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

TAPE 3 SIDE A

PAULETTE: We'll talk a little bit about the history of breast implant. I think throughout the history of the world every civilization has established its' norm for acceptable physical appearance. I think there was a time in the 20's when it was certainly acceptable to be flat chested and have the boyish look, but that was a very special time in history and most of the time we expect women to be voluminous.

WOMAN: 60's and 70's were Twiggy to.

PAULETTE: I remember Twiggy.

WOMAN: That's gone.

PAULETTE: Thank goodness.

WOMAN: No kidding.

PAULETTE: The ratio for augmentation versus reconstruction is approximately 8:2, 80% augmentation, 20% reconstruction. There have been 3 major successful means of augmenting the breast, injectable materials, prosthetic devices which today are referred to as implants and autogenous tissue transplantation. And no single method has occupied an ear to the exclusion of others.

First, I am going to talk to you a little about injectable materials.
Dr. Gerseney was the first to describe the injection of foreign materials into the breasts, that was in medical journals, that is he was the first. In 1899, Gerseney advocated the use of paraffin injections. That's wax.

Following these reports, surgeons began to use various substances besides paraffin including vegetable oil, lanolin, bees wax, liquid silicone.

In the Mid-60's, however, the FDA declared the practice of injectable materials not only unacceptable but illegal because of the persistent and devastating complications. Such as, the migration of the material, cyst formation, dermal infiltration with necrosis of the skin overlying the breast tissue again. Necrosis is literally the dying of the skin -it literally dies.

RO Genis tissue transfer a Dr. Sussenee is credited as being the first to perform this augmentation mammoplasty and that was in 1895. He successfully transplanted a lipoma which is a fatty tumor from the back of patient into the patients breast to correct a defect that was left from the removal of a breast/glandular tumor.

There was a Dr. Luxer and a Dr. Passett that are credited with the popularizing the use of autogenous fat transplantion. Fatty tissue is taken from the abdomen and the buttocks and transferred into a surgically formed pocket underneath the breast tissue. This type of a graft has a high rate of liquification for absorption. The body reabsorbs that fat and then it is gone.

In 1952, a Dr. Banes refined this technique by using dermal fat transplants accompanied by the phasa, phasa is the fibrous membrane covering that supports and separates the muscle. By leaving that on the absorption will be cut down -- so great. The use of the dermal fat transfer with accompanying phasa became very common but had an unpredictable resorption of the graph leading to asymmetry -- this is where women are not equal on both sides.

Patients and surgeons were also dissatisfied with the severe scaring of the donor sites. Also, understand that when you are creating donor sites you are creating infection sites and you have this kind of procedure going on you have a lot of different areas that are giving back tissue and that is a problem.

The woman, Marianne Hopkings the case in San Diego, this woman had an autogenous tissue transfer and when she came to court she was on crutches because the fat had been taken from her upper thighs, she was still on crutches because it takes a long time to get over this.

The cost of the implant surgery is going up all the time. The economic side of supply and demand because saline implants are the only thing on the market, they have gone from $400 to $900 but with the normal cost of what a Gel implant would cost, reconstruction surgery could run from $3000 to $5000 depending on where you had it done in the country. In Iowa it doesn't cost the same as in New York or California, there is a difference in where you have it done. Autogenous tissue transfer can run up to $25,000 to have this done. It is quite a procedure, it very expensive. I think that it is another element of this issue is the fact that if the only thing that is left becomes autogenous tissue transfer, then we need to look at some other aspects of labor unions, I mean we pay for when we have mastectomies, we are looking at a difference of cost here say from $5,000 to $25,000. This is affecting more than just the implant market. It is affecting other people out there too there are other tangents there that need to be looked at.

Prosthetic devices, devices that have been used over the years as breast implants. From the earliest of times, they used to use the breast prosthesis of various materials as being the easiest solution in correcting breast hypoplasia, which is the defective development of tissue.

The first prosthetic devices recorded were balls of ivory. In 1930, a Dr. Schwartzman advocated the use of glass balls so at that time they were using ivory or glass balls.

In the 50's and 60's, they came up with a sponge prosthesis. Before implantation the surgeon would have to carve the sponge to the shape and size desired, soak the sponge in water for 24 hours, then sterilize it and implant it. The sponge implants initially provided acceptable results but once the scar capsule began to form and tighten down on it, it was not acceptable at all and became very deformed. It would also make the implant shrink. Of course, the results were very firm, unnatural contours. It is not very natural.

A major development in this prosthetic device occurred in the early 1960's, in cooperation with Dr. Thomas Kronin and Dr. Frank Geroux, Dr Geroux was Dr. Kronin's Resident at that time, they came to Dow Corning with an idea for a breast implant which, in all by the way breast implants that silicone breast gel implants are based on Dr. Kronin's design from the very beginning. They introduced this breast implant, they called it natural fill celastic prosthesis at the 3rd International Congress for Reconstructive Surgeons in 1963. Dr. Kronin is the Father of the breast implant as we know it today. He is also credited with the development of the ear shunts, small tubes that they put in children's ears (which we also make by the way). The original silicone gel implants were constructed with seams around the edges and silicone elastomer walls. These implants were available in various contours and had dacron backings for adhering the implant to the chest wall. It was soon found, however, that the dacron patches/backings caused excess scaring with contracture of the fibrous capsule and the contour of the implant itself did not influence the ultimate shape of the breast. Once the scar capsule began to form around it, it didn't matter if it was shaped like a tear drop or a circle, it was going to become a circle any way. Subsequently silicone gel implants were manufactured in a sphere and without the dacron backing. Further improvements included softening of the gel and the encasing silicone envelope to promote a more natural feel and the elimination of seams to prevent palpability around the edges. It is important to know that the gel filled implants used today are all derived from the original Kronin design. Here is an original Kronin design complete with seams and dacron backing. Here's one with dacron backing that is seamless. In very thin women you could feel the seams on the outside.

WOMAN: You could really notice it.

PAULETTE: the tear drop, the different shapes they came out with in the beginning. It doesn't want to fit in there. Also, the dacron patches weren't needed because the pocket was created the scar capsule would form around it and hold it in place. But understand it is a learning process. As you learn more about the product, [low/garbled verbal]....Here this one is seamless but [noise] patches on the back. See how small they are. These are not Dow Corning [dropped item - loud noise]

WOMEN: That would be real – laughing — [dropping] Can you imagine you would feel that every day of your life. Sleep on your stomach.

PAULETTE: Could we sell them for novelty items. These by the way are all Arts'. [laughing]

In 1965, Dr. Blongsma who today is the Director of Continuing Education at Butterworth Hospital down in Grand Rapids and Silas Braley listed the following properties as an ideal tissue substitute, (1) that it would not be modified by soft tissue, (2) that it would be chemically inert, (3) that it would produce no inflammation or foreign body reaction, that it would be non-carcinogenic, that it would produce no stage of allergy or hypersensitivity, that the capsule or fabrication in the form desired and that it would be capable of sterilization. Silicone fulfills most of these ideal properties.

Further developments included the production of a symoplast inflatable breast prosthesis in 1965,

PAULETTE: Okay.

WOMEN: Is this a case where you can't do it yourself because it is all Union.

PAULETTE: You can get .... service to move boxes...What probably [undiscernible]

WOMAN: Then it probably will take them a week to do it.

PAULETTE: It does take three to stand around and decide and then they go get the material to do.....

WOMAN: And then they take a break and then they come back....still the same.

PAULETTE: From 1964 to 1968, we have a celastic mammary prothesis Kronin technique seamed envelope gel filled. There were four kinds of early implants which was a high profile time to work around high profile and low profile contour and a low profile round, and all of the implants were seamed and had the problem of the seam showing through the skin. This, of course, lead to seamless implants. In 1968 to 1976, there was a celastic mammary prothesis gel filled there were various styles, there were seamless envelopes with gel, again the seamless envelope was developed because of the palpability and the possibility that in thin women the seam could become visible. 1975 to 1988, we had celastic mammary prothesis gel filled, seamless envelope with spots of gel and that's is exactly what it was, the gel seemed to be more responsive for natural beauty. In 1977 to 1982, we had the celastic verifilled mammary implant. This was Dow Cornings only saline filled inflatable design seamless envelope implant.

WOMAN: What made it more responsive?

PAULETTE: They changed the gel and what they did was change the chemical make up of the gel and it was more responsive --- it became thicker. Looked more natural. This was a silicone elastomer envelope which was empty and the doctor would fill it with the saline solution at the time of surgery. These were on the market until 1982 -- again [undiscernible] still produce these types of implants today, we do not. Of course, we don't produce any today -- but we did do saline implants until 1982. And that can be very important, because women will tell you that they have their saline implant and they were implanted in 1989, if you have a saline implant in 1989, it's not ours, right that's why we [undiscernible].

WOMAN: Now the dates on here are 1977 to 1982, are these production dates?

PAULETTE: Those are production dates and that is a good point. If they are on the shelf after that time, a doctor still has the opportunity to use them.

WOMAN: They could have then?

PAULETTE: They could have, but that would have been a very old implant at that time. That was seven years on the shelf.

WOMAN: What is the shelf life?

PAULETTE: I don't think there is a shelf life per se of an implant. But with salines and the problems that are involved with them, I am not sure a doctor would implant them.

WOMAN: Well there are doctors and then there are doctors. So.....so they probably still have them on shelves.

[garbled all in discussion]

WOMAN: Well I heard that someplace in Caribbean have stockpiled implants...?

PAULETTE: That could be. I will tell you that my understanding, I have a letter sitting on my desk from Mainland China Doctor ..... of course, we do not sell them worldwide. Dow Corning believes what is good for the United States is good for world and if you are going to deal with those other markets then you have to [undiscernible]. Well just as we saw on that movie there, they were still selling and implanting Surgitec Implants in Great Britain after they had been pulled from the market here.

WOMAN: Well Great Britain has a ban on them now don't they?

PAULETTE: I believe so on the Surgitec. Interesting enough when the people came over from [name not coherent], Drs. making implants in their garages.....It is a different set of rules over there.

WOMAN: When we need these implants [undiscernible].

PAULETTE: I did tell them that if they had any problems to fly me over there.

[laughter and mixed, garbled discussion]

PAULETTE: When they came here to train, I trained them -- 6 people in two groups -- and I kept saying to them -- you paid for 6 plane tickets when you could have paid for one....

WOMAN: It did seem kind of silly. Except they needed you here.

PAULETTE: Well I guess that was it, you could have survived. From 1979 to 1988, there was a celastic gel saline mammary implant again seamless inner, seamless envelope outer gel filled mammary implant inner (GF stands for gel fill). These are what are referred to as a double woman implant. The silicone implant the smooth wall implant is designed with an outer shell which is filled with the saline. If you want to see one of these I have one on my desk. I thought I had more than this in this box...a lot of times we do [undiscernible] around the center which has a tendency to twist them into shapes. One of the girls who was a rotator touched [undiscernible] and ruptured it. she said "Well I suppose I better clean that up" and I said "yes, but don't throw it away it is worth $1200. We can take it next door and get our money". [laughter] They are returnable.

From 1988 to present [coughing] celastic II which is important because there was a change there. Gel saline implant seamless envelope outer gel filled implant inner, it was this seamless low bleed envelope responsive gel, of note, is that it was 1982, inside of the elastomer envelope that was coated with the florasilicone barrier to help reduced gel bleed and it did tremendously reduce gel bleed very, very minute amounts of silicone get through the permeated shell.

From 1982 to present, we did have the Celastic II Mammary Implant Gel Filled Seamless Low Bleed Envelope Responsive Gel.

From 1990 to present, we had the MSI Mammary Implant Gel Filled Textured Seamless Low Bleed Envelope Responsive Gel. The MSI was developed to help with the capture of trackture. On the outside of this implant there are 220 thousand small pillars [undiscernible]....

WOMAN: It makes it look kind of frosted.

PAULETTE: It looks exactly like it was a piece of velvet material, how fibers stand up on velvet. That is what it looks like --- it has that look about it.

[garbled discussion] I saw one at a glance.

PAULETTE: It doesn't look clear, but it looks. I have one too, if you do want see it call me. I have it sitting out in the Conference Room and somebody made a very good point, not to leave it out there, because someone walking down the hall, and I wouldn't be in my office, cause when we were putting the terminals into the offices, that are down the hall from us, people were getting on our phones. Well when you are not on a line, which you aren't [undiscernible] telephone, etc., clear off the hook that rings the trunk into the next line, see. So then we would put it back on, what's the phone doing ringing down there so go down there and someone had put it back on the hook.

[garbled discussion]

PAULETTE: We put signs on the door do not use these telephones any more. Twice they ripped both signs down. Some one said put Toxic Waste on them! They'll stay on a bit.

The Polyurethane Implant -- still called the urethane [coughing] The Pillars on the MSI are part of the implant itself. It is not removable it does not come off. The theory is that these small pillars help to break up the continuous growth of that scar tissue, that vacillates the implant and causes the capsulary contracture. These implants have been on the market for two years and in theory does appear to hold true. Of course, we won't know any further until we have .....

WOMAN: It's not what we are talking about, but it just kind of popped into my head, since it is not just the mammaries but the testicles and the chin. Are we getting calls on that?

PAULETTE: We do all the time on the testiculars. And the answer to a testicular implant or gel filled chin implant is much the same as the breast implant. What you can do is offer them package insert on the gel filled or [undiscernible], and I would also offer them the packing

information that we send out, we are still talking [undiscernible] silicone gel on the inside, very much the same in the chin, the breast and the testes really the answers are the same. I think one of the reasons that we don't see a lot of conversation about the testiculars is that these autoimmune diseases as Bob told you are prevalent in women like 4:1 than in men. So we just are not seeing those complaints. But I will tell you when you get the calls about testiculars, a lot of times it will be a woman calling because her son has had this done. A lot of times boys are born where both testicles don't form, and it is imperative that they remove the testicle that doesn't, then usually when a boy gets to be adolescent, he gets into gym class at school, it is very important for him to feel as part of the crowd and not to look abnormal and that is usually when they will have something done. Sometimes they do it when they are younger, we do make child size testicular implants and we also make adult. [undiscernible] usually just wait until they are adolescent age but we do get some calls. They are just concerned too. They know it is a gel filled implant, what should I be concerned about, what should I look for.

Okay, now we need to get to.....

WOMAN: I take it Harvey is going to come in.

PAULETTE: No, Harvey is in Washington.

WOMAN: Can we take a break.

PAULETTE: Sure.

I'm going to talk to you about how the FDA got into this whole procedure, how they were brought into it. We'll probably see surgical films tomorrow lady, I know that is a big disappoint but we'll do it before lunch tomorrow. So we won't have that problem.

The Medical Device Act came about in 1976. What happened is that the government said to the FDA, you will regulate medical devices...Breast implants are medical devices. In 1976, when the Medical Device Act came into effect, all manufacturers of implants knew that at some point in the future they would have to file PMAs. All medical devices, and we were not the only thing that was grandfathered in, breast implants had been on the market approximately 15 years at that time with no major problems that could be seen, they were grandfathered in. Pacemakers were something else that was grandfathered in. There were several devices that were grandfathered in. And what the FDA did was they decided that they would address what they considered to be the most controversial devices, first, with the knowledge with everybody knowing that sooner or later they would get to your product and expect certain things from you. So that is what they did. Well breast implants did not, the PMA was requested for submission no later than July 19, 1991, and as Bob told you this morning, 515B was sent out and it told you how many days you had to get your PMA in and what they expected to see in that PMA. So, they kind of gave you a list or an idea of what you had to send in. I think there is a misconception out there with the callers that somehow we are at fault, somehow FDA is at fault and what this is is just regular steps, just normal procedure that is what happened. I think there is also a misconception that these groups such as Sybil Goldrichs', the Man Trust Network, the Silicone Survivors Group in Florida, have somehow made this all come about and this is not

true. We all knew this was coming, we knew in 1988, that it was coming, we knew in 1990 that it was coming, so that's a misconception, they do not force the hand, if anything I think they have politically influenced what has been going on, but they certainly have not certainly influenced the regulatory steps as they are, and have been addressed. Here some important dates that you may want to remember, I don't know that you should jot these down, but you should certainly remember then.

MAN: I can't remember if I don't write it down.

PAULETTE: I am that way too. But not everybody has to do that. On July 8th, we submitted our PMAA, which stands for Premarket Approval Application. It was not required to be submitted until July 9th, but we did submit it then. And, I have heard now, I have seen the PMAA both in Memphis and the one out in Hemlock in what they called the cage, it is several hugh boxes with tall .... someone told me when they stacked it up, it was like 26 feet high, to give you an idea of how much paper was involved in this. Dow Corning submitted 50,000 pages of data concerning breast implant on that date.

On September 13th, FDA requested additional information. They came back to the manufacturers requesting additional information submitted for what they were calling major and minor deficiencies. I talked a little about deficiencies this morning. As you stated, all PMAAs are expected to have deficiencies. When we received the letter on September 13th, all other manufacturers received a very similar letter, as a matter of fact, if you put them side by side they look very similar. We agreed with some of the deficiencies, some of them we did not. Some were contained in the PMA and we felt that we just needed to point them out, some of the deficiencies could be taken care of, if you would take the answer to this portion and put it together, it would cover that deficiency. The problem being that with the FDA, if you had had a major deficiency and you addressed it, then that was considered an amendment to your PMA. You must remove your product from the market if you do that. We had a problem with what they were calling major deficiencies never being asked by 515B..so we said wait a minute, you are changing rules in mid-stream. You never asked us for that information to begin with, now you are telling us if we give it to you, it is an amendment and we must pull our product from the market. We were very confused as to what they are looking for.

On October 3rd, there was a meeting with the FDA to clarify the rules as to exactly what are the rules. In unprecedented steps, Kirk Campbell and Larry Reed, met with Dr. Kessler of the FDA to clarify some of the rules given for submitting a PMAA. It was unusual because Dr. Kessler when he became Commissioner of FDA, said he would not meet with manufacturers. It might also be of interest to you that Dr. Kessler is not only an M.D. but a lawyer -- he is both.

WOMAN: An article I read about him, which makes it even more amazing is that since he was a little kid, this is what he wanted to do, instead of being Superman he wanted to be the head of the FDA. He went after this in everything he did to get the degrees to do this. It takes a special man to do that.

PAULETTE: It sure does.

MAN: ...being kind.

PAULETTE: We are on tape.

MAN: Oh yeah.

PAULETTE: When the PMA is submitted you are giving a list of data which is required by 515B by the FDA that you must submit. When the letter was received on September 13th, some of the requests that were asked to be filled at time were not included on that original list, so obviously we are very concerned. So Kirk and Larry went to Dr. Kessler to clarify exactly what is it that you would like us to do – what do you want us to give you. I am not sure they ever got a clear answer to that question. I think there is a different atmosphere now, also I know I have heard that, that was you are right and this is [undiscernible], and that there is a different atmosphere now between Dow Corning and the FDA. There was a time when we were just throwing up our hands going, we don't know, what do you want? You know you keep asking us, we keep giving you, and we still don't seem to be able to come to an agreement or satisfy what you want from us. It was just very confusing and very hard on everybody, especially upper management. I mean you can't second guess them and we would go to our people, that we normally deal with, with devices at the FDA – what are we supposed to give them? What do they want? and they would say "we don't know". They are over there and they are making those decisions and we don't know what they are. So we were just in a quandary, what do we do about them?

The first Advisory Panel met on November 12th, 13th and 14th. On the 12th of November, the Panel was open to public comment, they would take into consideration any one who got up and talked publicly about breast implants and any one could speak – it could be patients...

WOMAN: Dow Corning employees...

PAULETTE: Or Dow Corning employees..It could be physicians, it could be Rheumetologists, it could be any one who would get up and speak and it is my understanding that 144 women, spoke about implants. So that is an impressive number. They got there.

On the 13th of November, the manufacturers presented their data and Dow Corning was the first one. We were not allowed to present all of the data that we had brought ... all of the data that we had. I talked to Bob LeViers' Assistant, who said that there were a boxes of material here that they would not let us give them.

WOMAN: Why?

PAULETTE: That was still that other era, there was no cooperation and we couldn't get any answers -- we just couldn't. In the Advisory Panel, I want you to know that the Advisory Panel was made up of Specialists in different fields, they may be Plastic Surgeons, Rheumetologists, they may be Oncologists, different specialties all around the table.

MAN: But in the medical field.

PAULETTE: Not necessarily. There was one manufacturer on the Advisory Panel, somebody from [undiscernible]..they were on there. When the Advisory Panel is fed up, and they have this panel of experts there, then they bring in the data -- the PMA or parts of PMA -- and if you specialty is Oncology, then you look at that part. If your specialty is [undiscernible], then you look at that part -- it depends on what your specialty, as to what part of the PMA you got. But no panel member saw the complete and total PMA as a package. You only saw your section of it. And that is very disheartening also because how are you getting the whole picture if you are looking at this small portion of it. So that also was a problem with the Advisory Panel. And then, of course, we know that there was another PMA, or another Panel/Advisory Panel that met in February, January 6th, when Kessler came down with the moratorium on the implants. It kind of just took us all by surprise, we really did not expect a moratorium at all, we expected either to be approved or disapproved or approved with conditions. Conditions could have been much like the Maryland State Law. It would be a Federal Law that if you were going to have an implant, you had to read the package insert. You had to be informed of all of the complications. But a moratorium was the last thing that we expected. As a matter of fact, when Dr. Kessler came out with his moratorium and said because there was new evidence, that had been found in this case in San Diego, we were just kind of aghast at that too -- what new evidence, what turned out to be memos, office memos, and I think we are all familiar with the fact that interoffice memos are not scientific data. And one side of the conversation, not two sides of the conversation. Also keep in mind that these memos are dated from the 70's -- those products were not on the PMAs, the products were not looking to be approved by the FDA. Only the products that are on the market today, with 20 years more of medical research behind them --

AUDIENCE MEMBER: And improvements

PAULETTE: And improvements. So it was really just kind of a bad situation there, and I have read and I do have them in my office if anybody would like to read it, the 800 documents which I am sure you help put together.....I have read them from cover to cover. I don't find it quite as bad as what the press made it out to be at all and when it is put into context, some of the prefaces that go before this are wonderful -- they did a very good job at that. But the memos, even themselves.....

WOMAN: The ten hot documents -- the ten hottest documents that the plaintiffs' attorneys were using against us, I looked at some of them, some of them I typed some of in my early days in TS&D, and I knew what the context was -- they were innocuous as far as I was concerned but if you had been and were looking for something else, it could say what you wanted it to say.

PAULETTE: I think another of the problems is too with the memos was that those documents were released in court cases, they were sealed, and they were supposed to be remaining sealed. However, plaintiffs' attorneys would leak them at their convenience and chose what they would leak.....

WOMAN: They were a client tiny client privilege that they leaked.

PAULETTE: So it was very bad situation and it was a very bad time to be on the phones. It

is really hard to face a situation like that when you can do no right and I had heard Keith McKinnon say and this is so true, you don't argue in public with a man that buys eggs by the barrel.

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TAPE 3 SIDE B

PAULETTE: .....and they printed what they chose to print and that was all. Chuck Leaches memo I think is a real good example. We are going to talk about the crossed fingers and what Chuck was doing was crossing his fingers for luck that the study would prove a certain point. Not that he was fibbing. And the retraction you know was a small one on the back page. It was a very bad time, it was a very hard time. During that time that the first Advisory Panel met and Phil Donahue did his show, that is when that San Diego trial was going, that is when that California trial was going on. Those jurors were not sequestered and even though two of her own doctors testified that she had signs of this disease two years prior to implantation. The media has a very hard or very ... we tend to believe these people, you know, you have them in your living rooms every night ... these are people you tend to trust. Obviously not any more, but you certainly did at that time. Any way the moratorium came about. So now we are dealing with the moratorium. The second Advisory Panel was convened, essentially from the same thing that the first one did -- there is not enough evidence to prove that they are safe, there is not enough evidence to prove that they are not safe. They did state a little more information in this one as to who they thought should have implants and who shouldn't have implants. I think there is a lot of controversy surrounding that and I think that the FDA is going to have a very hard time coming to that decision. If you are telling a woman that has reconstruction that she can have implants, is she going to come back and say "are you telling me that well I have already suffered through cancer so implants aren't going to hurt me?" and "if you are telling me that only a certain number of women can have augmentation a year, and no one within childbearing years, but yet they are safe enough for reconstruction patients", I think they are going to have their work cut out for them as to how they are going to define these lines. And, if you had augmentation six years ago and now you have capsulliary contractures so bad that you have to have surgery and have them replaced is that reconstruction now or is augmentation now because it was augmentation to begin with? So there are a lot of hard questions out there that they are going to have to come up with some answers to.

COMMENTS: I think that stinks.
I should get new categories, like reparative surgery!

PAULETTE: But you know these are things they are going to have to think about. But what about this woman who has had augmentation but now has to have contracture repair. If she is augmentation is she not eligible then to have them repaired? So then, what are her alternatives? What about women that are not candidates for saline implants? They are out there. Not every one can have a saline implant. Not all women can have the tissue transfer. There are a lot of questions and I am just ..... absolutely, yes you can have one, no you can't have one ... I don't like that. I think that women are outraged at that, and I am very curious to see what's going to happen in April. How is he going to legitimately decide these issues because they are out there. And, what about just as the woman Congressman that spoke to the Advisory Panel, who was you know just a couple of days away from an implant, when the moratorium came up and

now she can't have one.

WOMAN: Do you think there would be this much of a big problem if it were the men who were having their testicle implants withheld from them for their reparative surgery, etc.

PAULETTE: No I don't. I'm not sure that testiculars will ever become an issue. There is controversy on both sides of that too, because how many men are going to stand up and say they have testicular implants.

WOMAN: That's exactly right.

PAULETTE: We are just not going to that. Like you say they Mother is calling for them --

WOMAN: Their 90 year old Mother calling for them —— There was a Kamikaze.....

[various discussion not doing with subject matter]

PAULETTE: MDR requirements. In the Center, we kind of have a problem with MDR requirements. The reason that we have a problem with the MDR requirements, is because what we normally would have and need to report on an MDR is the things we don't always get in the Center. It would be preferable to have a name address and a phone number. We can't get that if they won't give it to us. If they will not give us that, then what you need to do on anything that is being evaluated for MDR, is to put under the name category there "REFUSED".

WOMAN: Tell me again what the MDR is? Medical Device Reporting? And what is it used for?

PAULETTE: When you are a manufacturer of a medical device, you are required by the FDA to report problems with that device and that's what we must do. Okay, a positive calls. She calls, "I love my implants and I am not having any problems with them, blah, blah, blah...." or she calls and says "I'm only looking for information, send me a packet or tell me what is capsulliary contracture or tell me about rupture or I'm not having any of these problems – just tell me about them – I'm looking for information". Those are not used for MDR evaluation. Everything else must be reported.

WOMAN: So any negative.....?

PAULETTE: Any thing at all -- any thing other than I love them and I want information – any thing else. We do not always report all of these things. There was a time that we only reported ruptures and certain things....If they are talking autoimmune it is reportable, if they are talking contractures reportable, if they are talking necrosis it is reportable, if they are talking pain it is reportable, if they are talking I am dying from these implants it is reportable.

MAN: It is not necessarily proof, it is just their opinion.

PAULETTE: It is just that we have heard this about that and for us that is enough. We are not

trained to do MDR determinations nor do I want to be trained to do MDR determinations. There is a lot more involved in MDR determinations than just sending it to Hemlock and saying here we heard this, they have to do investigations into things. There is a whole slew of things that they do, then enter them into log books, they do this, that and the other thing...I don't really want to do that. I do hope that after that meeting yesterday, and there is talk, of putting someone in our area who will determine what should be said to Hemlock and what should not. Hemlock does all the Celastic II's and that kind of product and DCW, Alicia Berridge, does the MSIs.

WOMAN: And, I am sure that just from the Litigation Department alone and the Claims Department, that Hemlock is just overburdened, they have to be backlog at least 6 months, so somebody in our area would be just perfect.

PAULETTE: I agree. That was the discussion that went on yesterday. Because they, Jerry is upset because, how do you expect me to report this because there is no name, no telephone, no address...I know that but my criteria is that I'll force these women to give me anything, and I'm not going to change that, their confidentiality is their confidentiality and I'm not going to jeopardize it. So he is in a fix, we are in a fix, what do you want us to report, what don't you want us to report and that is how it came down.

WOMAN: The thing also with MDRs is that there is a time requirement. You have to do this within 24 hours to the FDA.....

PAULETTE: You have five days. We have to get it to Hemlock with 24 hours. Every single day there have been envelopes full of call reports since this order came down, going to Hemlock -- every single day. It would be much better if they would put someone in the area to determine do these go? do they not go?

WOMAN: Then it's five days to the FDA?

PAULETTE: It's five days after Hemlock receives it they have within five days to report it to the FDA. And in their five days they have to do the investigation and everything and they have to get it done. It's horrible.

WOMAN: This is so critical, like, I know when I was in the Litigation Department several years ago, if you are not aware of what you are supposed to be doing like -- lawsuits come in, they come in Registered Mail, they come in in envelopes and they could sit on an attorneys desk for a couple of days before a paralegal could see it. You know there are so many ways it can fall between the cracks and you are faulting on this five days so that it is really important that everybody is totally aware of all this stuff.

PAULETTE: We don't have that problem, we don't have the time restraint, but because we are on top of that. But it is really hard for Jerry and the people in Hemlock because we are sending so many over there. They are getting them as Ann said from our Legal Department, they are getting from Claims in Memphis, they are getting them from Removal, here's another whole area created to send them. So it just really is a dilemma. But, what you need to know and what

we need to know is that anything that is not positive or that's is only looking for information gets a DI and on the bottom of the Call Report that we talked about down here, where we report Call Report made, that is where you put "yes - it was MDRd to Hemlock and the day it was sent" and that would be the day that you took this call.

WOMAN: What if they say "well I think I have Dow Corning implants".

PAULETTE: We still have to report it. The only time that we don't have to report it is if they say, I have a Surgitec Implant and this thing is.....well that is not our problem. We have to report our problems but if they state to you and I will tell you that everybody in the world has a Dow Corning implant.

WOMAN: If they think they do, then we report it.

WOMAN: The only time we don't have to do that is if they say I just want information.

PAULETTE: Or they say I have another manufacturer, etc.

WOMAN: Paulette are you going to touch on or do they even know what autoimmune disease is now. Is there a standard definition.

PAULETTE: We will get into that when we get into complications into detail about every complication and answers. But I'm going to do that tomorrow because I think that is better to have that closer to the time you that you are in the hot box. Definitely closer. We will talk about that, we will talk about the five [undiscernible].

WOMAN: I just had a conversation with my Dad who is a general surgeon and was just saying about our explant, and he said "autoimmune, if anybody knows what that is". And, if there is a surgeon saying that it is not like he is dummy or anything.

PAULETTE: And that is true. Well we will get into that .... It is not disease that hasn't been around, it is not something that is prevalent and when we get into it tomorrow you are going to wonder how can all these women have it if these are the statistics and this is what we know about it.

WOMAN: Didn't it become a buzz word with litigation attorneys.

PAULETTE: Well much as Bob was talking about this .... cancer now seems to be taking a backseat because we have all of this hard evidence about cancer so they need to find something else that is going to fit into that litigaceous society out there and create that for them. But we will get very into detail about all complications and to the point where you understand them because if you have any questions, do not let me go on. There are only eighteen of them.

[NOISE!!!]

....I don't have implants, they don't have.....

[NOISE!!!]

....right now, what am I going to do with them afterward?

WOMAN: What are you going to do next week. I know Jan mentioned she is going to be on vacation next week and other people.

WOMAN: I'll be back the 7th which is Tuesday.

WOMAN: You going to be on vacation next week too.

PAULETTE: No....vacation what's that.

WOMAN: I know Mark said that he wasn't going to like put me on the hot line right away but I thought all my bosses are gone next week and I'm going to feel bad if I'm sitting at my desk doing nothing.

PAULETTE: and I'm over there drowning.

WOMAN: And I could be over at the Implant Center helping out for that week when everybody else is gone.

PAULETTE: When is he coming back?

WOMAN: Tonight. We were supposed to sit down tomorrow afternoon and talk about what's going on....I'll suggest it to him.

PAULETTE: Would you? Okay, great. Because I was under the impression I was just going to take you.

WOMAN: The only thing is I have to have Friday off because we are going to Chicago for the weekend, that is the only Spring break we are taking.

PAULETTE: Again, on December 30th, at 6:40 P.M., we received this warning letter from the FDA, incidentally, we have several calls from newspapers prior to receiving this letter as to what our comment was on the letter. The Media Communications Department had gotten several calls and we didn't even have the letter yet.

WOMAN: That's something. We were just talking about things like that today.

PAULETTE: That happens. What this letter said and what this letter really meant is that they had had several people calling into the Implant Center, a place called Implant Center and ask questions. And, they did not approve of some of the answers that were being given. I will tell you it was shock to me when I first read this letter. Kirk was very angry about it also when he first read it but the next day on New Years day when I sat down at home and I read this letter, I said to myself I probably said half the things that are on there. Most of the remarks they talk

about are ....., then a sentence ..... this was a couple of sentences out of a 40 minute conversation, I don't know what preceded it, I don't know what followed it. Okay. Some of them I probably did say. Some of them I have no idea of where they came from and I certainly hope no one said them. No doubt, they probably were said. There were times when people were on the phones at the Implant Center during the time of the media blitz that were not trained. They were put on the phones to send a packet if you wanted a packet, take a list of questions and get them to somebody that could answer. I don't know if that is when it happened -- I'm not pointing a finger at anybody, I don't who did it, it doesn't matter who did it, it matters if the situation is corrected. The significance of this warning letter is that FDA said you are saying some things we don't want you to be saying, we consider this labeling, this is a labeling, and you have to abide by those rules. So we pulled ourselves off the phones -- we didn't agree with everything that they said, was incorrect, so from doing that from December 31st until February 17th, we were off the phones and we only, the remark was -- if you called in you did get a voice, you did get a person -- but the remark was that there has been a disagreement between Dow Corning and the FDA as to what has being said on these telephone lines. We always try to comply with what the FDA wants us to do. Until these differences are resolved we are not able to answer questions. We have removed ourselves from that situation. If you would like a packet of information, I can send that to you. Then, of course, the questions was "when will this be resolved" always. We would just tell them if you would like to try back in a couple of weeks, you know, it may be resolved then, we are working on it. It did take us from December 31st until February 17th, to come to a point where we could resolve it. And, we were worked out this with the FDA both ways. There is also a letter about things that they found wrong with the packet of information. We will go over that tomorrow when we talk about the packet. So what was significant about this is that it could have wound up in criminal charges. It could have put people in jail, if we did not cease and desist, Larry Reed was one Lynn was another, nobody wanted to put all of our bosses in jail so we went by what they wanted. Now the Temporary Restraining Order that was put on to the Center, I have the Order here and I will read it to you, and I will also read to you what is on the Implant Centers' BMX at this moment.

> This is an Order granting temporary restraining order. This matter is before the court pursuant to plaintiff's motion for a temporary restraining order. There is reason to believe that defendant's are taking action which may affect not only specific members of the class but in addition the course of this litigation. Plaintiff's counsel has alleged that defendant Dow Corning is dealing directly with members of the class, offering them a sum of money in return for a release and conditioning award of that money upon the return of the prosthesis previously implanted.

I'm going to remark here to that in the removal process, you do not have to return the implant if you do not want to, you chose that right.

WOMAN: They did change that.

PAULETTE: Yes they did.

WOMAN: We are not requiring it back for testing. In the beginning we were going to require

it back. But we are no longer requiring it. They can return it. We would like to have it for this testing but it is not a requirement to get into the program.

In Claims they usually do try to get them back -- it doesn't mean that you will. One of the reasons that we do is because we do want to do an analysis on our product, we do want to know what went wrong and, if it was the product, we do want to know about it. You know a lot of the people say, well if you are doing the testing, it is bias -- but we will release the analysis to the patient, we will do nondestructive testing so it is not destroyed, so if you want it back you can have it back. One of the reasons that Dow Corning wants to do the testing on those kind of prosthesis, because we have the knowledge. You know there is nobody else out there that has the knowledge that we have on them. Certainly, in Claims, if they will not return their implant to us, they can return it to an independent lab of their choice, but they will have to pay for that analysis. We will not pay someone to do an analysis that we could do. And it is not cheap -- it is very expensive. As a matter of fact in Claims I also know that they will put what Lynn calls the "road show" on and they will take a person that can do analysis and they take a kid and they'll go to a motel room [undiscernible] and they will give you back your implant.

WOMAN: Why do you want your implant back? To prove something?

PAULETTE: Evidence. There are women that have implants in their lingerie drawers, in their refrigerators, they won't call you. So I have my implant, what am I suppose to do with it? The women you heard me talking about earlier whose implant fell out in her hand. She was being admitted to the hospital, had bent over to take her sweater off, and the implant fell off in her hand, she stuck it in her purse and brought it home.

WOMAN: When you say that, that means her scar tissue had to have ripped as she went and lifted up her sweater.

PAULETTE: She never healed. He went in through the same incision several times --- without cleaning up the incision site.

The problem with that is -- obviously, that is a horrible thing that happened to that woman, but she took this implant that had been implanted into her body, put it in her purse and took it home. I mean we're talking hepatitis, we're talking diseases here.

WOMEN: And contaminating everything the patient is near.

And not only that if it hadn't healed to the point of things could fall out, she had to have been in great deal of discomfort and pain and infection and oozing and everything else.

[several talking at once]

PAULETTE: This woman, two days after surgery was admitted back into the Emergency Room where they aspirated 700 ccs of cirrus fluid. This woman had to have been humongous to take .... that doctor did not insert drainage tubes so there was no drainage. So all the cirrus fluid just stayed. These things happen.

If you should ever get a woman who says to you, I have my implant in my lingerie drawer. Number 1 put on a pair of rubber gloves, number 2 get a Ziplock bag, put that implant in the Ziplock bag and spray it like crazy with Lysol and zip that bag closed. Do not just leave that implant laying around your house. Not in your lingerie drawer, not in your refrigerator – these things carry diseases. They have been implanted in your body. That has happened.

We get implants returned to us and we'll talk about that too. You don't ever open a box in the Implant Center.

WOMEN: In your lingerie drawer!

That's going to smell.

PAULETTE: Oh no right next to my sandwich. But it happens.

WOMEN: All kinds of nuts out there. People are ignorant I guess. They don't think.

PAULETTE: Okay.

> While this court has strong feelings against temporary restraining orders, and particularly those that are granted exparte, it is obvious that if allegations and plaintiffs' motions are correct defendants may be interfering not only with the rights of specific members of the plaintiffs' class but may also be affecting the outcome of this case by destroying evidence. This may constitute irreparable injury or damage to the plaintiffs' class into individual members thereof. Accordingly, to all defendants, the agents and employees are hereby temporarily restrained from communicating in any fashion with members of the plaintiffs' class or pay any sums of money to the class without specific approval of this court and from destroying any breast implants returned to defendants by members of the class as a condition for any sums of money. In addition, all defendants are directed to cease forthwith the conveying of any information to members of the class by toll free 800 telephone numbers without prior approval of this court. This temporary restraining order shall take affect upon issuance and shall remain in effect until Midnight, March 27th, 1992. This court will hold this hearing at 11:00 a.m. on Friday, March 27, 1992, in Court Room 805 for the purpose of either dissolving this temporary restraining order or substituting therefore a preliminary injunction.

That is the order. That is what has come down. And I did not write this except for the last part. Communications wrote what we would say on the phone and what it says is that:

> Dow Corning is unable, at this time, to provide you with information regarding breast implants or to process your claim under our recently announced breast implant removal assistance program. On Monday, March 23, 1992, Judge Carl Reuben of the United States District Court in Cincinnati, Ohio, issued an order granting a temporary restraining order prohibiting these activities. The Hearing before Judge Reuben is now scheduled for Friday, March 27, 1992, to consider further this order. If you would like to leave your name and number, we will return your call, should legal conditions change.

And, that's it.

WOMAN: That's what Regis and Mark put together.

PAULETTE: I think Regis put it together, because Mark was with.....

WOMAN: That's right. You almost have to have a lawyer put it together.

PAULETTE: Oh, yes. Yes, there was great discussion – do they leave their names – do they not leave their names. Lynn and I were pushing for let our people tell them this on the phone because at least they are getting a warm voice – they didn't want that because they were not sure whether restraining order [coughing] or not. But now Wendy is at the Front Desk telling people this that are calling in on the 4000 number. And this is what she is saying, and she is not deviating from this in any shape or form, she has been called several names today and people are very upset, very upset. So you can bet if we are back on the phones next week, it is going to be hot. There are going to be a lot of upset people.

WOMAN: Clohe Miller called me yesterday...

PAULETTE: Clohe called me too.

WOMAN: A man called, his wife had implants for 18 years and he was really concerned and he called to try to get someone on the 800 number and got a recording, so he called our Legal Department. Lisa Schmidt took calls in the Executive Wing, Chief financial Officers. It was like these people wanted answers --- they didn't want 800 numbers, they didn't give a care about the FDA or this Order.

PAULETTE: Wendy has had several people who have said, it is unfortunate, but it sounds like they are blaming Dow Corning again for this whole issue. You mean to tell me I have a Dow Corning product and you won't talk to me. I'm sorry, it's a restraining order blah, blah, blah...Go through the whole thing again, cannot give out information.

MAN: Just say "Call Judge Reuben".....

PAULETTE: Could we just put Judge Reuben's home number in.....

WOMAN: Someone did tell me they were looking for Judge Reuben's number and they wanted to talk to that man, and what is the office number?

PAULETTE: I hope that we are able to turn the damage side, I feel this has done, back around. Because it is definitely going to affect the people that are calling in. Again, these poor women....
it started in July of last year and they still don't have an answer as to what they should really be doing. Am I safe? Am I not safe. Should I have them out or should I leave them in?