IN THE COURT OF COMMON PLEAS
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
CIVIL TRIAL DIVISION

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ELLA EBAUGH, et al. : JULY TERM, 2013
Plaintiffs, :
vs. :
ETHICON, INC., et al. : No. 0866

- - -

Courtroom 633, City Hall
Philadelphia, Pennsylvania

- - -

August 4, 2017
Jury Trial - Afternoon Session

- - -

B E F O R E: THE HONORABLE MICHAEL E. ERDOS, J.
And a Jury

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OPENING STATEMENTS: PAGE

BY MR. WEBB: 5

THE COURT: And our first witness is video?

MS. PALMER: Yes.

THE COURT: And who is it and how long?

MS. BALDWIN: Today we have Aran Maree. He is the Australian medical director. I might have that termed wrong. But our clip is 40 minutes and the defense clip is --

MR. COMBS: Judge, it's about an hour and three minutes total.

MS. BALDWIN: And we have a very short clip after that of Renee Selman, and I think it's only 25 or 30 minutes. So if you're inclined to take them right up to 5:00, we can --

THE COURT: I don't know. Between the opening -- what you just described, an hour and 45 minutes for the first witness, so that should probably suffice.

MS. BALDWIN: And then we will have a live witness Monday.

MR. COMBS: And, Judge, it's an hour and three total for Dr. -- not 30 minutes for them and --

THE COURT: So we probably can do the second one.

1 MS. BALDWIN: I think we can probably go
2 to at least probably about 4:30 with the videos
3 planned for today.
4 THE COURT: Yeah.
5 (Break)
6 COURT OFFICER: All rise as the jury
7 enters the courtroom.
8 - - -
9 (Whereupon, the jury enters the courtroom
10 at 2:17 p.m.)
11 - - -
12 THE COURT: Everyone may be seated. All
13 right.
14 Counsel, you may proceed with your
15 opening.
16 MR. WEBB: Good afternoon.
17 What you heard before lunch was one side
18 of the story. If it was the only side of the story,
19 we wouldn't be here. What I am going to tell you
20 about now is a combination of responding to what
21 Ms. Baldwin told you and laying out some history so
22 that you'll have some perspective about how some of
23 this stuff went down and how these products were
24 developed and why they were developed.
25 This case is about Ms. Ebaugh's, the

1 stress urinary incontinence, and her efforts to try
2 to find some help for that, to try to get that cured
3 or at least get it under control. What you're going
4 to hear is that one out of three women in the United
5 States at some point in time in their life are going
6 to have stress urinary incontinence. And it's not
7 what Ms. Baldwin talked to you about, about just
8 being one or two drops of urine that escapes from
9 the bladder and escapes from the urethra. It's a
10 condition that can be very embarrassing and can
11 affect women tremendously.
12 What you heard, and it kind of got
13 conflated together, was two different things that
14 Mrs. Ebaugh has. She's got stress urinary
15 incontinence and she's got urge incontinue
16 innocence. They're two different things. The
17 stress urinary incontinence -- and I'll show you and
18 we'll walk through the medicine on it -- is when you
19 have pressure put on the bladder from either
20 sneezing, coughing, athletic movements, something
21 happens that puts a little pressure on it. And
22 because of the aging of the pelvic muscles, what
23 happens is you get some urine leaking. That's
24 completely different than urge incontinence.
25 Urge incontinence is where normally your

1 bladder you feel -- as it fills you feel more full
2 and you feel like I need to go to the bathroom, and
3 you know that you've got time to do that because you
4 can feel it slowly building up. With urge
5 incontinence, you don't have that. All of a sudden
6 you'll be sitting there and you have to jump up and
7 go immediately. And if you don't make it
8 immediately, then you wet yourself. That's urge
9 incontinence.
10 And the reason that's important is
11 because you're going to have every doctor who
12 testifies in here is going to tell you that the
13 stress urinary incontinence is what the TVT products
14 are supposed to cure, and the urge incontinence is
15 completely different and none of them, none of the
16 TVT products have anything to do with urge
17 incontinence.
18 Why is that important? Because a lot of
19 what Mrs. Ebaugh complains about now is that she has
20 to stay close to the bathroom, that she doesn't have
21 any warning. It's two separate things. You can't
22 have -- Ms. Baldwin says, well, she can't control
23 her bladder at all. That means you would just be
24 leaking all the time. Or you can control it, but
25 you have this urge and you've got to get to the

1 bathroom immediately.
2 The stress urinary incontinence, the only
3 thing that TVT products are supposed to cure, are to
4 treat. And the urge incontinence is completely
5 different. You use medications. That's overactive
6 bladder, bladder spasms. There's a number of
7 reasons for it. And that -- drugs are other things
8 that are used that have nothing to do with the
9 products that we're talking about in this lawsuit.
10 Let's talk a little bit about, you know,
11 what this SUI is. We got a combination of this
12 model here with two pictures because it's hard. And
13 a two dimensional way. You see the bladder. And
14 it'll filled about halfway up with urine.
15 That urethra that Ms. Baldwin was talking
16 to you about -- and I don't do well with
17 centimeters -- it's about three inches long, okay.
18 Basically from the bladder. It passes through the
19 muscles at the pelvic floor to the outside, and
20 that's how you urinate or pee.
21 This model will show you what you see
22 there. If you'll notice on the side you've got this
23 pelvic girdle, spine in the back, hip, where the
24 hips go in here, the hipbones, and then you've got
25 on the bottom here, across. That's red on that

1 model. Those are the pelvic muscles at the bottom
2 of the pelvic girdle.
3 And what happens, as Ms. Baldwin tells
4 you, as you age those muscles weaken or it can be
5 done with child birth. Mrs. Ebaugh had five vaginal
6 birth children and -- so she had five childbirth.
7 She's getting older. She was very active. You're
8 going to hear about her physical activity playing
9 softball competitively up all the way up into her
10 30's.
11 When pressure is put on that bladder by
12 either coughing, sneezing, jumping up and down,
13 physical activity, what happens is it forces the
14 urethra to open up. And normally your muscles on
15 your pelvic floor, when you're young and they're
16 tight enough that it keeps it squeezed off. But as
17 you get older with either aging -- it could be
18 aging, it could be because of childbirth, it also
19 could be for lack of estrogen. What happens is they
20 weaken up, they open up, and the urine will flow
21 from there.
22 One of the things that you're going to
23 hear about both SUI and surge is that untreated it
24 usually gets worst with aging. You get older, it
25 gets worse. So you're going to hear that

1 Mrs. Ebaugh when she goes to see Dr. Douglass --
2 and, by the way, Dr. Douglass is her treating
3 Ob/Gyn. He delivered her first two babies going way
4 back to the 80's, he seen her in the early 2000's
5 here, so he's got a long-term relationship with
6 Mrs. Ebaugh. And she's reported that she's had this
7 stress urinary incontinence in the years going back
8 to 2005 when she's talking to Dr. Douglass about
9 this and talking about the need to get something
10 done.
11 February 23rd 2015. This is a medical
12 record from Dr. Douglass's medical records for
13 Mrs. Ebaugh. It talks about, saw her in the office
14 today for evaluation of urinary incontinence. Okay.
15 If you're leaking just a couple drops of
16 urine, you're not going to make a doctor's
17 appointment to go in -- your primary reason to see
18 the doctor is for evaluations of urinary
19 incontinence. I mean, that's what the medical
20 record says from back in 2005. She was 39 years old
21 at that time. She had five babies. She presents
22 with a mixed type of incontinence in that she has
23 some urgency issues.
24 Now, when we say mixed incontinence,
25 that's the stress urinary incontinence and the urge

1 incontinence. She's a very active woman and notices
2 leakage during athletic activities especially.
3 Okay. She's 39 years old. She tells us
4 in her deposition, she reports that she was still
5 playing competitive softball at that age. So it
6 wasn't like it was just a matter of going for a walk
7 or riding a bike. She was actually very physically
8 active at that point of time in her life and she's
9 reporting that she was having problems with this
10 incontinence at that point, and a possible urethral
11 stenosis.
12 Let's step back a little bit. Because
13 the thing about life with leakage is that you will
14 hear report after report after report in the medical
15 literature about how embarrassing this is, how it
16 can cause social isolation. Not only is there a
17 problem that you can't control the urine when you
18 cough, sneeze and walk, activity, but also there's
19 odor associated with it. You can use pads or you
20 can use Depends, adult diapers.
21 But there is also an issue about social
22 isolation. You don't want to go out in public
23 because of having this problem.
24 Mrs. Ebaugh reported that when she was
25 playing softball, sometimes with sliding in or doing

1 physical activity, that she would end up wetting
2 herself. Reduced enjoyment of life. Reduced
3 exercise and activity. Problems with intimacy.
4 Many women will report that during sexual activity
5 that they actually have leakage related to stress
6 urinary incontinence. And, of course, the leakage
7 with coughing, the laughing, the sneezing, just any
8 kind of physical activity. It can be a serious
9 issue. And Ethicon developed treatment options for
10 it.
11 But let's talk a little bit about the
12 history. First off, this goes back, the efforts to
13 try to find, the doctors trying to find a treatment
14 for this condition go back to the 40's and 50's.
15 You heard Ms. Baldwin tell you about the MMK
16 procedure and the Burch procedure. Okay. Those
17 were surgical procedures that doctors came up with
18 to try to correct this stress urinary incontinence.
19 The problem with them is that it's a
20 large incision across your abdomen. They go in,
21 they tunnel down toward the vagina. They lift that
22 up and then they take sutures to tack it up. It can
23 be a serious operation. You have usually several
24 degrees -- several days in the hospital. Compared
25 to the TVT and the TVT-S, which is an outpatient,

1 can be done in a half an hour and the patient can be
2 sent home.
3 Also she mentioned the native tissue
4 slings where you have to go in and harvest
5 either -- when she says horsing, that's pork.
6 They'll take it from either an animal and implant it
7 into the body, or they'll go into your own body and
8 strip out a piece of the fascia. And they take that
9 fascia and they treat it and then they go -- so you
10 have one incision either in your leg or your abdomen
11 where they go in and take that out, and then you
12 have another large incision across the abdomen where
13 they go in again to make a sling to try to pick that
14 urethra up so that you don't have the slackness in
15 it that allows the urine to pass through.
16 And then, finally, in the 70's, 80's and
17 90's, there were other synthetics. You heard about
18 the polypropylene mesh that was developed. They
19 tried nylon. They tried vortex. They used sheets
20 of vortex, they tried that. They tried mesh with
21 vortex. None of those are used anymore. The risk
22 associated with the MMK and the Burch, which she
23 said were the operations out there at the time,
24 wound healing, wound separation, the problems with
25 anesthesia, pain, pain with sex, scarring, injury to

1 the organs, infection, and even death.
2 Okay. So what do we got now as far as
3 the development of the next generation? TVT
4 products began with the history of going back to the
5 60's of these prolene sutures. These sutures were
6 used in surgeries. And there's hundreds and
7 hundreds of studies that show the safety and
8 efficacy of this prolene material, which is the
9 polypropylene material that's used in the mesh.
10 In the 70's, the mesh was used not only
11 for hernia repairs, but also in battlefield
12 conditions it was used for war wounds. They were
13 treating them in the emergency hospitals out in the
14 war zone.
15 In 1998, there was a doctor who actually
16 developed this procedure with these midurethral
17 slings. So the doctor is the one that developed it.
18 It wasn't developed by Ethicon. But they bought it
19 from him because they thought -- and he tried a
20 number of other different kinds of meshes before he
21 decided that prolene was the best mesh to use.
22 And so that prolene mesh was something
23 that the doctor independently decided to use before
24 Ethicon ever bought the idea from him and started
25 developing it commercially. So 1998 the TVT

1 products went on the market and it's still being
2 used today.
3 There are TVT -- you're going to hear
4 from treating physicians. Dr. Douglass, who was the
5 implanting; Dr. Mirsky, who did one of the ex-plants
6 in cutting out some of the mesh; Dr. Wright,
7 Dr. Chai. Every one of those doctors used TVT
8 products and every one of them still use it today.
9 Except Dr. Douglass who retired in 2011. But he
10 used it.
11 In fact, what he will tell you is that
12 when the TVT products came on the market, he was a
13 teacher at the University of Pennsylvania and he no
14 longer taught the residents that anymore because the
15 Burch and the MMK, because he said that was no
16 longer the standard of care, that he said that he
17 would only teach the TVT products. And that's the
18 only thing he taught any of his students.
19 There's a TVT-O. And the only reason we
20 bring this up is because when she first goes in in
21 2005 and Dr. Douglass sits down and goes through all
22 the risks and the benefits, he describes the risks
23 and benefits of the TVT-O, which is just a different
24 method of implanting a miniurethra sling.
25 And, finally, as you heard, the TVT-Secur

1 came on the market in 2006. She was implanted on
2 May 31st of 2007. Dr. Douglass told her before the
3 surgery that this may not work. He knew that there
4 was a higher rate of failure with TVT-Secur. But he
5 said because she was so young and because she was so
6 active, that this was the most minimal invasive
7 technique and he was hoping to get her back out
8 doing what she wanted to do, which was playing
9 sports and having a very active lifestyle.
10 But he told her before the surgery that
11 it could fail. And he also warned her about this
12 urethral erosion and all those other things that
13 we're going to get to when we get to those records.
14 But the bottom line is that it failed. She came
15 back in and he told her we could put a TVT in if the
16 TVT-Secur didn't work. When it didn't work -- it
17 was put in on July 12th of 2007. This date right up
18 here. And it worked.
19 She does not report to any doctor
20 anywhere in any medical record between 2007 to 2011
21 that she had any problem with stress urinary
22 incontinence. There's not a single doctor and a
23 single medical record that indicate that at any
24 point in time up until 2011.
25 You remember this picture we had of the

1 bladder half-filled with urine, the urethra, the
2 pelvic floor muscle that we're talking about. Well,
3 here is how this TVT tape works. You go in and what
4 they found was, if you try to support the urethra
5 too close to the bladder, it doesn't work. If you
6 try to support it too close to the outlet down by
7 the pelvic muscles, it doesn't work.
8 It's a midurethral area, the mid area is
9 where you have to have that support. Whether it be
10 with a natural sling or the Burch or the MMK, that's
11 the area of support that allows you to cut off the
12 flow of urine when you're having a sneezing,
13 coughing or anything like that.
14 This tape is less invasive, and we'll
15 explain why that is as we go through the operations.
16 Quicker recovery. Fewer surgical complications.
17 Remember that list of surgical
18 complications I told you about with the MMK and the
19 Burch? There are fewer surgical complications.
20 There is no surgery, no surgery that has no
21 complications or no risks. That doesn't exist.
22 In fact, when you talk about this pain
23 with sex or pain on the pelvic floor, what the
24 doctors will tell you, every surgery, whether it's
25 the Burch, MMK, the natural sling, anything else,

1 the TVT, you have a risk of having pain associated
2 with the pelvic floor muscles and with the -- just
3 the pain with the sex and pain in that area.
4 All right. Here is how this works. As
5 you see, what we've got is we've got the diagram up
6 there. The red area is the bladder. The dark gray
7 in the background is the uterus with the ovaries.
8 This tube coming from the bladder down is the
9 urethra. And this dark gray area is the vagina.
10 And this is the edge of the body here.
11 What happens is there's an incision made
12 in the vagina. And she showed you the two trocars.
13 Those are detached after you pull it. There's a
14 passageway that's made up to the lower abdomen on
15 both sides that's retropubic. It's behind the pubic
16 bone. There's an incision here and incision there
17 and incision inside of the vagina.
18 Then the doctor -- that mesh is covered
19 with a sheet that allows it to slide through the
20 tissue easier. Then the doctor has to do a tension
21 test to make sure he's got the proper tension, and
22 that means it's supporting the urethra at the right
23 level with the right tension. He does a cough test
24 to make sure that when the patient coughs she
25 doesn't pass urine, that you've got the tension set

1 right. And then you trim the mesh here, you trim
2 the mesh here, and you seal the three incisions.
3 That's the TVT product.
4 The TVT-Secur. Now, you notice the
5 difference in the size. This is about 18 inches of
6 mesh. This is about three inches of mesh.
7 In this procedure, once again, there's an
8 incision inside the vagina. That TVT-Secur is
9 passed through. But as you've noticed, it's
10 anchored in the muscles here and you don't have that
11 passageway up to the lower abdomen, you don't have
12 any incisions in the lower abdomen. So you actually
13 have one incision in the vagina, and then you close
14 that once you get it properly tensioned.
15 That shows the TVT, TVT-Secur. If you'll
16 notice, just the mesh portion, which is what's left
17 in the body, is 18 inches. I don't do centimeters
18 too well, so that's why I just keep putting
19 everything in inches. And the TVT-Secur is about
20 three inches.
21 The one thing that Ms. Baldwin told you
22 that I agree with, this is the same mesh, the TVT
23 mesh, that's been on the market since 1980 in which
24 there are hundreds and hundreds of studies -- and
25 we'll talk about that -- in the medical journals

1 that talk about the TVT, they talk about the
2 polypropylene, they talk about the results, they
3 talk about the risks and the benefits in the women
4 who have had this product.
5 There's been over three million women in
6 the United States that have had the TVT -- I mean,
7 excuse me, midurethral slings, not just the TVT.
8 The TVT-Secur, same polypropylene mesh.
9 All right. We talked a little bit about
10 the product. And, by the way, Ms. Baldwin said
11 you're not going to hear us talk anything about the
12 Ethicon documents and the Ethicon testing. That's
13 not true. You're going to get so bored hearing on
14 some of these depositions, video depositions, about
15 one study after another after another after another.
16 Not only the good stuff about the TVT-Secur and the
17 TVT, but also the bad. Because doctors -- you know,
18 we can't win on this one.
19 Because what happens is if we don't do
20 any testing they said, well, you didn't do any
21 testing. If we hired doctors and pay them to do the
22 testing they say, well, you can't trust the testing
23 because you hired the doctors, you paid them to do
24 it. You can't get doctors to do the testing for
25 free. You can't get doctors to go out and train

1 other doctors for free.
2 So you can't have it both ways. Either
3 you don't want us to do any testing, which is not
4 right -- and you're going to hear about the testing
5 that was done on the TVT, hundreds and hundreds of
6 studies, and the testing that was done on the
7 TVT-Secur. There was animal studies done before the
8 TVT-Secur went out, there was cadaver -- and what
9 that means is they take dead bodies and they
10 practice the surgical procedure on dead bodies
11 because you can't do it on live people when you
12 first start off. You know, it sounds bad, but the
13 idea is you can't practice a surgical -- it's
14 unethical to practice a surgical procedure before
15 you know whether or not it's safe and effective on a
16 live person, so you do it on animals first -- you'll
17 hear about the sheep studies, you'll hear about the
18 cadaver studies.
19 And then they were actually in 31 women
20 before they went on the market. But the TVT had
21 been on the market since '98, the same polypropylene
22 mesh. The procedure is different from the
23 TVT-Secur, but it's the same mesh. And we've got a
24 long track record with that.
25 Let's talk about the docs. I already

1 told you that Dr. Douglass was the implanting
2 surgeon. He was also Mrs. Ebaugh's treating Ob/Gyn.
3 Delivered the first two babies that Mrs. Ebaugh had
4 and had been treating her for a number of years.
5 Board certified. Learned urodynamics and
6 urogynecology during medical residency back in 1974,
7 assistant professor at the University of
8 Pennsylvania, trained under Vincent Lucente in TVT
9 and TVT-Secur. Meaning he actually before he
10 performed this -- now, these are medical devices,
11 prescription medical devices.
12 You can't go down to the corner drugstore
13 and say give me a TVT. With a prescription medical
14 device, there's got to be a doctor who does what a
15 doctor does, which is the patient comes in and
16 complains about something. He listens to it and
17 says, okay, what are those complaints? What is the
18 differential diagnosis, meaning what are the
19 different things that could be causing these
20 complaints? He makes a determination based upon his
21 experience about, all right, now that I know what
22 the complaints are, I think I know what caused it,
23 how can I treat it or cure it? He then makes a
24 recommendation about what to do.
25 In this case, Dr. Douglass makes the

1 recommendation that she use TVT products. And then
2 he actually sits down with the patient and goes over
3 the risks and the benefits. Because a doctor has to
4 be able to tell -- you may listen to the risks and
5 benefits and say, you know, those risks are not
6 worth it. The benefits are just not worth that much
7 risk. Or you may say, the risks are small enough or
8 I don't think it's going to happen to me and I'll go
9 ahead and have this operation.
10 He continued performing TVT surgeries
11 until he retired in 2011. Now, what's important is
12 Ms. Baldwin said, well, he didn't know about, you
13 know, Mrs. Ebaugh. Well, the reason he didn't know
14 about Mrs. Ebaugh is he retired in 2011. And up
15 until 2011, she's not reporting having any problems
16 with her SUI, not to any doctor, including
17 Dr. Douglass. You look through his medical records,
18 there's nothing there. And he implanted close to a
19 hundred TVT products during his career.
20 As I mentioned, once he learned and got
21 comfortable with the TVT, as a professor or
22 assistant professor at the University of
23 Pennsylvania, they would have residents that would
24 come to their practice and they would train them on
25 what they would do. And he no longer trained on the

1 Burch and MMK after the TVT's came out.
2 And, by the way, Dr. Douglass was not
3 paid a penny by Ethicon or Johnson & Johnson. He's
4 not one of these doctors that either trained other
5 doctors -- all he did is buy the products or his
6 hospital bought the products. He just used the
7 products with his patients.
8 Dr. Douglass testified that he discussed
9 the risks with Mrs. Ebaugh. All right. April 1st
10 2005, Mrs. Ebaugh comes in to see him. He talks
11 about the problems with stress urinary incontinence.
12 Remember, the urgent incontinence, TVT doesn't have
13 anything to do with that. Every doctor that comes
14 in is going to tell you over and over again, she's
15 got two conditions, the mixed incontinence. The
16 stress urinary incontinence is the only thing that
17 the TVT will cure and treat, but the urge
18 incontinence is not even on -- it's something that
19 they have to use a completely different treatment in
20 order to try to control that.
21 He goes through some of the possible
22 risks associated. First off, he discusses the
23 particular issue. I showed her on pictures how the
24 TVT-O is done. We discuss the routine complications
25 of TVT-O, which would include bleeding, infection,

1 tape erosion, inability to urinate, and it might
2 work. That's April 1st of 2005.
3 As Ms. Baldwin told you, she
4 decided -- her daughter was busy or had a little
5 miss or some type of beauty contest she was
6 associated with and she decided not to go forward at
7 that time. But she came back in 2007, and he sat
8 her down and went through the risk and benefit
9 analysis again and he warned about these risks.
10 If I could do this. There you go. She's
11 aware that erosion of the tape can occur through the
12 urethra. That's exactly what happened to her.
13 Erosion through the urethra, vagina or bladder. We
14 discussed the suprapubic procedure as well with the
15 same risks, except at a higher risk of perforating
16 the bladder with the procedure.
17 Now, why is he talking about two separate
18 things here? Because if you're doing the TVT-Secur,
19 which is what he put in in May of 2007, why is he
20 talking about the suprapubic? Because he told her
21 that the TVT-Secur might not work and if it didn't
22 we could go back in with the TVT. And that's the
23 one that goes up and comes out of the abdomen. And
24 that one has a higher risk of perforating the
25 bladder because you've got to go up and make those

25

1 passages on both sides of the bladder to come out of
2 the lower abdomen. So he talks about both of them.
3 And that's where he says that he told her
4 that the TVT-Secur had a higher rate of failure, but
5 because it was less invasive that he thought that it
6 would be the proper thing for her to use because he
7 wanted to get her back out there being active like
8 she was before.
9 All right. Let's step back and look at
10 this. And I just discussed with you -- you see that
11 TVT-Secur, which is the one he put in in 2007. You
12 don't tunnel up through here. You don't have to
13 worry about perforating the bladder because you're
14 down here only in the midurethra area. But if
15 you're doing the TVT, then you use those trocars
16 that Ms. Baldwin told you, and you make a passage up
17 through the tissue here through the lower abdomen.
18 And then that's where it exits the body.
19 Okay. We know that the TVT-Secur didn't
20 work. So he comes back and has a third discussion
21 with her about the risks and benefits. So he does
22 it in 2005, he does it in May of 2007, and he does
23 it again in June of 2007. He says, in particular,
24 we discussed the complication of erosion into the
25 bladder, erosion of the urethra, bleeding,

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1 infection, perforation of major blood vessels,
2 perforation of the bladder, possibility of having to
3 wear a catheter for a week or so if the latter would
4 occur.
5 He goes through the exact problem. He
6 tells her it's a possibility that happened to her,
7 erosion into the urethra. He told her in May of
8 2007 and he told her in June of 2007. On both of
9 the surgeries that she actually did, he went over
10 that exact risk that occurred with her.
11 And she signed, you know -- a little
12 explanation. At the time this was performed,
13 Mrs. Ebaugh got her divorce and remarried, so it
14 shows up here as Ella Cederberg. And this is the
15 consent form where he talks about the tension-free
16 vaginal tape, which is the TVT. All my questions
17 about the procedures have been answered to my
18 satisfaction. And it's signed by Mrs. Ebaugh.
19 Let's talk about where Dr. Douglass gets
20 his information. One of the things that Ms. Baldwin
21 wants you to believe is that a lot or most of the
22 information comes, that the doctors get comes from
23 the company. What the doctors will tell you is,
24 yes, we look at the company literature, we listen to
25 the company representatives that come around, we

27

1 listen to these preceptors who are teaching us the
2 techniques, but they also know that they're salesmen
3 and they also know that there's other places to
4 look.
5 For example, the medical literature. Why
6 is the medical literature so important in this type
7 of case? When you talk about peer-reviewed medical
8 literature, it's not a process to where Ethicon can
9 say, here, write me an article and we'll just send
10 it to this medical journal and they'll publish it.
11 When you have peer-reviewed medical literature, what
12 happens is an article is sent in, there's an editor
13 that takes that article, he sees what the area is
14 that's being discussed, and it's sent out to
15 reviewers that are experts in that area for them to
16 review and make comments on.
17 And they may make comments and send it
18 back to the editor that said this needs to be
19 addressed or it's not proper studies or we don't
20 believe this data, and it may go back to the author
21 of that medical literature and they have to redo it.
22 You've got medical literature general like New
23 England Journal of Medicine. You probably heard of
24 that one.
25 But there are also specific journals that

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1 are specific areas. Like you'll hear journals for
2 there's urodynamics and urogynecology. And those
3 are specific -- and doctors that work in specific
4 areas will take those journals because they want to
5 keep up with what's the new medical literature, the
6 new procedures, the reports of adverse events, the
7 reports of case studies that don't seem to make
8 sense.
9 So you'll have peer-reviewed medical
10 literature that doctors rely on -- and when it says
11 peer-reviewed, that means experts have looked at it,
12 commented on it to make sure when they publish it
13 it's got validity and it's got the ability.
14 Medical meetings. Doctors go to these
15 medical meetings not just so they can go somewhere
16 nice and have a convention and have food and drink,
17 but also they can have these meetings and get more
18 education and learn things. You'll have what you
19 call poster board presentations. There may be a
20 doctor that has an interesting case or is working on
21 a new product and he -- before he even submits in an
22 article, he may make a poster board to show at this
23 meeting. And there will be a specific point in time
24 where he can stand out by that poster and have a
25 discussion with any doctors that are interested in

1 that area and tell them what's going on.
2 Then they may have committees that talk
3 about these issues. And that -- if it's a
4 significant enough medical area, then that may lead
5 to an article that goes into one of these medical
6 journals. These doctors are not on islands. They
7 talk to each other. You're going to hear that the
8 problems that the TVT-Secur had in Australia, the
9 three doctors were saying, wait a minute, I am
10 having a problem here with this procedure. Are you
11 having the same problem? That's exactly how doctors
12 find out.
13 If the TVT product didn't work, you
14 wouldn't have all these doctors still using it. And
15 we'll get into the doctors that are still using it.
16 And then, finally, the personal
17 experience. The doctors rely upon what happens. If
18 they're having bad results, they quit using it.
19 You're going to hear from Dr. Sepulveda.
20 He's an expert that we hired to come in here. He's
21 got a lot of experience with TVT-Secur. He doesn't
22 like the fact that it's no longer on the market. He
23 liked the product. He had huge success with it. It
24 was minimally evasive. He could get the woman out
25 and have her back on her feet immediately. This is

1 not the type of product where you have to wait for
2 the swelling to go down like surgery or anything
3 before. You get immediate relief with the stress
4 urinary incontinence. And he'll tell you he wished
5 it was still on the market.
6 Dr. Douglass specifically told Mrs.
7 Ebaugh that there was a higher rate of failure with
8 the TVT-Secur before he put that in and that we
9 might have to do the TVT, and that's what was
10 reflected in those medical records.
11 Let's talk a little bit about the doctors
12 that treated her. Dr. Douglass, you already heard.
13 He used miniurethral slings. And we talk about TVT.
14 There's the tensionless tape, midurethral synthetic
15 slings. They've got a lot of names. But that's
16 basically the same product as the TVT.
17 Dr. Mirsky. Now, this is the first
18 doctor. When she was having problems in 2011, she
19 goes to see a doctor. Dr. Douglass is no longer
20 around by this time. Dr. Mirsky, she's -- it's a
21 doctor she selected. It's not a doctor that Ethicon
22 sent her to or Johnson & Johnson sent her to. She
23 picks Dr. Mirsky. He goes in and does the surgery.
24 What he does first is he does the scope.
25 He goes up the urethra and he sees where there's

1 been a midurethral erosion, just like Dr. Douglass
2 warned her might happen. He said, yeah, it's acting
3 like a little bit of a dam and that because the
4 urine is backing up against it, you've got crystals
5 that are forming on it because of the calcium
6 deposits.
7 He goes in and his medical records
8 indicate into the urethra. He's not taking out the
9 whole sling, but what was eroded into the urethra.
10 And he takes out 98 percent because he thought that
11 would take care of the problem. Dr. Mirsky will
12 tell you he still uses the midurethral sling to
13 treat SUI today.
14 She goes about a year having the same
15 problems. She goes back to see Dr. Mirsky.
16 Dr. Mirsky says, well, it looks to me like you've
17 still got some of that synthetic material in there.
18 I am going to send you to Dr. Chai. Dr. Chai at
19 that time was with the University of Maryland. He's
20 now up at Yale.
21 She goes to see Dr. Chai. He does an
22 ultrascope. He thinks he sees some of this mesh up
23 in the bladder, not just in the urethra. So he
24 makes an incision across the abdomen, tunnels down
25 to the bladder and discovers he can't find any mesh

1 there. Goes up to the urethra, there's a couple
2 strands in there that he takes out. He will testify
3 that he still uses midurethral synthetic slings to
4 treat SUI today.
5 Dr. Wright. In 2016, still having some
6 problems. She goes in. Dr. Wright goes in, he says
7 I took out every piece of mesh that I could find.
8 And every doctor that has examined her since then
9 has not been able to find any mesh.
10 Think about that. You're going to hear
11 that Dr. Margolis, who was hired by the plaintiffs
12 to examine her, didn't find any sling; Dr. Tomezsko,
13 who was hired by the defense, didn't find any.
14 There's no evidence that she has any -- that any
15 doctor since then has discovered any synthetic
16 sling.
17 Let's see what they say about the TVT
18 product. Dr. Douglass -- now, remember, every one
19 of these doctors, not paid a penny by Ethicon or
20 Johnson & Johnson. Remember when Ms. Baldwin talked
21 about, you know, they bought all the doctors or
22 there's at least a potential bias because they made
23 a lot of money off of Ethicon and Johnson & Johnson
24 and you can't really trust the studies because
25 there's potential bias because they got paid money.

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1 None of these doctors -- and these are doctors that
2 either she went to see on her own or that they
3 referred to another doctor.
4 Dr. Douglass calls TVT a ground-breaking
5 procedure. Minimally invasive. A miraculous
6 advance in the treatment of urinary incontinence.
7 The TVT is the gold standard for treatment of SUI.
8 Dr. Mirsky did not conclude that
9 Mrs. Ebaugh's erosion was caused by a defect in the
10 TVT.
11 Dr. Chai. He was asked about what
12 happens when you have to have a repeat,
13 reimplantation, kind of what happened with Mrs.
14 Ebaugh when she had to have the repeat from the
15 TVT-Secur to the TVT. He says the need for repeat
16 implantation is either me or the patient or a
17 combination thereof. The patient factors, physician
18 factors. He didn't say a word about the TVT product
19 was defective, any of them were defective.
20 Dr. Wright makes the comment, no finding
21 that the TVT mesh was defective.
22 Remember, you're going to hear from two
23 doctors on the plaintiffs' side. Dr. Rosenzweig,
24 who's going to come in and talk about all the bad
25 things and all the bad literature and all the bad

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1 Ethicon documents. Then you're going to have
2 Dr. Margolis, who is out from the San Francisco
3 area, who is going to come in and say I examined
4 Mrs. Ebaugh and she's got all these problems all
5 caused by the TVT product.
6 On the defense side we hired
7 Dr. Sepulveda. And he comes in and he says this is
8 a good product, I've used it over a thousand times
9 in all these women and I stand by it. And, yes,
10 she's had a bad result, but it was something that
11 was warned about.
12 And basically this erosion in the
13 urethra, by the way, you're going to see that that
14 happens in about one-tenth to one percent of the
15 women that are treated with these midurethral
16 slings. One in 1,000. One-tenth of one percent.
17 So it's a very rare -- in fact, Dr. Douglass in his
18 deposition calls, he calls Mrs. Ebaugh a very rare
19 outliner.
20 Let's talk briefly about Mrs. Ebaugh's
21 complaints today. She has recurrent UTI's, pain
22 with sex, pelvic, abdominal and flank pain,
23 bleeding, SUI urgency, anxiety and depression. The
24 complaints that were in her medical records before
25 she had the TVT or the hip implant are UTI's, pain

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1 in her abdomen and pelvis that would literally
2 double her over in pain, stress incontinence,
3 bleeding, urgency, anxiety and depression.
4 And, by the way, when you talk about this
5 timeline about she saw Dr. Douglass in 2005, she
6 came back and had the TVT-Secur in 2007, in May of
7 2007, and then she had the TVT in July of 2007.
8 Well, three months later she has a hip implant, and
9 then she has a revision of that hip implant, meaning
10 another surgery, in 2010.
11 One thing we would disagree vehemently
12 with, and our doctors will -- Ms. Baldwin told you
13 that she had three erosions. What she basically had
14 was one erosion and then had to have three
15 operations to go in. Because Dr. Mirsky, he takes
16 out 98 percent; Dr. Chai goes in and takes out a
17 little bit more; and then finally Dr. Wright takes
18 out everything he can find. But it's all the same
19 erosion. It's one erosion, not three separate
20 erosions.
21 All right. I told you that they have
22 these two experts that they've hired, paid money to.
23 We have two experts that we hired and paid money to.
24 And then you've got these doctors in the middle like
25 Dr. Douglass, Dr. Mirsky, Dr. Wright and Dr. Chai,

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1 not paid by anybody and every one of them used TVT
2 products and none of them said that it was
3 defective.
4 She saw this one coming. She tried to
5 jump on it early. But there are associations that
6 all these doctors belong to. The American
7 Urogynecological Society called AUGS, the Society
8 for Urodynamics Female Pelvic Medicine and
9 Urogenital Reconstruction.
10 Now, what they say is -- and this is
11 their position paper that came out in 2014 -- the
12 polypropylene mesh midurethral sling is the
13 recognized worldwide standard of care for the
14 surgical treatment of stress urinary incontinence.
15 The procedure is safe, effective and has improved
16 the quality of life for millions of women.
17 Polypropylene mesh midurethral slings are the
18 standard of care for the surgical treatment of
19 SUI and represent a great advance in the treatment
20 of this condition for our patients. The
21 monofilament polypropylene mesh midurethral slings
22 is the most extensively studied anti-incontinence
23 procedure in history. Full length midurethral
24 slings -- now, to be fair, the TVT is a full length
25 midurethral sling and the TVT-Secur is a mini-sling.

1 But they're talking about the full length
2 midurethral sling both retropubic, which is the TVT,
3 and the transobturator, have been extensively
4 studied and are safe and effective relative to the
5 other treatment options and remain the leading
6 treatment option and current gold standard for the
7 stress incontinence surgery. A recent survey
8 indicates these procedure are used by 99 percent of
9 AUGS members.
10 This brings us back to -- she says, well,
11 they paid money to all of these people. Well, we
12 didn't pay money to 99 percent of all the AUGS
13 members. And you don't have another position paper
14 from somebody else saying that we disagree with this
15 and that we're half the people that are in this one
16 or ten times the people in this. You don't have
17 that.
18 The bottom line is, the professional
19 societies that treat -- the doctors that treat this
20 kind of condition have come out and said that the
21 TVT midurethral sling is the gold standard, it
22 works, it's worked in millions of women over the
23 years and it's approved.
24 And this statement was approved by the
25 AUGS board of directors and the SUFU board of

1 directors on January 3rd of 2014. This is not
2 something that happened just recently. It happened
3 three years ago after the extensive looking at the
4 literature and the studies that are out there.
5 Let me talk to you a little bit about the
6 whole idea of company documents, company witnesses.
7 In this litigation there have been millions and
8 millions of documents produced by Ethicon and
9 Johnson & Johnson. The plaintiffs' lawyers have
10 gone through and they've picked out the ones that
11 they want to use at trial. And you're going to hear
12 from them.
13 Now, some of them we've got an
14 explanation for. They may be taken out of context.
15 Some of them, for example, when they say there's no
16 testing, didn't we have to go -- and you'll hear in
17 one of these depositions -- and you're going to
18 shoot us by the end of this thing because you'll
19 have the same guy in a deposition for five days
20 long. The whole day for five days.
21 But at the end of it, part of the problem
22 is they said, well, there's no testing. So we've
23 got to give him a study and have him say does this
24 talk about the risk and the benefit? Another study,
25 does this talk about the risk and the benefit?

1 Another study. We're forced to do it because,
2 otherwise, they take certain documents out of
3 context or pick a very small universe out of
4 millions and say, well, you didn't do any testing.
5 You did insufficient testing. They point the finger
6 at us and we've got to be able to defend ourselves.
7 I apologize up front. I wish y'all
8 didn't have to sit through this, but we've got to be
9 able to defend ourself. You know, I am the oldest
10 of seven kids. My mama learned a long time ago
11 that, you know, you listen to the first one that
12 runs up to you, but you don't pick up the switch
13 until you heard the other side of the story.
14 And this is going to be the other side of
15 the story and it's going to be tedious and it's
16 going to be long. And I apologize for that, but
17 we've got to have a right to be able to put on our
18 side of the story.
19 The hip implant. We're not going to
20 spend a whole lot of time talking about the hip
21 implant, but the fact of the matter is she had that
22 hip implant in 2007. She's testifying between the
23 time that she had the hip implant to the time she
24 had the revision, that it ruined her life, that she
25 had terrible pain associated with that. And we've

1 got to be able to point out that that's the hip
2 implant, that's not us, and that during that whole
3 period of time from 2007 to 2011, she's not
4 complaining about our product at all or that it was
5 not working at all.
6 JUROR NUMBER 8: Can I use the bathroom?
7 THE COURT: Sure. Why don't we take a
8 break. We need to excuse everyone.
9 JUROR NUMBER 8: All right.
10 COURT OFFICER: All rise as the jury
11 exits the courtroom.
12 - - -
13 (Whereupon, the jury exits the courtroom
14 at 3:10 p.m.)
15 - - -
16 THE COURT: I believe, counsel, you have
17 ten minutes left.
18 MR. WEBB: I was within about two minutes
19 of shutting it down.
20 THE COURT: That's fine.
21 MR. WEBB: If she could have held out a
22 little longer. But that didn't look like it was an
23 option, so I didn't say anything.
24 _ _ _
25 (Whereupon, a brief recess was taken.)

1 _ _ _
2 (Whereupon, the jury enters the courtroom
3 at 3:27 p.m.)
4 - - -
5 THE COURT: Everyone may be seated.
6 All right. Counsel, you may proceed.
7 MR. WEBB: I was going to tell you I was
8 that close to being done, but we can go ahead and
9 stop when we need to stop.
10 Let me talk to you a little bit about the
11 burden of proof. One of the things that we're
12 having difficulty making sure that we get across is
13 we could have a failed procedure and that's not a
14 defect in the product. It just didn't work.
15 Because you're going to see that there are -- every
16 one of these products, there are some women either
17 because -- as Dr. Chai said, because of him, because
18 of the patient, or a combination of them, it just
19 didn't work.
20 But the fact of the matter is, you know,
21 that's different than having a defect. You could
22 have a defective product. It could break or it
23 could not be appropriate or not tested right. But
24 just because Mrs. Ebaugh's TVT-Secur didn't work
25 doesn't necessarily mean that it's defective.

1 And that burden of proof is something
2 that we talk about that if you listen to all of this
3 evidence, at the end of it you think that we've done
4 our job, we've proved that the TVT-Secur and TVT
5 product is not defective and we were not negligent
6 as a company the way that we tested it and put it on
7 the market or, on the flip side, the plaintiffs have
8 proven that we were negligent and there was a defect
9 and they win. We prove it, we win.
10 But it comes out at the end of it you're
11 sitting there saying it's 50/50, they haven't met
12 their burden of proof. They've got to prove by a
13 preponderance of the evidence, preponderance of the
14 credible evidence that, in fact, there was a defect
15 in the TVT-Secur, defect in the TVT, or that we were
16 negligent, Ethicon and J&J, the way that we tested
17 and marketed this product.
18 Let me tell you we are sorry that
19 Mrs. Ebaugh did not have a good result. No company,
20 no doctor wants a patient to have a bad result. The
21 fact that you may have, that you may have a very
22 rare occurrence that happens, one in a thousand, we
23 wish that it didn't happen at all. We would like
24 nothing more to have something that we could market
25 that a thousand women out of a thousand women got a

1 good result and it corrected the problem.
2 Unfortunately, there's not anything out there like
3 this.
4 What you're going to see is there was an
5 evolution between the MMK, the Burch, the natural,
6 the testing of the synthetics, the TVT and it
7 continues. It's going to continue in the future.
8 As we get better at this, it's going to get better.
9 There are going to be better products, they're going
10 to be less invasive, they're going to have a better
11 result. But we can't guarantee a result, a good
12 result, every time.
13 And we're sorry for the fact that
14 Mrs. Ebaugh had a bad result, but it's a risk that
15 we knew about, that we told the doctors about, that
16 the doctor knew about before he performed her
17 surgery and, unfortunately, it happened to her. And
18 we're sorry for that, but it doesn't mean we had a
19 defective product and it doesn't mean we're a bad
20 company.
21 Thank you again for your attention. I am
22 sorry I didn't get finished a little quicker. I
23 appreciate your attention.
24 Thank you.
25 THE COURT: All right. So we're now

1 going to start the testimony in this case.
2 In cases such as these, actually a
3 majority of the testimony you're going to hear is
4 going to be on that screen rather than this chair.
5 The rules say that you're allowed to take trial
6 testimony of someone. It's recorded and there's
7 direct examination and cross-examination. And
8 you're to treat that testimony the same way you
9 would as if the witness were sitting in the chair.
10 Now, one of the downsides to seeing it on
11 the screen, rather than having someone in the chair,
12 is that it's just -- we've all experienced this. It
13 could be hard to sit through lengthy testimony when
14 you're watching it on the screen. Watching anything
15 on the screen. After a while, it can be difficult.
16 And there are going to be many days worth of video
17 testimony. So there may be times when you feel like
18 you're losing focus, there may be times when you
19 feel like you're getting sleepy. Those are all
20 human reactions.
21 And rather than have you miss out on
22 something important, because all the evidence in
23 this case and all the testimony is very important, I
24 would rather you just get my attention, ask for a
25 five-minute break. And we'll take breaks

1 periodically.
2 I will be asking you about every 45
3 minutes to an hour, even if I don't hear from you,
4 whether you would like a break. But, again, I think
5 it's much more important that you guys just candidly
6 tell us when you need a break. It's no big deal. I
7 may do it myself at times.
8 I should also forewarn you that there may
9 be times where I am not here. The objections have
10 already been ruled on. You won't see any objections
11 or judge's ruling on them. So that way I can do
12 other things having to do with this case. And I'll
13 be in the back. You should not take that as a sign
14 that that testimony is any less important than any
15 other testimony. It just allows me to kill two
16 birds with one stone.
17 MR. WEBB: Judge, are they allowed to
18 stand up and stretch a little bit if --
19 THE COURT: Absolutely. As long as it
20 doesn't get in the way. But you can come down here
21 if you need to. You'll see me standing all the
22 time. I just want to forewarn you that that's one
23 of the arguable downsides. But there's lots of
24 benefits to doing it that way too in terms of not
25 having people fly all the way down here for trial

1 when it's not exactly sure what hour or what day
2 they're going to be testifying.
3 So with all that being said, we're ready
4 for the plaintiffs' first witness.
5 MS. BALDWIN: Yes. The plaintiffs' first
6 witness will be Aran Maree, medical director of the
7 Ethicon Australia, vice president of medical affairs
8 and the chief medical officer. And the date of his
9 deposition was July 22nd 2013.
10 And just so everyone knows, the
11 plaintiffs' clip is about 33 minutes, and then there
12 will be a defense clip which is about 29 minutes.
13 So it's about an hour. And then we have one short
14 clip after that.
15 THE COURT: That's fine. And what that
16 means is that it was all one deposition, but each
17 side gets to choose which parts they want to show
18 you. So the total here is a little over an hour.
19 MS. BALDWIN: And, Your Honor, I have
20 clip reports, if you would like a copy.
21 Can I pass them up?
22 THE COURT: Sure.
23 Last thing, technical point. We will dim
24 the lights a little bit so that you can see more
25 easily. If you need them dimmed more or you need

1 the air conditioning turned down, just let us know.
2 - - -
3 (Whereupon, the video deposition of Aran
4 Maree played.)
5 - - -
6 THE COURT: I am sorry. One of the
7 Members of the Jury astutely reminded that we forgot
8 to hand the books out, so we will do that now.
9 (Pause)
10 THE COURT: Is everyone set? Okay.
11 We can resume the video, please.
12 - - -
13 (Whereupon, video deposition of Aran
14 Maree played.)
15 - - -
16 MS. BALDWIN: That concludes the
17 plaintiffs' clip of Dr. Maree.
18 THE COURT: Okay.
19 MR. COMBS: Your Honor, this will be the
20 defense questioning of Dr. Maree.
21 THE COURT: That's fine.
22 - - -
23 (Whereupon, video deposition of Dr. Maree
24 played.)
25 - - -

1 MS. BALDWIN: I believe that concludes
2 the defendants' part.
3 MR. COMBS: Yes, Judge, that's the end of
4 questioning for all sides of Dr. Maree.
5 THE COURT: And just so I know -- we
6 talked about this -- the next witness is 20 minutes,
7 a half an hour?
8 MS. BALDWIN: The next clip is exactly 30
9 minutes. So if the jury wants to work until ten
10 after 5:00, we can do it today. If not, we can do
11 it next week.
12 THE COURT: I am sensing a consensus to
13 break for the weekend.
14 MS. BALDWIN: Seems like a fine idea.
15 THE COURT: I didn't take a vote, but if
16 we ever work past 5:00 I would need everyone to
17 agree. And it's been a long day.
18 So we'll ask you to leave your notepads
19 in your chairs. We want you to have a nice and safe
20 weekend, and please remember not to discuss the case
21 with anyone.
22 Just a reminder, next Friday we will not
23 be working. And I don't know if I mentioned this,
24 but this coming Wednesday we'll only be working half
25 a day until about 1:30. We'll ask you to be in the

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1 jury room at 9:00 a.m. on Monday morning.
2 JUROR NUMBER 7: Monday at 9:00?
3 THE COURT: Yes. Thank you.
4 COURT OFFICER: All rise as the jury
5 exits the room.
6 - - -
7 (Whereupon, the jury exits the courtroom
8 at 4:40 p.m.)
9 - - -
10 THE COURT: All right. I guess we will
11 meet around 9:00 or 9:15 on Monday?
12 MS. BALDWIN: Sounds good.
13 THE COURT: Okay. Have a nice weekend.
14 - - -
15 (Court adjourned.)
16 - - -
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1
2 CERTIFICATE
3
4 I HEREBY CERTIFY THAT THE PROCEEDINGS AND
5 EVIDENCE ARE CONTAINED FULLY AND ACCURATELY IN THE
6 NOTES TAKEN BY ME ON THE TRIAL OF THE ABOVE CAUSE,
7 AND THIS COPY IS A CORRECT TRANSCRIPT OF THE SAME.
8
9
10
11
12 SHARON J. RICCI
13 OFFICIAL COURT REPORTER
14
15
16
17
18 (THE FOREGOING CERTIFICATION OF THIS
19 TRANSCRIPT DOES NOT APPLY TO ANY REPRODUCTION OF THE
20 SAME BY ANY MEANS UNLESS UNDER THE DIRECT CONTROL
21 AND/OR SUPERVISION OF THE CERTIFYING REPORTER.)
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