

IMPLANT HOTLINE PROGRAM  
TRAINING SESSION  
MARCH 25, 26, 27 1992  
INSTRUCTOR - PAULETTE WILLIAMS

TAPE 1, SIDE A

PAULETTE:

First thing I want to talk about is what is the Dow Corning Wright Implant Information Center, and I want you to know we started this because Connie Chung did a show, which we will see, in December of 1990. December 10th. Phone calls started coming into Dow Corning concerning breast implants, and actually I'm surprised at the number of calls that we do get. I realize that this is the first 800 number, for approximately 2 million women, however, we only hold about 15% of the market. We don't really have a lot of breast implants out there. So many calls came in that myself, Lynn Diebold, and Shelly Blair, who are paralegals in Memphis, I am a paralegal by the way. We were feeling these calls, but it got to a point where we could do nothing but feel these calls, and claims were falling by the wayside, my job was falling by the wayside, we had to do something to create an outlet for the questions and the answers that we needed to give to these people, and so we opened for business on July 8, 1991 and that was also the day we submitted our PMA to the FDA. The center was created to distribute current and accurate information, to not only the patients and women who call in, but also to the doctors, media, lawyers, anyone that was calling for information. There is a way to sort through the calls, and we will talk about that later. When we first started out, there were 3 of us in the Center, and we started taking about 25 calls a day, that was our average in the beginning. Each call lasted about 40 minutes. Now, we take approximate 1,500 calls a week. Obviously, we can't answer 1,500 calls a week so there is a back log that has been created. The 1500 calls a week, also I want you to understand involves both Memphis and Midland. Just because we established a center doesn't mean the calls stop coming into Memphis. They have come in there for almost two years. It's kinda hard to stop them. We try to reroute them back up here. but..

ASSOCIATE:

Is there an 800 hotline down in Memphis?

PAULETTE:

It's not a hotline, but there's an 800 number for Dow Corning Wright. It's usually where they come in at. We never advertised that number, we never did anything like that. However, they would pass it to person to person, by word of mouth it got out, and it soon became so bad that none of the 3 of us could do our jobs because we were so busy answering questions about Mammary Implants.

PAULETTE: (cont.)

We have quite a back log both here and in Memphis, that is our job to take care of them.

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That's what were looking for, we don't want a back log, we want to answer as many calls as we can, and as I see it, what we will do when everyone is in place, is that everybody will take there turn working on back log. Back log calls are really easier then taking a call coming in. There are several reasons for this. A call coming in, is usually from a woman who is very upset, she is either seen a news program or read something in the newspaper, she's talked to a friend that has told her all of these things, so she is very upset. When you do a callback, they're usually calmed down by the time you call them back, they are not in that high agitated state, so it's a lot easier to deal with them. Plus, when you do a callback you usually know what there questions are, because what we have done with the people who are leaving their name and number on vmx, is that we have four temps in Memphis who are calling these people saying "we got your call, we really want to talk to you, but understand that it may be a while before we get back to you. Do you have specific questions?" then they would write down the specific questions. "Would you like a packet of information?" if they want that, they get it out. I also want you to know in our vmx, the message is changed now, and we will talk about that later, but normally what it says is: "if you would like a packet of information, leave your name and address, if you have specific questions also leave your telephone number and we will get back to you." So any question or I mean any address that is left on our vmx gets a packet sent out immediately, if it's off of vmx, what we do is say in the letter, " we received your call, we do care about your concerns, rather than delay you of getting any information at all, we have sent this packet so that you do have that information. When you do get the call back you will be able to address your concerns better." We are trying to service them the best that we can, but were really under staffed right now, and that's why were doing this, is to increase the staff. The calls now last approximately 50 minutes, that's a long call. They have a lot of questions, there is a lot in the media that has been brought out. They are a lot more educated now, then they were in the beginning. We hear a lot more of what is in the media.

ASSOCIATE:

So the average call is 50 minutes?

PAULETTE:

The average call is 50 minutes, I will tell you I have seen it last 10 and it's over. I have been on the phone for over 2.5 hours. I've been on the phone for 70 minutes, it just depends on the person.

ASSOCIATE:

It's an average

PAULETTE:

It's an average. We feel that the associates can handle approximately 30 calls a day, I've seen them handle more. I seen, as a matter of fact, the other day, when Burston-Marsteller were in the center we took in a call report pad to Wendy, a pad has 50 call reports on it, Wendy had started the day with a full pad and had two left on hers and Dawn had none left on hers. So there are times when you can get more in. The reason we say thirty is because it's more or less

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an average. Sometimes there is a lot of follow up to a call, you have to do a lot of things when you get off the call. It's very important you do those things. It is part of your job. That's why we say 30, and there will be days when you don't take 30 because either they are really long calls, or they are really stressful, and you need to get off the phone. I don't want you to have to be on the phone if you are stressed out. If your feeling when your reaching for the phone that you shouldn't be on the phone, then don't pick it up. It will come through to that person, and we don't want that at all. Also, I might tell you when it gets hot and heavy, and there are times that it does, it will come just like that. I would prefer that you finish your call report before you take another call. It will begin to run you down. They will begin to run together. Did I say this to that one, did I say this to that one, I don't know.

There is only one answer for each complication. You may state it differently, depending on the person level of comprehension, but there is only 1 correct answer for capsular contracture or rupture or any of the other necrosis or any of the other things that we will talk about, but if you finish that call report there is no way that your going to forget it, there is no way you will run it into another call.. it brings closure to that call. You don't have to worry about that call, it is done and over with. We had at one point, hoped to have our database to be able to call up names, did this person call me before, we have found that just does not work. Every time a call comes in, it is treated like that is a new call. You put in a new call report, but I will tell you that even after the thousands of calls that I have taken, I can get on the phone with a person and begin to talk to them, and I will remember things. It all comes back, it may not sound like it will, but it does, believe me it does, it does.

Most of these calls you don't forget. You just don't.

The duties I see the associates having are first and foremost is to answer the telephone. The one thing I want you to remember when you are on the telephone is that you are Dow Corning. What ever you say we are responsible for. What ever you promise, you must deliver. You have to be very careful on what you are saying on the phone. You have to stand behind whatever you say. I know that I don't want to be scary but I can guarantee you that, you will be called on the run, if you promise something we cannot deliver. Something that is out of your realm, that you promise and you will know by the end of this training session what to say and what not to say, and if you are not sure, don't say anything. I don't know.. is perfectly acceptable. I don't know is an acceptable answer. You have to be very careful about what you are promising. Remember that you will be talking to doctors, you will be talking to the media. And they will try to get you to say anything they want you to say. I might also point out while your talking think about the content of your conversation. It would not be unusual for them to pick out one sentence out of a 40 minute conversation. In the front page headlines "Dow Corning Says....", whatever

ASSOCIATE:

Do we get close to plaintiffs attorneys?

PAULETTE:

Yes, and that was my next point. You do get calls from lawyers. They are not ... all the lawyers out there are not ethical. They will not tell you they are a lawyer, they will try and get information from you. They will try to trick you every time you turn around. This is reality. You will get calls from the FDA. We will talk about this when we talk about monitoring.

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They will try to lead you down the garden path and get you to contradict yourself. They will try to get you to say something that is not true. That you know is not true, but they will do it. They make frequent calls to the center. Later on this afternoon we will talk about FDA, we will talk about the warning letter, that the center got from the FDA. The next thing after a warning letter is criminal charges. I don't know about you, but none of us want to be responsible for putting Larry Reed in jail. It would be management that went to jail on these issue. These are criminal charges. We come under labeling laws by the FDA. They consider this labeling. They have jurisdiction not only on what we say but our package, the content of our conversation. They have control. I don't want to make it represent that we don't have anything to say about it at all. We do. But they are the governing force. Again, it is perfectly acceptable for you to say "I don't know." If you only think you may know, then the answer is "I don't know". If you know your positively sure of your answer then go ahead and tell them your answer. If you have doubts on anything, then go ahead and say "I don't know". You will be provided with a list of resource people, it's a 5 or 6 page list, they are very prompt about getting back with you. You might have to take initiative to dig for the answer. It is your responsibility to get back to the caller. We do not give, there are certain people on the resource list that we do give out their names and numbers but very few of them. If we did that these people would be spending all their time in litigation courts and none in their work areas doing what they do. Usually communications is the number we give out. Claims is referred to as Customer Relations. We will go over everything later.

I want to talk to you about call report forms. I just made this one up last night. Can we all read it?? When a call comes in, for every call we do a call report form, you start out with the time that they called. If you notice I didn't fill mine out, I am terrible at that. The date that they called in, the associates initials, or your first name. Understand also, that from this form the support people put this in Inmagic. You have to write legible. It is not unusual to be messy, but then just copy the report over. You may want a legal pad, however it is comfortable for you. That's how I want you to do it.

**ASSOCIATE:**

Getting the information down is the important thing.

**PAULETTE:**

Is the important thing, right; and the reason that I brought up numbering their concerns is because, one of the things we want to be sure to do is to cover all of their concerns. By numbering them you can say "now lets talk about the questions you asked me. First thing that you asked me was about capsular contracture. The second thing" we want to make sure we cover all their concerns. Get all of it down, everything they want us to do. This report made by, it could be patient, husband, doctor, lawyer, friend, mother, father it could be who ever calls in, and we have talked to all of the above. The patient's name is hopefully the woman who has the implants. Sometime's it's two names. I've had a mother call in, whose 2 daughters have implants, and wanted a packet sent to both. So you may end up with two names here. The doctor name, you may get that and you may not. Women tend to protect their doctors. Very much so, unless of course, they are so very angry at them that they are ready to sue the doctor. Otherwise, they tend to protect the doctor. They don't always tell you. But one thing I will tell you is that during the conversation be very alert to what she is saying. She might be calling in

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about Auto Immune Disease, she is very upset, hear what she is saying. At some point in the conversation it is very common for them to say, "my mother has Rheumatoid Arthritis" and she doesn't have implants. Those are things we want to find out. Prior medical history. These are things we want to know. If at some point this turns into a claim, or this turns into litigation. We would want to know that this women stated that this is in her family history. These things run in her family, we need to know that.

ASSOCIATE:

At some point are you going to be doing studies, based on what is in the database, based on these call reports. Of the 500 calls, 499 have realities who have lupus.

PAULETTE:

Yes, it will be used for many things. The database that we have. The data entry is not real easy, so it is kinda a pain for the support people. But, it has wonderful search capabilities. You can say on March 3rd, how many people from South Dakota, called on rupture, and it can find it. So it really can break it down for us. That's what were looking for.

ASSOCIATE:

Are study's like Vicki was talking about, is that what Marion Woodbury does?

PAULETTE:

Marion did the Gregory study. But, Bob Levier is really the one. He is going to be in at 10:00 and talk to us. He will tell us what studies have been done and what the results are, what were doing now, and what is in the future. All of those things.

ASSOCIATE:

Are all of the people who have implants women?

PAULETTE:

We will talk about that later. San Fransico has a lot of other communities. And I have to tell you Mark has a real hard time with that. We talked about putting patients in the removal program, and at first he said no, women I cant deal with that.. women. And I told him the one thing about that is by the time your to that point, they usually want to be refereed to as a woman. It's been our experience, that they will have a female name, and they wont even tell you what her male name was. It's not unusual at all. We have many callers that are like that. Many. and some that call regularly.

He/she is to be treated with the utmost respect, he has implants, he has questions and that's what were there for. Again you may not always get the doctors name, but certainly be alert to what she's saying.

ASSOCIATE:

But, we can ask her for the Doctors name?

PAULETTE:

Yes, you can, but I want you to know that you cannot ask for their name. Only if they volunteer that, do we take their name. They have the complete and total option of being anonymous.

ASSOCIATE:

The callers do?

PAULETTE:

Yes, the callers do. And then you just write unknown where the patients name would go. When we talk about MDR'S we'll be writing refused on there. The reason for that is that this is a very private issue, and there are a lot of women who don't care to share this information with anyone. There are alot of women out there whose husbands don't even know they have implants. Whose families don't know they have implants. Either they had them before they were married or whatever the situation. 800 source can be anywhere, newspaper, doctor, friend, magazine, anywhere. They get the 800 number. It can also be Y-me, many, many ways to get this number.

Product, size, catalog number and lot number, these are things we use to identify our implants. All Dow Corning implants have a catalog number and a lot number. I will teach you during this course how to find out, through a catalog number and lot number, exactly what implant this woman is talking about.

ASSOCIATE:

Is it common for them not to know?

PAULETTE:

Very, but we can also teach them how to, and I got that covered here a little later. You will get to know so that if she is rattling of some numbers or a name, your gonna know the name of her implant. Don't be surprised if it turned out to be our implant and you didn't know. We do make some special implants. We were in business for four months before we found out that we made an implant named "Gold"

ASSOCIATE:

We made alot of custom fabrications, too.

PAULETTE:

Exactly, but the custom fabrications really do cover the same package insert as the Silastic. What it is, is that the 250 or 200cc envelope with maybe 250cc fit. The doctor will make that determination, not Dow Corning. It's the same materials but it just might be a deviation of an irregular form for that product.

How she can find out her implant, while lets do that.

Specific concerns she's going to start talking to you about certain concerns, it may be rupture, it may be leakage, and I want you to know that leakage and gel bleed seem to be inter-mixed with rupture. We really have to determine if they say leakage, what she is talking about. The main key to this whole thing is to listen to what she is saying. What is she saying? She may be talking about Auto Immune. She may say " I don't know what my concerns are...everything concerns me." When I talk to someone like that my usual remark is " is there something specific that is really a concern to you? Is there something you have heard of that is really bothering

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you?" This will give you a point to start. If she cant give you a point, then we will go through the complete complications, we will go through it as much as she wants to hear. Prior medical complications is again mother, sister, father, whatever she tells you will go in there. Was the call report made? This refers to MDR'S, we will get into that later. I will tell you that almost everything we have is MDR. It didn't used to be that way, but it is now. If it is not a positive call, it is not a call just looking for information. It's MDR. We kinda have a problem when it comes to MDR, because the reporting process, MDR'S stands for Medical Device Report. Anytime you have a problem with your product, you must report it to the FDA. What we have a problem with, and the problem with Hemlock, where Gerry Haas is, is that in the center, we don't always have this patients name. If we do not have a name, and they don't give a name, then we have to write refused there. So they can say that is was refused. We also don't always know who's product they have. There are changes coming down in our area.

ASSOCIATE:

Historically, the only time a MDR would get reported is in litigation. We would get a claim or a lawsuit from an attorney that gave some charges, and when I was in legal I had to do this, but read through it and see if what they are saying is something to do with our implants. Then it was a judgement call on the paralegal part to call Gerry.

PAULETTE:

We are not trained to do MDR'S at all in the center. It used to be that we didn't turn in everything. It didn't be that you turned in contracture or Auto Immune Disease, but since the FDA has been to Hemlock, those controls are stricter. I was in a meeting yesterday for this very purpose, MDR reporting, out of the center and out of the Removal Program , it was being kicked around.. do we need to bring someone in that is stationed there that will say, " yes, this should go to Hemlock, or no it shouldn't" and to me I think that is a wonderful idea. Because were not trained to do that and it's a judgement, in which we would like the same people making those judgement calls so that it is straight across the board call.

ASSOCIATE:

Consistent

PAULETTE:

Yes, it's always the same call. I think it is a wonderful idea. We really do need somebody from Hemlock there to look over these call reports and say "yes it is" or "no it isn't". That's what I am certainly going to push for.

ASSOCIATE:

The fact that Gerry's name is on this, is that the key that it is on there?

PAULETTE:

No, there is no key that it is a MDR call because when these were made we didn't report them. The call as it stands at this moment, is that if it is something positive or they are calling for just information, then it is not MDR. Everything else across the board is an MDR as it stands right now. Whether we have their name or we know what product it is, it doesn't matter write it in.

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Certainly all the ones we send to Hemlock are not MDR'S. Gerry Haas is not the only one who does MDR's, we have a woman in Memphis who's name is Alica Farage who does MDR's for MSI's. An MSI is our textured implant.

ASSOCIATE:

As your talking on the phone, as your making the call, are questions asked? Do you follow this? The person is unloading and talking at that point you can start filling this stuff in. However,  
if the conversation turns or slows down...

PAULETTE:

You do not ask questions.

ASSOCIATE:

You do not ask questions?

PAULETTE:

You only take in what they are giving you. There may be a point where you have to ask a question,

ASSOCIATE:

Well, to get the specific's, if they are just covering the laundry list or they are just fishing.

PAULETTE:

Your gonna have to try to get specifically to what they are talking about. One good example is they might say " I am calling leakage" then you have to determine are they talking gel bleed or are they talking rupture? Then you have to do that by asking questions. We do not pry for information. I will tell you they will unload so much information on you that you will have no problem filling out a call report. It's usually, I have seen the girls write on this side, the back side and.. you'll have no problem.

ASSOCIATE:

I seen Wendy fill out four sheets of legal pad the other day.

PAULETTE:

That was on the women who has McGhan.

ASSOCIATE:

If it is another manufacture like McGhan, do we give this information to McGhan.

PAULETTE:

No, we do not. What our job is, is to talk about Silicone gel implants in general and Dow Corning products specifically. Because you have McGhan implants does not mean I wont talk

to you, however, we will also offer you McGhans 800 number. I always do this, if I find out they have another manufactures implant I would encourage you to ask the other manufacture for a package insert. It may be a little technical, then you just take it to your doctor. However, its going to give you all the information about that product. That's what package inserts do.. they give the low down. I don't know how many of you read package inserts, but since I came into this job I start reading package inserts. Read them sometime. You will stop using aspirin, you will never use another tampax. It is just amazing what is in package inserts. Like you, shaking your head no, I have never read package inserts. \

ASSOCIATE:

The one time I read the package insert in tampax I was sure I had toxic syndrome.

ASSOCIATE:

I cant even understand the writing on the outside of the package let alone the writing on the inside.

PAULETTE:

Package inserts tend to be very technical, as are ours.

ASSOCIATE:

The main intent is to cover yourself.

PAULETTE:

Yes, while we live in such a litigates society that manufactures must do that. That's the society we live in.

ASSOCIATE:

Where is the common sense?

PAULETTE:

That's right. The action taken is what you did with this call report. I sent a packet, I referred this to customer service, Removal Program. Whatever you did, is what goes in action taken. Whatever you have to do to that call report. Again, every call that comes in must have a call report form.

ASSOCIATE:

I can see why your making the point to don't take another call until you filled this out. If you have 4 pages of notes to rewrite on to this call report form.

PAULETTE:

It's very hard to.. I will tell you from being in this situation, it is very hard to sort out the call. By the time you have taken three, you don't know if you talk to which one did I talk to. You remember the conversation but which one did I hold it with?

I'm not sure. So it's very important to bring that closure. Close up that call report before you

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go to the next one. If they would really like a packet, but won't give you their name, I have go so far as saying give me a fake name, give me a friend's name. I can send this in a plain envelope. Tell me where you will be at 10:30 tomorrow and I'll Federal Express this to you. No one else will have it. Anything we can do. That's our job... to address the concerns of these women and to get their concerns met the best possible way. I will tell you the people who work in the center are very good at this. We have been very innovative, not only with the people on the phones, but the support people have become very innovative in finding ways to get that information to the patient without delay, in a speedy matter. If you have something you need to address, ask. I would encourage you to discuss calls among yourselves. Sometimes you just don't know what the answer would be to that, sometimes you have an answer, but you don't know how to word it. If you discuss it among yourselves, I guarantee you will come up with an answer. Keep in mind, the people in the center have experience. Draw on that. I assure you they are more than willing to share their experience. So draw on that, use them to your advantage, it will only make you a better person on the phone to do that. One of the things that we had in the very beginning, was that people were saying, "If what they are saying in the Media is not true," which most people are intelligent enough to realize that it is not all true, "then why don't you do something, why do you let them say that?" Of course, Dow Corning does not believe in sensationalism, we don't believe in promoting the issue. I am here to give you scientific knowledge and the benefit of 30 years experience of this firm. We don't have to attack the media, we don't want to attack doctors, we don't want to attack anyone. We are just here to give out information. I will tell you that there will be times when you are going hear these women who say "My doctor broke my ribs to put these implants in." and you're going "No way!" Either she is just not reporting it correctly, or the doctor is way off base. Do not contradict the doctors, doctors are our customers. Do not do that. We are just here to give out information. We don't want to attack anyone. We don't attack other manufactures. As a matter of fact, when I give out the 800 number, one of the remarks I say is that, "here is the 800 number for McGhan, a very reputable company, I would be more than happy to answer some of your questions regarding their implants." That's the way we need to continue.

ASSOCIATE:

Keep the integrity high.

PAULETTE:

Right, if we don't buy into the slander, and slam em against the wall technique. I think we will be much better off. We will be much more... the patients will have much more confidence with us. That's another thing with saying, "I don't Know" you will be surprised to hear these women saying how wonderful we are because we gave them all this information and then when you didn't know something you actually told me you didn't know. But, you will find the answer for me, that's great. Don't lead them a stray, just say you don't know. Again, make sure you close out your call reports. The next thing that is a responsibility of the associates are letters. We do have a standard form letter that goes out with the packet. It's a very nice letter. It was designed specially to go out with the packet. Your name is on the letter. You will sign each and every letter that you send out. There will be no signature stamp. I send out and sign, probably over 200 letters a day, and I have been approached several times to get a stamp. The reason I don't do that is because it is not personal. I don't care if I have to sit there for two hours every

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night to sign letters. That's what I am going to do. I am not going to have a signature stamp on the letters. We are there to provide a personal service to these people. I want you to understand, that sometimes when your done with this call, a form letter is just not going to fit. Maybe she has her catalog and lot number, and she wants to know what implants she has. You probably will not have time to look it up immediately. If she has only just the lot number, you cant look it up just with the lot number alone. Doris Michaleson can. You will have to proff Doris. Doris is very busy, she is very back-logged. Do not press Doris. She is a very wonderful lady, and she is so over worked and under staffed. I have nothing but sympathy for the poor woman. I made up this book, and it has helped a lot. You no longer have to have everything go to Doris. We don't send 80% of what we used to, to Doris. I also sent this to Memphis, and Lynn said " Big pat on the back for you. Everyone here just loves it." It is really very simple. But, when you are in the middle of all these phone calls, chances are, even if she has the catalog and lot number, you're not going to have time to look it up. That's when your going to have to put it in a letter with the packet. This is probably a real good time to make this point. We do not offer package inserts. We have package inserts that go all the way back to the beginning. If this woman calls and says "I had surgery in 1978, and my catalog number is 582, and the lot number is HH whatever," we have her package insert. If she asks for that package insert, I will give it to her, if she does not ask for it, I will not give it to her. In the packet of information, there are package inserts. Package inserts in the very beginning, when these were introduced in 63 until now, has grown. It used to be a couple pages and now it's like 17 or 18 pages long. What was in that package insert in 1963, is still in that package insert today, but more things have been added. So I am not cheating her out of anything, she still gets to read whatever, but she gets to read the whole scope of everything we know. But, if she says, " I want my particular insert." we will do it.

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IMPLANT HOTLINE PROGRAM  
TRAINING SESSION  
MARCH 25, 26, 27

TAPE 1 SIDE B

[Noise]

MAN: No overheads today.

WOMEN: All right.

[Noise] MAN: The FDA issued a thing called the 515B [undiscernible]. That is a Federal regulation that states [noise] manufactures of PMA (Premarket....Application) is needed and tells you what the contents of that PMA should be. Under the law PMAs are due 90 days after the [undiscernible] so we filed our PMAs July 8th, 1991. We filed two PMAs. One deals with the Celastic II Implant which is the smooth one, and within that PMA we covered two products, Gel Filled Celastic II and the Gel Single Celastic II. The second PMA was for the Celastic MSI [undiscernible] both Gel and Gel single. On September 13, the FDA notified us and all other manufacturers that there were deficiencies. Refer to virtually no such thing as a filed PMA that does not have deficiencies. There were minor deficiencies .... we answered all of those deficiencies between October and December of 1991. On November 29th of last year, we got another letter from this Agency telling us what we will have to do to hope to have an approval of the PMA. That resulted in a meeting with the FDA in December in which we discussed, characterized and negotiated what we would do if they would accept. That then formed the basis for presentation, I made in February of this year to an FDA, Advisory Panel, in which I outlined to them what we intended to do. Originally what we started to do came under 3 categories, physical and chemical [noise], safety starts involved. And, of human studies of which there were 2 kinds, epidemiology studies and prospective clinical files. That terminates that discussion let's go back up and I will tell some of what is in the PMAs for safety and then I'll come back to this subject. Our PMAs were approximately 33,000 pages and contained all the required s\_\_ parts that was manufactured and on the labeling [low verbal] let's just restrict ourselves to safety [undiscernible].

First there are two categories, first we'll talk about 921 studies. We had over 300 animal studies ... These studies covered acute toxicity ....uticinicity meaning [undiscernible]. pharentology, meaning birth defects, immunology..... distribution studies, meaning when you implant silicone fluid gel or lasamer, where does it go in the body and at what rate does it go there.

We have sub-chronic studies, the kipso-chronic are defined differently by different people. But I will tell you how I defined them in the PMA. The acute covered studies lasted not more than a few hours to a few days. Sub-chronic was defined as studies that lasted longer than that but not longer than 6 months, then chronic is six months or longer. That's the way we did it in the PMA. So we have sub-chronic studies, these are generally implantation materials in rabbits, sometimes rats and looking at what sort of tissue reaction there is immediately adjacent to the

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implanted material and we also marked the effects on major organs: liver, heart, brain and that sort of thing.

There are a number of different kind of chronic studies but the most important ones are called lifetime rat studies. By convention, scientists and the government agree that lifetime of a rat is 24 months. Rats will live as long as 4 years but by 24 months under today's conditions, ordinarily as many as 80% of the rats will die, so we call it two years. In those studies, we study the behavior of the animals, we look at their blood chemistries and we look at the effects on all the organs and tissues which amounts to something over 40 tissues and organs that we look at. By looking at them, we look at the histopathology under the microscope to see what is going on. These studies are chronic toxicity studies, very importantly, they are also cancer studies. Laboratory rats, beginning at about 1 year rate, begin normally to show cancer, very often the cancers appear in a pituitary gland which is on the bottom of the brain. If you draw a line between your ears and a line straight back between your eyes that is about where the pituitary is. But then other tumors show, by the time a rat reaches two years of age he has multiple cancers. So what one does is control group and then plan a group of silicones and look for differences and the kinds and incidences. The outcome of all these studies was that virtually no systemic disease is found in animals in response to silicone. The length of their lifetime is normal compared to the control. The kinds of what we call intercurrent disease are the same in the treated group as in the control, there are lots of diseases, lesions of the lungs and all kinds of things. Same, all are treatable. A very notable event, however, is that an animal implanted under the skin with silicone is important to remember that any other foreign material, there occurs a special kind of cancer immediately after sighting elsewhere in body called sarcomas. This is called the solid state effect or the Oppenheimer effect. This is called the Oppenheimer because in the late 50's or 60's a man and wife research team did a lot of studies on this effect - their name was Oppenheimer. We have found no alterations or diseases of the immune system in animals unlike what was reported in the media. We find no birth defects with regard to blueprint materials let me describe the core experiment. This is a study which was not done in rats it was done in mice for a number of technical reasons. Radioactively labeled silicone gel without an envelope was put under the skin and we looked these animals (21) over to see where the radioactivity went in the animals. At envelope rate and how much. The way the experiment is done, we know the radioactivity is following bleed is what it is called. With that over 21 weeks at the maximal fraction of a dose of gel under the skin had moved was 0.009% that is a very small amount. The study was designed so we could find one, one millionth of a dose in any one tissue. It was designed for smaller animals. We found radioactivity, would you believe, in only two locations. Regional lymph nodes, that are lymph nodes that are close to implantation and what is called depot phase, is stuff that most of us don't like. That is it is an energy storage form. There is reason to believe, based on the totality of science, that bleed does go some other places but that it just goes there so slowly and such small amounts that it is less than one millionth. Let me tell you where those tissues are where it undoubtedly goes, in the liver, the spleen, bone marrow, lung and other lymph nodes. I have just named for you the major tissues and organs of the major lymphatic system. So those are the major findings from our animal studies.

There is also a large component of PMA that deals with clinical studies either done by Dow Corning or done independently by surgeons who gave us access to them. There are five such

studies in PMA, accounting for a little over 1,000 women. In those studies we determine the incidences of the short term complications, infection, contracture, hematoma, all of the things you see in the package inserts. The incidents of those 5th are general expectation a low percentage. No systemic diseases of any kind were noted among these 1,000 women. Some of who have been followed for as long as ten years or more. However, the diseases of greatest interest at the moment namely diseases of the immune system, typically referred to as autoimmune disease or connect a tissue disease, occurs so rarely that it was statistically unlikely that we would see them among a 1,000 women even followed for ten years. For that reason, 6 to 8 months ago, we started a large epidemiology study at the University of Michigan that is looking at connect a tissue disease in women with implants. The primary disease being looked at is Scleroderma. All immune diseases, connect a tissue diseases, as it turns out are two to five or even ten times more common in women than men. One of the few advantages us guys have. And that first occurred in women in the same age range as those who received breast implants the 20 to 50 age group.

The total number of cases reported so far of autoimmune diseases in women who have implants is, by my estimation and the estimation of some others, consistent with the ordinary background of the disease, these diseases occur in women and some women who have implants will have these diseases. Now that is what I think that is not what I know, we will study this. That study will be done in 1993, they hope/they plan. We are also sponsoring a large breast cancer study at New York University. The cancer issue is tending to go away, there was great consternation and concern over the sarcomas, lots of bad P.R. and screaming of researchers who had in the last two years fading into the background because there is no evidence any where to support the connections. So right now, there is no convincing evidence of a connection between silicone breast implants and autoimmune disease. This does not mean that there is not a connection. The way it looks right now is as follows:

If there is a connection, it would appear that it is a very small fraction of women who are at risk. They may be at risk, for example, because they have a genetic predisposition to disease. They may be at risk because they are going to develop the disease and somehow a foreign object promotes or accelerates the occurrence. Only through this Epi Study will we come to know. Now even that Epidemiology Study won't give us a final answer and proof because it is in the nature of these studies that you determine a risk ratio, that is we will be able to tell, we hope, that there is an association provided that there is an increase in these rare diseases between two and three times the normal background. It is so rare that two or three sounds like a big number but it isn't. There could be a 1 1/2 times increase in risk and statistically you would be unable to see it. It is theoretically possible to do a study that would measure a relative risk of 1 1/2 but would require tens of thousands of women. What I am talking about is the relative impossibility of proving a negative, proving that something doesn't happen. So where our animal studies provided a lot of support saving, the clinical studies show that the implants are not without risk there is infection, there is some tracking, there is hematoma, there is rupture, but so far no convincing evidence of serious disease.

The FDA looked at all of our data and all of the data of other manufacturers and they said, your data does not show the product to be unsafe, however, the data our [noise], they want more data. Some of the data they want deals with determining the chemical and physical properties

of materials over time after implantation. They want more paracology data and things of that sort. Very importantly, they want additional clinical evidence and they want that in the form of what called prospective trials, that is you recruit women who wish to have an implant either for augmentation or reconstruction. You determine their health status before they are implanted and you determine their health status at various times after implantation. At this time, the FDA wants us to follow these women, yet to be implanted, for three years and then provide a complete report of findings. It should be understood that while they say that, you all understand we want to follow those women five years, ten years, etc.

We have been to the FDA a number of times. We were there a week ago discussing the details of what needed to be done. There was particular focus by the way on a retrospective registry. The idea is that the women could voluntarily join a registry such that if adverse findings arose at some point in the future there would be a means of communicating with them. This is presently a very hot subject among the manufacturers for two reasons. One is retrospective registries for other products in the past have failed, they don't work. They don't work because the patients who tend to register are only the ones who have problems or think they have problems. Secondly, there can be massive loss to follow up. I am going to make a remark that sounds sexist but I don't intend it that way it is a reality. Women in particular are harder to follow, they move rather frequently and most irritating of all they change their names, which makes it very difficult. I'm am in favor of the retention of the maiden last name from the experiences I am having. But those are realities that cause great difficulty. So here we are with a situation that would appear to be, based on history, highly ineffective which leads to the second concern extraordinarily large expense. A retrospective registry could easily cost 25 million dollars a year, every year from now until finish. There are other ways to make it less expensive but any way you cut it, it doesn't seem to work. Nevertheless, if the Agency wants such a registry, we will comply. It is a situation that you argue till you lose then you do as requested. It is probably the responsible thing to do because those problems are your problems. Well, as you all know on January 6th, Commissioner Kessler put into place a voluntary moratorium on further distribution, sale of product for any company within the confines of the United States until he makes his decision on the status of the PMAs. He must make that decision on or before April 20th. Dow Corning and all the other companies complied with the request for voluntary moratorium in the United States, Dow Corning went further and made it Global, you cannot get an implant from us anywhere on this planet since January 6th. On Thursday of last week Keith McKenna, our new C.E.O., Barry Carmichael and myself appeared at a press conference at the National Press Club in Washington. At that time, Keith had a press conference and made three announcements. One of those announcements was the establishment of a ten million dollar fund to do the research I just outlined in the last few minutes. With the understanding that if it needs more than ten, we will spend more ten. Our present estimate was ten million dollars. Secondly, the implant patient assistance program. [low verbal] And, thirdly, we announced most unequivocally we will not reenter the business under any circumstances, we are gone. Not only are we gone from the breast implant, we are gone from all plastic surgery products.

WOMAN: Does that mean TR80?

MAN: Now that statement about exiting the business has the following characteristics. It will

not be possible and has not been possible to buy a Gel Breast Implant since January 6th and will be impossible for all future time. As of yesterday or the day before, I can't remember which, you cannot buy any other Gel filled product from us, all of which are only two and they are very minor -- the chin and the Gel testicle. The third feature is that surgeons may buy our tissue expanders which are good and effective products until such time as the inventory is exhausted. We are not now manufacturing them nor will we. Our present estimate is roughly 6 months those will be used up. At that point, will be out of it. Keith was very careful to state that these decisions have utterly no influence on our prior announcements which regards [several coughing]...we will do all these studies, with an exception, we will not do any prospective clinical trials because it makes neither ethical nor scientific sense to do so on a product you have no intention of selling. What we will do in addition to the Epidemiology Studies is at large about 1,000 patients retrospective to study, that is women who have implants to determine more accurately the incidents and common complications and tracking infections. We will do all the animal studies, I have been totally engrossed in setting up the explantation testing program which we intend to do a very large number of physical and chemical tests of implants retrieved from women, we have a little problem called TRO Judge Rueben in Cincinnati such that you guys are not going to be able to answer the phones right now and I have letters on my desk from women that I cannot answer, that is absolutely criminal. As far as I am concerned it is an unconstitutional interference with freedom of speech and it certainly does not serve the needs of women. There will be a hearing on Friday in Cincinnati. I have no firm idea of what the outcome of that will be. I and (name) feel so strongly about this explant program that we are forging ahead, we are not going to just stand around and see what happens, we are forging ahead and getting it all set up. It is going to be very bad news for everyone if we are unable to do that testing. It is a tremendous disservice to women, well we'll see how it goes.

WOMAN: Do you know who is going to that hearing from us?

MAN: It is not -- it's a technical issue -- it difficult at this moment to figure out, I got a meeting from 10 to 12 to talk about that. We may not have any one from Midland or from Dow.

WOMAN: Outside counselors.

MAN: Outside may handle everything. I have some great four letter real cheap words for this guy. Not the judge. The judge is just doing what he has to do. This attorney has really got my goat, but probably Frank can answer that. Well that's the situation there.

There are any number of possible elements of research that I haven't mentioned because that will have to do because I just don't know what they are right now. Whenever you do research and you answer one question, you come up with five questions not answered. Called the Scientists Unemployment Act. So there will be others, we just don't know what they'll be right now.

Have I missed anything real important to you?

PAULETTE: One of the things I would like you to talk about is that the women who call in and say I want to be part of the study, you talked to us about that before, that we don't chose

those women.

MAN: We have to be very certain that the science will do whether it is in the medical arena or the lab arena. It is designed and executed with extreme care to follow the rules of science and doesn't accommodate other kinds of issues. We do get and we will get calls from woman who say "I think I have an autoimmune disease and I would like to volunteer to be part of your clinical program", your answer to that has to be "that we very much appreciate your willingness to do that but we can't do it". Individuals for these trials must be selected according to extremely rigid rules. If you begin to take volunteers, you necessarily begin to compromise the study. There are certain possible exceptions. In the U of M Study, we are trying to identify all the women in the State of Michigan who have Scleroderma. If a woman called and said I have Scleroderma, [garbled verbal] I think the thing to do at that point is not to make any promises but transmit that knowledge to Dr. R. Cook, not to the U. of M. I haven't talked to him about this so I don't know if that would confound things to much or not. But from other parts of the country, woman with breast cancer or some disease, we have to tell her with regret that the hard rules of science just don't allow it. The science and the medicine and these things become extremely hard, very hard and strange to explain to people, I just don't think we have any reasonable way to explain satisfactorily in any detail but it has to do with statistics and founders of the strange [garbled verbal].

Do you guys have any questions? I'm always around and when things arise or questions, pick up the phone or send me a message. I'll ignore it as long as possible but answer it. I try to answer quickly.

WOMAN: So you are kind of a medical, technical expertise here, resource.

MAN: We flaunting right now a new Troika to try to deal with this issue and it is badly needed consisting of Myron Harrison, Medical Director. Ralph Cook, who is director of Epidemiology as of a couple of weeks ago they are both MDs and myself, I'll deal with star wars issues. The science stuff.

WOMAN: They are dealing with the medical issues?

MAN: We will substitute for one another. If you can't get one on the phone call the other one. We will deal with it. I answer within narrow limits essentially medical questions all the time, it is not hard to do because I am neither Myron, nor Ralph nor myself can, in fact, answer a medical question -- it depends ever so much on that individuals whole history, basically what you do is give a little bit of information and steer them to a physician who has or who can obtain all that information from them. I am not going to practice medicine on the telephone.

PAULETTE: We will get into that very quickly. I don't ever even remember coming to you with a medical question -- I don't think we get that many that we steer them to their doctors.

MAN: We get some strange questions, for example, the woman how inquired about how she was skiing at 8,000 feet and hearing her implants slosh. The answer is go to the restroom before you go skiing. We can answer questions like that. They are easy to answer. I get letters

all the time, even photos, from physicians, dealt with one earlier this morning, where the thing called neoseniphilicspongeosis, which is sort of a brownish red raised wart looking thing that she had between her breasts. It is associated with some allergic reaction. She has implants, so I just talked to the guy about what that means and what that doesn't mean based on the science of the thing, not on the medicine. So often we can help out the physician or surgeon just by talking about the science of the thing. But at the moment we can't do any of that. By the way, I am not even answering letters from outside the U.S. until we get clarification, I am not answering them.

PAULETTE: I have a stack of letters also. I am forging ahead with them, hoping against hope.

MAN: I try to write answers and put them in the file and wait -- date them later.

PAULETTE: Any other questions people? Want to take break?

MAN: We are getting more efficient now.

PAULETTE: I noticed that Bob.

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

TAPE 2 SIDE A

[Noise]

MALE: Training

PAULETTE: Why don't we start to talk about what the Implant Center is and what we do and why we are there. Then Bob can come in and talk about technical information.

MALE: There are some legal do's and don'ts.

PAULETTE: We have gone over the Call Reports once.

MALE: In talking with these women on the phone you should try to be as factual as possible. There are certain doctrines that apply when you are dealing with us.

Okay, Attorney Clackburn, who is an attorney, word product protects her information. Doesn't protect facts that you receive. But it would protect any, for instance, if you got in a situation where you did not know how to deal with it and you talked to Paulette and Paulette said call Legal. You would call Legal and I gave you some information, that's protected and it doesn't have to be disclosed under the Attorney/Client privilege.

If I asked you to obtain certain information or to do something with a patient or patient file, that could be attorney word product. Again that's privileged. We don't have to turn that over, although in some rare circumstances we do, but in most cases we don't have to turn that over in law suits.

If you are taking down notes on the phone and some lady comes in and you say, "boy this lady is a real witch", and you'll get them like that, believe me there are some calls that come in -- horror stories and ladies who are just crazy. They'll cry and scream and you will find you will have to have thick skin to deal with some of them. Don't write it in your notes, you can write that this lady is upset or something like that but don't write, this lady had it coming to her -- real witch or any other derogatory terms -- because chances are this lady is part of a law suit. They are going to subpoena all the records from our Implant Center. I see that coming. Nobody has done that yet, surprisingly, but these attorneys are real big shooters and they know what they are doing. They are representing a lot of women. Cost is no object.

This guy, Chesley, he had some women approach him about filing individual law suits for them in breast implant cases and he told them no -- it's too small potatoes. Small potatoes is, you know, 1 or 2 Million Dollars, 3 Million Dollars, that these people sue for. He then brings class action.

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He's the one who just settled with [undiscernible] Heart Valve, class action, I don't think it's official yet but there is a tentative settlement of 200 million dollars. So he doesn't play with any small potatoes. And, cost is not going to be anything that is going to bother him. In fact, I think he has approached some of the people in California in some of the law suits out there. Individuals who since have filed class actions and to move them into the folds so they can combine their class actions with his. He's started talking about what the expenses are in a recent case in San Francisco where we got hit for 7.3 Million. If you take away the punitive element, which always can be reversed in an appeal, the compensatory damages were only at 830,000 dollars or something. The attorneys out there in that case had about 200,000 dollars in costs. Direct out of pocket costs that they paid for experts, for depositions, filing fees, travel, everything, and they showed about another 350,000 dollars in attorney time. So, if you took away the punitive damage element in those cases, those attorneys lost money because basically the cost would be subtracted from the top and they would get 1/3 after that, of this money. So that is why he has been trying to get them to combine into class action and he has been pretty successful so far.

He won't stop at anything to get any information that we have, so we have to be really careful about what you write down. Keep it very factual. The other thing is, because of all the hubbub that is going on and the questions about misrepresentation, you have to make sure that you are very clear as to what you are telling these ladies, again make sure you are very clear. If you are not sure of an answer, if it is not part of the information you have been taught to give don't give it. Don't give anything off the cuff – it only comes back to haunt us. Even casual comments, "wow, I don't see there is any problem", "this stuff is safe"...The FDA jumps all over us Number 1, Number 2 [undiscernible]... so you want to confine your statements to things that have been approved to say, information that has been approved to give out.

If you have problems you may want to direct to your supervisor, you can also call Legal and talk to any of us in litigation, this is where you want to call. Some of the other Sections are just not up to date.

PAULETTE: They are on your resource List.

MALE: All the other attorneys? Just Litigation?

PAULETTE: No. Litigation – those people in that area to call.

MALE: Right now would be Greg Theis, Barbara Anderson or myself or Carol \_\_\_ Davis. Don't be afraid to call if you have questions or if you have problems. If it is something Paulette can't help you with, give us a call. Sometimes we can help and sometimes we can't. Sometimes we just have to say you have to listen to some lady for two hours and it'll drive you nuts. We just tell you to get therapy in your off hours.

PAULETTE: I have already told them just come into my office any time, rant and rave, walk up and down, that's fine. I probably will continue to do what I'm doing.

MALE: One of the things that is important from our standpoint, something I tell everybody handling claims to do, is don't ever promise anything more than you are sure you can deliver. Because that is the surest way to get somebody P.O.'d at you, is to tell them well I can have that to you tomorrow morning and it doesn't get there. Always hedge your bets a little bit. Only promise what you can deliver. That is really important, otherwise you get their expectations up and if you then don't fulfill them, they are in some lawyers hands.

Somebody had questions on privilege. It's hard to explain what the privilege is, okay. The privilege is, let me give you an example of the privilege. Ann Boyer calls me up and says I have a problem with a lady and this lady is threatening to file a law suit and she has given me this information, what do I do? And, I give her some information as to what to do in this case. She then goes back and deals with the women on that basis okay. You don't want to tell the woman what I told you, okay, because in doing that you just then waive the privilege. Okay. You can do what I tell you to do, I may tell you to tell the woman something, if I do that then obviously you tell the woman, the general advice I give stays between me and the person I give it to unless I tell you otherwise.

PAULETTE: So we don't quote you?

MALE: No. Unless I tell you to quote me, if you quote me you just waive the privilege for that conversation. And it is all discoverable. I may, for example, in a Claims Arena, I may tell somebody, well you know, tell us what we [undiscernible], it is our feeling that she has no legitimate claim and we will pay a minimal amount and that is all there is to it and then I may say, "well in actuality, the woman could probably collect a lot of money in a law suit, if she files, just because of this, this and this." If you then reveal that it comes out as an admission on the part of the Company. And, I may have told you that to set the parameters on dealing with the client, okay. For example, I may say well, you know, tell her it is not worth anything, we'll give her 500 bucks but if she persists, pay her up to 2000 dollars because these things could be bad and cost us a fortune and she may have a decent claim. If you talk about that part of it with someone else, then you have just waived the privilege, everything I have said is discoverable.

The patient's attorney may come and say "Okay, Ms. Woodard, you told the patient this and where did you hear that?"

"I heard it from my attorney, objection privilege is waived."

"Tell us what your attorney told you."

"Well he said this claim is worth a lot of money."

And that is exactly what can happen. So you really have to be careful. Now there are certain times when things can be discussed with Supervisors and there are somethings that can be clarified between you and the person involved, whoever, legal person involved. But even if, say you went out after you and I had that conversation and told someone else, arguably you have waived the privilege because you have come to me. The privilege is established when the client

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comes to the attorney with a request for legal advice. Legal advice is given to that person. If that advice is relayed to someone else outside of that group, 2 persons or 3 persons, whatever, you have a waiver, it has been revealed, it is no longer confidential. It is discoverable, you have to be real careful with that.

Attorney word product is similar. Say I asked you to go do research on something or I asked you to go get some information for me. However, I asked for your opinion(s) on a person, what is your opinion, and I do this a lot with people in claims because I don't deal with the ladies nor do I want to deal with the ladies because these other people that are handling the claims are much more aware than I am. I will ask them what is your opinion? What do you think? Lily, Shelly or Rosalyn will give me their opinion. Well I think this lady is nuts, she is asking for a million dollars and I think she's probably looking for 2, 3 or 5,000 dollars. I tell them to try to settle for 2,000 dollars. That is an example of word product. I have asked their opinion, I have asked them to do something for me, that is protected. But, if that is conveyed again around outside of the group of 2 or may be a Supervisor, it's a little bit looser, that can be waived also. Claims attorneys have a little easier time getting at word product, if they can show them that there is relevant information there and there is no other way to obtain it, but it is still pretty protectable. So that is another thing that is important.

WOMAN: Do the woman that call into the Implant Information Center and state they want to talk to somebody about making a claim do we then refer them to the Claims Center or Customer Relations.

PAULETTE: There is a way to deal with that and I'll talk about that when we get to questions and stuff. Because I want you to understand that just because they call in and say "I'm hiring a lawyer tomorrow" doesn't mean that by the end of the conversation that they'll be calling that lawyers office tomorrow. It depends on what they are looking for, if we can answer their questions. A lot of women are just frustrated because they haven't got the answers and they don't have any where to go get them. Doctors are very busy and they don't spend an hour on the phone.

You know our calls last about 50 minutes. They spend an hour on the phone with each one of these women that have been implanted and so they are just kind of looking for information, not necessarily will it go to there but when it gets to the point. We'll talk about this in great detail later, but when it gets to the point that someone is going to pay for this and you are going to be the one to cover me for all of these things. I have lost work and you know I'm out all this money and whatever, at that point, it will probably will go to Customers Relations and, there are some steps that need to be dealt with before it is sent there also. First of all we have to make sure it is our product.

WOMAN: I have a question. When we are talking to these people, have I given them my name?

PAULETTE: Definitely. That is one of the first things you do and one of the last things you do.

WOMAN: Okay.