out there, where the [undiscernible] and they don't even know it is even ruptured. So it has to be ... these are the only hard facts we know based on our returns.

WOMAN: How many returns did we get.

PAULETTE: I don't have our quote to give you on that and we wouldn't quote something like that on the phone. If someone asks you how many lawsuits does Dow Corning have, the answer to that is I have no idea ... I don't work in the Legal Department. But those are the kinds of things that we certainly would not want to advertise. [low verbal] and if they say well it's probably quite a number, you can say again, I don't work in the Legal Department so I don't really know what is going on over there, I'm just here to give out information. Then they'll come back with well this is information and you are not giving it to me, again I don't work in Legal.

WOMAN: If they got really insistent on that, I mean if this was a fishing, tricky call like from the FDA or a plaintiff's attorney or something, we do then refer them to Customer Service or Customer Relations.

PAULETTE: No that is not a Customer Relations call at all. If they get belligerent, if they get really persistent, you may want to refer them to the Legal Department. Would you like to call the Legal Department [low verbal] is used to that. We very seldom do that but if it is someone who isn't going to give up on that, there not going to get the answer there either but you have done what you can do. They are at the Legal Department and they will very bluntly tell them that that is not information that they share. I can understand that.

)

How about my joints are swelling and I am to tired to do anything? I just don't know what to do with my life and the last six months, I have just been in so much pain, and I know it is all caused from my implants. So what is happening to me. The first thing out of my mouth will be "have you seen a doctor? have you addressed any of these concerns with your doctor? what did he say? perhaps you need to see a doctor and he could help you."

WOMAN: If you say to them "have you seen a doctor" and they say "yes", "what did he or she say" and they go through this ahhhhhh and they say is that true.

PAULETTE: Then your answer to that is that I am not a doctor. Your doctor knows your medical history, he knows you, so obviously he can diagnose what is going on with you, I cannot do that. I am voice on the other end of the phone, I can't see you, I don't know you, I don't know anything about you. He is the expert in this.

WOMAN: If they come back and they like you said have moved away, made a new life or whatever and they don't have time to go to their doctor, he's lost his [low verbal] is there another referral number? Do we get into that later with referral.

PAULETTE: We will get into that with Resources but that is a real good question. The answer to that is "I understand that happens a lot, what I would like you to do is that I have two 800 numbers here, one is for the American Society of Plastic and Reconstructive Surgeons, and you must understand that Board Certifies Plastic Surgeons, I also have an 800 number for the American Academy of Cosmetic Surgeons. Either of those two 800 numbers can give you a list of doctors in your area which you can chose from.

Another thing that you may hear and you may not, I do not know if the television shows will come back and pick up again or they won't but we used to hear all the time, you know I saw the Phil Donahue Show and boy I don't want to go through any thing like that.

WOMAN: I bet you that sister on that from yesterday is going to be on all those shows.

PAULETTE: That could be, that could be. Or, I saw Jennie Jones, I don't want to do anything like that. So what's going on. I think the first thing I would start with this woman is that are you having any problems, are you having any difficulties. If she is not having any difficulties, then I would talk to her about, well what are your fears and, you know, give me some fears and if she talks about cancer, then address cancer, talk about the Defin and Brody Study, 3100 woman had implants, 5 to 25 years, if sarcoma then is her fear then talk about the fact that in 13 years 445 cases were reported none of whom had implants.

If her fears is autoimmune, then talk about autoimmune diseases. They don't occur all that often. Quote from the packet that there are 70 to 90% cases of scleroderma every year that the FDA states as does the American Medical Association, the Arthritis Foundation of the American Medical Association, that there is no clear cut evidence connecting implants, breast implants, with autoimmune diseases. She needs to understand that you do not have her medical history. You cannot diagnose what is going to happen to her.

I'm having my implants out does Dow Corning recommend the scar capsule for tissue come out with it? What do you recommend I do about that? Understand that we are the manufacturer, we make the product, we do not have your medical history and we cannot practice medicine. What does your doctor say should happen? He knows you, he knows all about you, he knows all about what has gone on with you in the past. I do not know that.

I'm having my gel implants out and I want them replaced and I want them replaced with Dow Corning products and you are not making them now any more. Why aren't you making them any more. What am I supposed to do now? What has your doctor suggested that you do as a replacement for your implants? Understand that your doctor knows you. His recommendations are what you should follow. Has he named a specific implant or a specific manufacturer that he plans to use? If she comes back with yes, he has talked to me about some Mentor or McGan or ... Say I could certainly give you an 800 number for that Company. I might suggest that you ask them for their package insert. Package inserts report what the manufacturers know about their product.

If this product is safe why did you stop making it? You must not think it is safe or you would continue to make it. Please understand that the withdrawing from the market of breast implants and plastic surgery, in general, has nothing to do with the safety of the product. It is strictly a business decision. Dow Corning has 15% of the implant market. The total sales from breast implants make up less than 1% of our total sales. It is not a product that we feel that we can continue to make in a business sense. We have put \$10,000,000 on the table to do research for breast implants. We will not be taking any of the \$10,000,000 back, we will be making all of those test results available to the FDA. We will continue to study this product. We will continue to stand behind our product for the women that have our product.

WOMAN: Do they ever come back with "okay you say you are out there to support the women and [low verbal] how are you supporting the women other than doing the test, you are not going to give them what the want at that point?

PAULETTE: I think that's going to be a very typical response in some cases. How are we supporting the women. We have a packet of information which we have sent out thousands and thousands of, we have an 800 number which is available to give information, we are trying to help women find the answers to their questions in any way that we can. And the research is very important, because it not only applies to certainly Dow Corning products, but the other silicone gel implants that are out there — that we do not make but we are supporting women by creating the knowledge that is needed about these implants. Even though we choose not to make them.

Here's a good one. How could you make a product and not know if it was safe or not? You

have been making it all this time and you don't know if it is safe or not? Dow Corning was the originator of the implant. We have 30 years of research. We have more knowledge on breast implants than any one out there. We do believe that breast implants are safe and effective product. Again, remember that safe doesn't mean risk free. There are always risks involved with medical devices. Devices that are implanted in the body always contain risks.

Any other questions? Want to throw some at me?

All lot of answering the questions, think about how you would like that question to be answered. You know, how would you like to be treated if you were asking that question, and it was very important to you. Because it is very important to them. It is very important. It is real important to keep in mind that you need to think of how you feel you want to be treated too.

Let's talk about monitoring.

We do monitor the phones at Dow Corning and this is how we do it. On a daily basis the Center Supervisor will monitor by walking around and listening to telephone conversations. Any misstatements will be addressed immediately with the operator upon completion of the call and a return call or letter, if the telephone number was not given, will be made to correct any errors. Midland Dow makes [low verbal] full time operators are located here. Memphis back up is needed [low verbal] we do have two people in Memphis that do do call backs. Have been through this training to do call backs.

As new or updated information is received, the Supervisor will disseminate it to all operators either individually or at a staff meeting. Detailed information will be disseminated in writing. Brief or routine updates may be given orally at the 1:30 meetings every day. It is keep in a log book, all of the updates are there.

In the Supervisor absence, she will designate someone at the center to be responsible for this task. The Supervisor will be available on a regular basis to respond to questions, concerns from the operators, I am always there, my door is always open. Don't ever feel that you are intruding on me ever. You may come to me at any time. And don't feel guilty, because I just sat down to lunch -- come right on in and do it any way.

At random innermost, planted calls will be made to the Center. Oral reports concerning these checks will be made to the Supervisor and to the Manager.

Monitoring question. These are the random calls that are being called in, these are the questions that they will be looking to answer. Are the operators responses accurate? Is the operator allowing the caller to control the direction of conversation? You do not lead her, she leads you. Is the operators tone of voice, phrasing and choice of words appropriate to the callers level of understanding? Are the operators responses complete at the end of the call? Are there any other questions? Can I tell you about anything else? What else would you like to know? Are there any other questions -- will be fine. Is the operator calm? Is she on the telephone when she shouldn't be? There are going to be times when you shouldn't pick up the phone -- and don't pick it up -- let it go. Do [undiscernible] to that next number [undiscernible] out of there for

you.

WOMAN: Okay, now there are going to be [coughing] full time people.

PAULETTE: Seven. Ten, we are shooting for ten now.

WOMAN: But right now, when we start Monday ...

PAULETTE: When you start Monday, there will be seven ... cause she's on vacation. ... her Mother's 75th Birthday.

WOMAN: Will we also have temporary's?

PAULETTE: I want to really keep the temporary's off the phones. You have been through a lot of training in the last couple of days, I don't like to put someone on the phone that isn't trained. It really scares me since the warning letter from the FDA. If I don't have somebody trained, I really don't want them on the phone.

WOMAN: I guess what I was referring to were floaters, like you had in the past.

PAULETTE: Oh, no. I will not have any floaters. Unless it gets so horrendous that I have to, then I will. But I would really prefer not to do that. We have kept so many people away from their jobs for so long by doing that ....

WOMAN: Okay, so when I begin, which is next week, when I get back — at any time do the new people sit with someone whose been there for a while and just listen to what they are saying.

PAULETTE: We have never done that before. But, if you would feel more comfortable doing that ...

WOMAN: I am wondering, I may want to because I'll be gone for an entire week, just to [laughter and mix verbal] ... I just wondered if that was at all part of the training.

PAULETTE: No it has never been part of the training. As a matter of fact, after the hot box tomorrow, I truthfully don't think you will need to do that. I don't. Nobody ever has. We have just gone right to the phones after that. After tomorrow, I guarantee you, you will remember. You will definitely remember.

AUDIENCE: [All talking at once]

PAULETTE: That was a good try.

WOMAN: Are you going to be taking a couple operators off of the Explant Lines and bringing them over to us.

PAULETTE: Yes. We tried to do that and no one wanted to come.

We will be trying to get some more people involved in the Implant Center, definitely.

Okay.. Do's and don'ts.

Do be certain that the caller has your name and telephone number so they can reach you again without having to retell their story.

WOMAN: They still have the 800 number though?

PAULETTE: That's correct.

WOMAN: We don't give them our personal number?

PAULETTE: No don't give them your private number either. Somebody has been giving out my private number and that's really hard. Especially, when you are picking up the phone, and I picked up my phone, Paulette? Paulette?, and I have the caller on the line. It is very hard, very hard. Don't give out the private number.

WOMAN: It is hard [low verbal] answer those questions ... it's hard.

PAULETTE: You shouldn't be answering questions.

AUDIENCE: No but I mean trying to redirect to someone that can answer the question.

Once they have someone they probably are reluctant to get passed to another person.

PAULETTE: Oh, yes. Especially yes, if they have called in and got BMX and then called some other number and then they get transferred to my private line and then it is like ... I am not letting go until somebody talks to me. So it is hard.

Do encourage patients to discuss questions and concerns with their doctors. Offer to send the patient information packet. Stick to the facts. Be open about what we do and do not know. Use the information in the patient information booklet. Provide other sources of credible information. See the [undiscernible] including the ASPRS, FDA and other manufacturers. I have very often said to women, to call the FDA, they have a packet of information. Call the ASPRS, they have some information they will send you. Make a balanced decision, you have gone this far, you have made the phone call to me so make a couple more, get some more information. Make a balanced decision. Read as much as you can on it. I don't know that they do but I certainly encourage them to do that.

Do respect the callers right to privacy. Treat the details of each call as confidential to be discussed only with those who have the need to know. Please do not run throughout the Corporation talking about the calls you have received.

Do try to address the callers immediate concerns during the conversation and then offer to follow up with the written information.

One of the things I want to talk about privacy there to is that, we don't even at the plant, you know they have their mail boxes in the hall. We don't even have our mail boxes in the hall because of the names and stuff that are on these packets that are going out. I mean it could be somebodies sister, cousin, aunt or something going out — and here's the name sticking in the hallway, you know this is the Implant Center. We really try to protect them as much as we possibly can.

Be sympathetic and human. Take as much time as the caller needs. You do not have a time limit on the phones. Talk to them as much as you need to talk to them. Women appreciate that greatly, they really do.

WOMAN: I have a question on that one. Just knowing human nature the way it is and I can foresee that I feel on a lot of the calls and then all of a sudden I have heard this story about 15 million times, it is not like I am cold and callous to it, but I just like those, I found myself getting turned off listening to those women on the TV last night, all the videos and stuff

PAULETTE: [Undiscernible]

WOMAN: ..and my first reaction is, yes I want to be very factual and give you that information but the sympathetic just kind of goes a little bit. It seems like a strain.

PAULETTE: And, I think it can be a strain to be sympathetic, especially once you become seasoned to calls ... but try to put yourself in their place. Try to remember that if you were out there and you had those concerns, again you are coming into this call with a lot more knowledge than this person on the other end and she is scared for a reason. She is scared because she doesn't know all of those things. So try to be as sympathetic as you can. If you are not sympathetic, and there are cases where I am sure you will be, be factual, be tactful, be pleasant.

WOMAN: Be professional then.

•

PAULETTE: Exactly, be professional.

WOMAN: Like a Sybil Goldberg, sympathy doesn't even come close to that.

WOMAN: I have a question on the statement before that about offer to follow with written information. We are offering to send the packet and that on the phone call, what other information, is there always a letter that follows?

PAULETTE: Well there is a letter that goes with every packet. What we meant by written information there is that if she gives you a catalog and lot number, offer to send it out to her. If there is some questions that you had to go research or one of the questions that we just wrote a letter on not to long ago was that this woman was having Grandbole Seizures and she wanted to know if silicone could get into the brain stem. We went to Bob LeVier and there has been

many tests and no it cannot enter into the brain stem. So that was written in a letter to her. Understand that any letters that deviate from the norm, again must be checked. Any letter that is not in there, that is that normal letter, has to be checked.

Do be sensitive to the callers tone of voice and hidden agenda. Dr. Garamey is available to take referred calls from callers who exhibit suicidal or emotional, unstable tendencies. Be very, very open to that possibility. Understand that if you take a call like that and you need to be off the phone, I understand, I have been through it. All of us have. And it wipes you out, it will wipe you right out. It is a very hard thing to do. You know, Dr. Garamey can tell you that, you know you can have a loaded 45 and hand it to this person, if they pull the trigger, they are the ones that are responsible for taking their own life. However, you still have this in here to deal with, up here may be telling you that, but you still have to deal with it in your own mind.

I don't think that we, certainly with the number of calls that have come in, it is a very small percentage that fall into this category. Do use the 800 number if you need, but also, please understand that it takes some procedures to get them to use the 800 number. Like here call this 800 number, it just doesn't work. Again, be aware that if the people in this Explant Program need help over there, they will be coming to find one of you — we'll send them somebody because they are not trained at all to deal with this. They cannot answer questions, so they really are blind. They just can't [low verbal]....

Do not guess or speculate about an answer. If you do not know the answer offer to find out and call back or refer the call to the appropriate person on your reference list. Not everyone can be called on the reference list but there are some and when we go over it, we will talk about who those people are.

Do not talk about other manufacturer's products. We don't make them, we don't why these people doubt them. And, I will tell you the truth, I try not to read anything about them. I try not to know anything about them. If you know about it, you have a tendency to talk about it. Especially, in these kinds of conversations and I just, we don't know, I don't make them, I don't know anything about them, I have their number if you would like to call them you can ask them. And, again you know we try always to be very above board about everybody. These are reputable companies. They are willing to answer those questions.

Stick to silicone in general or Dow Corning products, specifically. Do not give personal opinions. Any opinion you express is the opinion of the Company. You can answer questions based on your factual personal experience. For example, have you ever had surgery? Do you have implants? Do you know anyone who has implants? [coughing] that is a personal opinion. Do try as quickly as possible to turn the conversation back to the caller.

Do not commit to what the Company will or will not do. Your job is to provide accurate information and not to practice law, medicine, science or marketing. You are just here to talk about implants. It's little hard to do marketing any more but used to be one of our basic statements. I am not here to sell my product. I am here just to talk to you about the product.

Again, stick to what you know. If you start talking things that are outside of the realm of this training, and I don't, the Company will stand behind you as long as you stick to this program, to the hilt. But you take it upon yourself the minute that you step out of this and start giving opinions that do not belong to Dow Corning.

Do not ask for more information than the caller wishes to give. If they do not want to give their name, their doctors name or any other information, do not press. Some of those things when you are trying to question to pin down what she is talking about, if she is just refusing to give you any information, then there is just really nothing you can do. Well I'm just not getting the point as to what you are talking about. Maybe you could clarify it a little better for me. And, if all else fails, then she will have to see her doctor because we just don't understand what she is trying to get to. And, what point is it? Because we only want to answer what she is asking us. We don't want to read things into it. We don't want to lead the conversation, that's her job. She made the phone call, let her take you where she wants to go.

Do not read to the caller. A tape recorder could do that. Answer questions in your own words. But be certain that your explanation is consistent with the patient information packet.

Do not get on the telephone if you are upset, tired, uncertain of some fact, etc. Calls can be extremely stressful and you do not do yourself or the caller any good, if you are upset or stressed out.

There will be times, I am sure, when the phones aren't hot and heavy, when you feel like I just can't take myself off the phone it is just not fair. It is fair. Everybody has done it. So don't worry about it.

These people I keep in a plastic sleeve in the top drawer of my desk. You do use these, and I don't care how you want to set these up, if you want me to get you notebooks, I'll do that.

WOMAN: Just thinking organizationally, notebook with tabs.

PAULETTE: That's what I have. It's about that thick actually. That's what we did we just tabbed it off. We could have copied notebooks and given them to you but we can learn a lot more from writing it down and by organizing your notebook the way you want it organized, is going to pull it a lot closer together for you.

WOMAN: By writing it in your own words, you have to listen twice as hard, and you retain it ... much faster.

PAULETTE: Martha Biggs again is the first one on this list and all technical reports. It talks about the 10,000 pages here. She also has that 800 pages. Or the memos as it is referred to also.

Technical Information, Bob LeVier - here, [name] - in Memphis, both are very busy people. We do use them and we utilize them and they do get back with you. They are very good about it. Besides breast implants they can answer questions about tissue expanders, nose and ear

implants, etc.

WOMAN: Is Sheryl going back to DCW?

PAULETTE: Yes. She is back.

WOMAN: She was up here training?

PAULETTE: Yes for the training and she is going back right away.

John Gawker and Sheryl Edwards and [undiscernible] questions. Silicone Orthopedics Elden Fersh, who you know has retired. But he is still available to be called. JoAnn in Marketing for Orthopedics. Jim Hook and Mark Hoek, it is scheduled Jim Hook to come up here to teach Orthopedics to all of us [low verbal] to answer questions on orthopedics. Dawn, Wendy and I can answer questions on orthopedics, we have been trained on every implant that there is.

I do not feel comfortable teaching orthopedics, I don't feel I know enough to teach orthopedics but Jim certainly does and he is a wonderful guy. He's friendly, he's nice, he's helpful. I have had him talk to a patient about an implant and he's quick, he is real quick.

Vera Taft and Bernie Tetra as I scan, Mark Hoek, Jim Hoek again. Grass roots...I don't know if you have heard of the grass roots effort. Okay, grass roots is an effort that was put together about August and Joy Murray and Gene K—, have [coughing] regular jobs to deal with grass roots. What we were trying to do with grass roots was to get an effort going for doctors and for patients who have had positive thoughts about implants. It didn't mean that they had to have positive experiences, okay. But if you get a phone call from someone who says, and Joy by way handles patients and Gene handles doctors, if you get a call from a patient who says, "You know I had my implants replaced three times but I love them. I think there wonderful. I would love to be a spokesperson for Dow Corning.", you get her name and address and phone number and pass it to Joy. Joy will handle it from there.

If you have a doctor or a researcher, or a radiologist, or rheumatologist or any kind of doctor at all that says, you know, I have a cure all for your problem. Believe me you will get a lot of those. Gene K— is the person who handles that. Now I am not talking about doctors calling in who say I want some information about implants. Because there are a lot of GPs that are calling in that want some information about implants because they have patients coming to them. You can talk to them, share you knowledge with them, that's fine. Offer to send them the packet, offer to send them several packets. Would you like me to give you, send you out ten packets so you have them on hand for your patients that come in. That's perfectly fine to do that. I am not talking about the doctors that call in and say I want 25 packets sent to my office, we do that all the time. I am talking about doctors who deviate from those two things. I have the answers, I know all about this problem...those go to Gene K—.

Legal, Customer Relations - Lynn DeBolt, Shelly Blair, Rosalyn Wakefield. Again, we probably should start from the bottom up there. When you are giving out this 800 number that is listed here. These are numbers that can be given out. You can also give out Joy Murray and

Gene K---. You can give that number out they have an 800 number there. And, I would probably say, you know, you can call Customer Relations for help with that ask for Rosayln Wakefield, Shelly Blair, Lynn DeBolt, at 800-238-7188.

WOMAN: And Gene and Joy are considered part of Customer Relations?

PAULETTE: No. Gene and Joy are considered grass roots. I just went back because I forgot to say you can give that 800 number out.

If the woman says I would like to talk to somebody say, I have the perfect person, her name is Joy Murray, and she would be more than happy to talk to you.

WOMAN: [Low verbal] give this number out or what?

PAULETTE: We have in the past given her number out for this 10,000 pages. It is really much simpler if you say give me your name and address and phone number and I will have them send you an order form to get this. Martha is already barraged with things to do. I mean, I think it's easier, it gives her printed matter to work from. She can print off her props and work from that. I think it is much easier to send her [low verbal].

Law Suits, Legal, here is the place where someone is just not going to give up on legal issues. Well how many law suits do you have or I want to know the answer to these things. Then write these Jim Hayes, Barb Anderson, Carol ——, any of those and any of those numbers. I wouldn't give them out at random but certainly if you need them they are there to be used. They may love you beyond belief for it ....

WOMAN: Do you ever not give out their number but tell the people that you will refer them to the attorney and have them try to call them?

PAULETTE: Yes. You can do that also if you can get away with it. You can certainly do that. That is preferred but if you have someone you can't do anything with, you just can't do anything with, you've tried, but there's just nothing you can do, then I would give them the name and number. Again, they probably are not going to get the information over there either but they'll deal with them in a manner that you cannot.

In Hemlock, Chip Burdock, is a good source of information, if you can get to Chip. He is very busy also.

WOMAN: He and Doris...

PAULETTE: As far as testing questions, you can certainly ask Bob LeVier. Lot traces Herb-, you can go to Alicia Berridge, for silicones Doris Michaelson. Again only go to Doris if you
only have a lot number. If you have a catalog number, we can find it. If you are having
trouble finding it, then somebody can help you do it until you get used to it. But if there is only
a lot number go to Doris because we can't look up all the lot numbers, we just don't know. It's
good to [undiscernible] Doris also.

Understand, and you should make it very clear to your caller also, that if you only have a lot number, it could be several days to more than a week before you can get back to them. Some people don't understand that. They think it should be at a touch of a computer that you get it. Not all of these things are in a computer, she has to literally look some of these up by hand. It is only the last few years that it is in the computer. You may use that with them, that you don't know what the schedule of this person is so you cannot promise — but please understand that it may be several days before you get this information. And, at that point, if they really are throwing a fit, you might say if you could get me the catalog number, I could get that quicker, but you are only giving me one number to go on.

Literature, Zeke Connor in Hemlock. Lee Grant I guess is not in Memphis any more is he?

AUDIENCE: That's what we were told.

)

)

PAULETTE: Somebody else is going to take his place.

Package inserts, Shelly Bennet or Terry Nebble. We have most of the package inserts. We also have, I have, and I believe [name] does also, and I am trying to get those for you. Lee isn't there any more. We have package inserts for every product that we make. [coughing] organized that kind of stuff and trying to get them for everybody ... Once in a while I've seen a couple of time where they have had to call for special package inserts but not very often.

WOMAN: When you send those package inserts is it a copy of the package insert or the original insert?

PAULETTE: Copies. We don't have that many originals around to do that. So it is a copy. But it would probably be very good to print in your letter, enclosed is a photocopy of the package insert which you requested per the numbers that you gave, catalog number whatever, lot number whatever ... I always want you to remember to say the numbers that they gave. Or somebody out there to say you made up these numbers and you gave them the wrong package insert on purpose because in that it didn't say this and in that it didn't say that, so you need to make sure that they realize you are working off their numbers.

This can't be updated either because they still have Bob G--- on here.

WOMAN: [undiscernible] replaced him ....

PAULETTE: I don't think any body can to tell you the truth.

WOMAN: He's a sweetie.

PAULETTE: He's wonderful, the man is smooth and so together and not afraid to get his hands dirty and not afraid to get down in to it. He'll be hard to replace.

In the Media Communications group, Bob G is gone. Scott Seeburger, Burnett Kelly, Burnett is a wonderful man to, I think. He is a really a great guy, really helpful and very understanding

and very kind.

AUDIENCE: Laid back ... gentlemen ...

PAULETTE: BPU82 hospital, surgical, technical questions, Jerry Hawes or Diane Atcheson [coughing] Eugenia Knox, Bernie Tetreau. Distributor List, Gale Molen. Gale, by the way, is one of our back up people.

\*:

## IMPLANT HOTLINE PROGRAM TRAINING SESSION MARCH 25, 26, 27 1992

#### TAPE 7 SIDE A

PAULETTE: Tape is undiscernible. She is discussing the Resource People and the list of telephone numbers. The following are pieces that were audible.

The 301 number for the FDA is a recording. The White House number is a recording. The number at the White House takes a toll of how many calls come in. There was a time during the controversy that there wasn't a number to call the FDA. Women wanted to call the FDA. This 800 number was not created until after the last advisory panel. There was a number to call if you had a complaint, but if you just wanted to state your opinion about implants, there was no where for you to call. But we used to give out that 800 number anyway. We would tell them that you may want to back up that with a call to the White House. And then, of course, we have Commissioner David Kessler's number. This is his main office number in Washington DC. You never get past his secretary. I've called that one and I have gotten through to his secretary. People are ranting and raving and their questions should really be directed at the FDA. You can give them the FDA number and David Kessler's number. A lot of women are concerned about who is going to fit into augmentation and who is going to fit into reconstruction. And I want to know because I'm one of those women and this 800 number is not helping me, I can't get through. We don't give it out to just anyone, although I'm sure the FDA and David Kessler think we do.

ASSOCIATE QUESTION: What about the Crisis number?

PAULETTE: That is a 24 hour hot line with counselors that are available. It is for us too! If you feel you need to talk to somebody, call them and talk to them.

ASSOCIATE QUESTION: What is the Hot Box?

PAULETTE: The hot box is - one person will sit in the hot box chair a time and will take two calls. I have no idea who the callers are.

ASSOCIATE: These are real calls?

PAULETTE: These are real calls. They are not patient calls. They are people staged to do this. This is a test. I did not arrange for the calls this time; usually I do, but this time it was not me that did that. I will tell you however, that on the message it does say "have fun and be mean". You take two calls, you're on video tape the whole time. Both sides of the conversation are recorded. Everyone is sitting there listening to you; I have headphones on listening to both sides of the conversation. In the afternoon we will go over the calls. The one that goes first usually gets hit the hardest; not because they do more wrong than the other people, but you are pointing it out and others tend to repeat the same thing. So the first one does usually get

critiqued the hardest. And again I'm saying that because I don't want anyone to think that I'm picking on you in particular. And maybe you won't make any mistakes.

ASSOCIATE: Oh sure! Dream on.

PAULETTE: It's not to point a finger at you and say "Boy you really blew that call". It's to teach you how to respond and how to listen to what they're saying. Its important to listen to what they're saying; and its very enlightening because you're giving the answers and I will guarantee you that if you are giving certain answers the people are going to pick up on it. And they are going to say "do you mean to tell me....." And then you're going to go -Oh why did I ever say that!

VICKI WESTBROOK: This is a very basic question. Do we just answer the phone and say" Hello this is Vicki Westbrook in the Dow Corning Implant Information Center. How can I help you?"

PAULETTE: That is a very good question. Pick up the phone. Dow Corning Wright Implant Information Center. This is Vicki Westbrook. May I help you?

JANIS SMITH: And I would answer my phone 'Jan Smith' Ha ha laughter)

PAULETTE: When you hang up the phone, say: Is there any other question I can answer for you? Remember my name is Paulette Williams, if you need to get a hold of me, call back the 800 number, tell them that this call is for Paulette and they will get the call to me. If someone else answers, tell them that you would like to talk to me. If you get VMX answering device, leave the message for me and it will get to me.

Don't be scared of hot box. I know its horribly mean. Everyone says its horrible mean, but its also the best learning experience.

VICKI: I would rather go through it with someone from Dow Corning than a patient and make those mistakes. What haven't I understood in the last two days about this training process.

PAULETTE: One of the things I need to tell you is that when somebody asks you, "what kind of training have you been through?" The answer to that is that you have been through extensive training by the top technical people in the corporation.

ASSOCIATE: Do we get French speaking people?

PAULETTE: Sometimes we do get French speaking people from Canada. Try to get their name and number, Dawn can speak a little French. Dawn lived over there with her husband for a while. She is not fluent, but she know enough to get their name and number. We have an girl named Meena who speaks French well. You profs her the name and number and she calls the person back. Her number is not on the resource list; we get very few of these calls. Come to see me. I will give you her last name, profs ID and phone number.

ASSOCIATE: Doesn't the packets to Canada need to be in French?

PAULETTE: They have packets in French. I only handle English packets.

ASSOCIATE: Brian Groulx and Burt Miller in Canada have been working on this program. They had a meeting yesterday on putting together a prep program for Canada in Canada, so there will be some literature coming that will be dealing just through that office.

TAPE 7 SIDE B: HAS NOTHING ON IT

## IMPLANT HOTLINE PROGRAM TRAINING SESSION MARCH 25, 26, 27 1992

### TAPE 8 SIDE A & SIDE B

)

This is a critique of the tape recorded hot box sessions.

Caller says: I am totally outraged at Dow Corning for selling implants in the first place and then pulling them off the market when you found that they were an unsafe product. What do you have to say about that?

Say: Dow Corning does stand behind our product. We do have 30 years of research behind this product. (Qualify that) Safe does not mean risk free. This is a man made product. Man made products are known to fail. This is a medical device. Medical devices have risks.

Caller says: Don't you think its a little late to do testing now?

Say: We have done 30 years of testing. We believe there are some unanswered questions out there. There are some things that need to be discovered about implants and we have put the 10 million dollars on the table to get the answers to everyone's satisfaction.

Caller says: Why are you doing this now? Why didn't you do this before?

Say: Understand that the medical community has advanced 30 years during the lifetime of this product. We have always during those 30 years, as new technology became available, incorporated that knowledge into our testing. We have steadily tested the implants. This is new medical knowledge. There are new medical questions out there. That is why the 10 million dollars on the table now. But we have always tested our products to the medical norms according to the times.

Caller Says: FDA says these implants are only to be used on reconstruction and not augmentation patients (and caller went on and on about it) (when caller takes a breather interject the answer).

Say: I'd like you to understand that was an FDA Advisory Panel decision. It was not a decision of Dow Corning. I understand that you can obtain transcripts from the advisory panel. Understand that it is not a final FDA decision, but I do have an 800 number here for the FDA, If you would like to call that, you can request those transcripts.

Caller Says: What details make it a business decision?

Say: Understand that Dow Corning does carry only 15% of this market. The implants make up less than 1% of Dow Corning's total sales. It was strictly a business decision. And I think that if you look at the facts, Dow Corning is still interested in research on this product. We

have set 10 million dollars on the table which will be used for research on these products.

Caller says: I would like that answer about the business decision in writing.

Say: This is corporate policy. I do not deal in corporate policy. You would have to go to Communications. I can give you the number. If you would like the press release on that, I will give you to Communications; and someone can get that to you.

Paulette: When you are looking for information. Say: I want to give you correct information, so I'm looking this up here, please be patient with me. If it is taking you a while, say "How's the weather where you are?" Draw her into conversation a little so it doesn't seem like its taking you so long to look.

Caller says: What is in the packet?

Say: What this packet contains is a culmination of our 30 years of research. It is put into layman terms that anyone can understand. It talks about the benefits as well as the risks of implants. (You may want to point out) There is a package insert included that tends to be very technical as they are aimed at physicians and you may want to talk to you physician about it. When you get that packet, you may want to sit down with a pen or highlighter and highlight what you don't understand. Either call myself back or call you physician and discuss it with him.

Caller says: Are there more risks with implants than there are with other products?

Say: We have done 30 years of research. That Dow Corning believes this is a safe and effective product. Safe does not mean risk free. (You can't not give personal opinion on call i.e. say, "In my opinion it is safe to use.") (You must say when you say Dow Corning feels the product is safe, that safe does not mean risk free. You cannot predict what a medical device will do in a human body.

Caller says: Is the package insert is what is in the box that the surgeon gets and shouldn't the patients have one?

Say: Yes the surgeon does have copies of this package insert; and yes they are available to patients.

Caller says: I have left a message on you recorder for the last four days with no response. And I am extremely upset.

Say: Understand that there are a lot of women calling the line. This is the first time an 800 number has been made available to the estimated 2 million women that have implants. We are in the process of hiring more people and training them, but please understand that they have to go through extensive training to be able to answer your questions and this process takes time. I apologize for any delay that you have had.

Caller says: I have rash, joint aching. I know I must have silicone running through my body.

Say: Have you been to your doctor? What does he say?

Caller says: What kind of physician should I see?

Say: Just as you would seek a specialist in any other field, an internist, a cardiologist; a specialist in the field of breast implants is a plastic surgeon. And I would strongly suggest that you do seek a plastic surgeon.

Caller says: It costs so much to go to a doctor. I don't have the money to run to see a doctor.

Say: I understand that it can be expensive, but we are talking about your health here, and we need to look out for you. I realize it can be expensive, but stop and think that your health is at stake here and you need to see you physician. You need to find out what's going on with you.

Paulette: You need to speak to caller on a level she will understand. You need to sound knowledgeable and professional so she will listen to you, but you must also talk on the level of each individual caller in a way she will understand.

Caller says: Why is one implant moving and one is getting hard?

Says: Explain what capsular contracture is (the formation of scar tissue around the breast implant. The body will form scar tissue around any foreign object implanted in the body whether it is a pace maker or a sliver in your finger. This scar tissue grows in a continuous way around the implant; the fibers grow all one way. It can begin to tighten down on the implant. This may be what you are experiencing in the breast that is hard. Again I would advise you, if you have a sagging breast and one that is hard, that you should seek a physician's help for this.

Sagging - If you have had them for a number of years, it could be just natural aging (ptosis). That one could look more lax because the other one is hard.

Caller Says: The packet of information must be one sided. How can I really trust it if Dow Corning wrote it?

Say: The packet of information contains 30 years of research that Dow Corning has done. At the end of each of these articles, there are references. You can go to any medical or college library. You can read about them for your self. This information was drawn from these references. We do have some FDA information that is included in this packet also. There is also in this packet, the 800 number for the FDA who also has a packet of information. Perhaps you would like to call them. Get their packet. Read it. Read our packet. Make a balanced decision. We have a number for the OSPREYS. They have information they can send you. You've gone as far as to call me, why not call them. Get all the information you can.