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                         IN THE COURT OF COMMON PLEAS
09:25AM
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             FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
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                            CIVIL TRIAL DIVISION
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                                      ____
              ELLA EBAUGH, et al., : JULY TERM, 2013 Plaintiffs :
         6
         7
                  VS.
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              ETHICON, INC., et al., : Defendants : NO. 0866
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                                      ____
        11
                                 August 4, 2017
                    (Morning Session - Plaintiffs' Opening)
        12
                             Courtroom 633, City Hall
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                                  Philadelphia, PA
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                                       ____
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              BEFORE: HONORABLE MICHAEL ERDOS, JUDGE,
        16
             And a Jury
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1 2	A P P E A R A N C E S:			4
3	KLINE & SPECTER		1	
4	BY: KILA B. BALDWIN, ESQUIRE	11:41AM	2	· · · · · · · · · · · · · · · · · · ·
	ELIA A. ROBERTSON, ESQUIRE TRACIE PALMER, ESQUIRE	11:41AM	3	
5	MICHAEL A. CAVALIERE, ESQUIRE 1525 Locust Street	11:41AM	4	
6	Philadelphia, PA 19102 (215) 772-1000	11:41AM	5	, ,
7	Counsel for Plaintiffs	11:41AM	6	
8		11:41AM	7	
9		11:41AM	8	
10	BECK REDDEN, LLP BY: KAT GALLAGHER, ESQUIRE	11:41AM	9	p p
11	CURT WEBB, ESQUIRE 1221 McKinney Street	11:41AM		,
12	Suite 4500	11:41AM		
13	Houston, TX 77010 (713) 951-6208	11:41AM		·
14	an d	11:42AM		, , , , , , , , , , , , , , , , , , , ,
15	THOMAS COMBS & SPANN, PLLC	11:42AM		
16	BY: PHILIP J. COMBS, ESQUIRE DANIEL R. HIGGINBOTHAM, ESQUIRE	11:42AM		ic in out a sea out position that it simply
17	300 Summers Street Suite 1380	11:42AM		•
18	Charleston, W V 25301 (304) 414-1800	11:42AM		,
19	and	11:42AM		
20		11:42AM		•
	BUTLER SNOW, LLP BY: JORDAN WALKER, ESQUIRE	11:42AM		3
21	1020 Highland County Parkway Suite 1400	11:42AM		
22	Oxford, MS 38655 662-513-8000	11:42AM		, 3
23	Counsel for Defendants	11:42AM	23	with it, but I think showing it during
24		11:42AM		,
11:24AM <b>25</b>		11:42AM	25	v. Edmunds.
	3			5
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11:40AM <b>2</b>	THE COURT: Your all right. What do		2	
11:40AM <b>3</b>	we need to discuss before openings?	11:42AM		, , , , , , , , , , , , , , , , , , , ,
11:40AM <b>4</b>	MS. BALDWIN: Your Honor, we just	11:42AM		
11:40AM <b>5</b>	exchanged our Power Point slides for the	11:42AM	5	, , , ,
11:41AM <b>6</b>	openings and we each have an exhibit to	11:42AM	6	
11:41AM <b>7</b>	the other's opening. If you would like me	11:42AM	7	
11:41AM 8	to go first, I can.	11:42AM	8	
11:41AM 9	THE COURT: You said you have an	11:42AM	10	<b>,</b>
11:41AM 10	objection?	11:42AM		
11:41AM <b>11</b>	MS.BALDWIN: An objection, yes.  THE COURT: Okay.	11:42AM 11:42AM		
11:41AM 12	MS. BALDWIN: I have an objection to	11:42AM 11:42AM		
11:41AM 13	defendant's slide and I can pass it up to	11:42AM 11:42AM		
11:41AM <b>14</b>	Your Honor. It's an AUG's position	11:42AM 11:43AM		- '
11:41AM 16	statement about the use of transvaginal	11:43AM		
11:41AM 17	mesh, which will come in on cross with some	11:43AM		· · ·
11:41AM 17	of the experts, but I believe putting the	11:43AM		
11:41AM 19	statement up itself would violate Aldridge	11:43AM		
11:41AM <b>20</b>	v. Edmunds. I think it's not appropriate	11:43AM		
11:41AM <b>21</b>	opening statement.	11:43AM		
11:41AM <b>21</b>	THE COURT: If it's hearsay it won't	11:43AM		·
11:41AM <b>22</b>	matter because the guy is going to testify	11:43AM		
11:41AM <b>24</b>	to it; right? Is someone going to testify	11:43AM		
11:41AM <b>25</b>	to it?	11:43AM		
	09:40:10 PM Page 2 t			W hat's your objection?

6 8 1 1 Judge's Opening Remarks 2 2 MR. WEBB: We withdraw our objection, I'm first going to describe in a 11:53AM 11:43AM general way what will take place during the Your Honor. 3 11:43AM 3 11:53AM THE COURT: Okay. An hour each max. trial. First the plaintiffs' attorney will 4 11:43AM MS. BALDWIN: Got it. make an opening statement in which she will 11:53AM 11-43AM THE COURT: Any objections you make, 6 outline the plaintiffs' case against the 11:53AM unless it's something really outrageous 7 defendant and the defendant's attorney will 11:53AM 11:43AM that the other side has said, I'm going to make an opening statement as well. 8 11:43AM 11:53AM hold those in abeyance until we're done the The plaintiffs' lawyer goes first 9 9 11:43AM 11:53AM openings and we'll discuss them. 11:53AM 10 because they have the burden of proof, 10 11:43AM MR. WEBB: Judge, if you want to take which I will explain in greater detail 11 11:53AM 11 12 time to do it now, we can get you set up 11:53AM **12** later on during the trial. 11:46AM for realtime. After the opening arguments, then we 11:46AM **13** 11:53AM 13 THE COURT: You can even do it have the presentation of evidence. The 14 11:53AM **14** 11:46AM tomorrow. plaintiffs' lawyer will first present 15 11:53AM 15 11:46AM THE LAW CLERK: Please stand as the evidence. She will call witnesses to 11:51AM **16** 11:53AM 16 jury enters the courtroom. 11:53AM 17 testify and may offer exhibits such as 17 11:51AM (Jury enters courtroom) documents, graphs, charts, or physical 18 11:54AM **18** THE COURT: All right. Members of the objects. 11:52AM 19 11:54AM 19 jury, the first order of business is for The defense counsel has a right to 11:54AM **20** 20 11:52AM **21** you to be officially sworn in as a juror. 11:54AM **21** cross-examine witnesses called by the 11:52AM **22** Ms. Wicclair. 11:54AM **22** plaintiff in order to test the truthfulness 11:52AM **23** THE LAW CLERK: Thank you. 11:54AM 23 and accuracy of their testimony. Please raise your right hand. Do you After the plaintiffs' lawyer has 11:52AM **24** 11:54AM **24** presented the plaintiffs' case, defense and each of you swear, and those of you who 11:52AM **25** 11:54AM **25** 1 Judge's Opening Remarks 1 affirm, do declare and affirm that you will counsel may present evidence for the 2 11:54AM 11.52AM truly try the issues joined between the defendant, however, there is no obligation 3 11:54AM plaintiff and the defendant and render a for the defendant to offer evidence or to 11:54AM 11:52AM true verdict according to the law and the testify. The plaintiffs' lawyer may of 11:52AM 11:54AM evidence? If so, please respond I do. course cross-examine any witnesses that are 6 6 11:52AM called by the defense. 7 THE JURY: I do. 7 11:54AM 11.52AM THE LAW CLERK: Thank you. 8 After all the evidence has been 8 11:54AM THE COURT: You may be seated. presented, the attorneys for each side will 11:52AM 11:54AM All right. Welcome back. As you now 11:54AM 10 have the opportunity to make their closing 10 11:52AM know, each of you has been selected as a arguments to you. I will then give you my 11:54AM **11** 11:52AM juror in this case, and what that means is 11:54AM **12** final instructions on the rules of law that 12 11:53AM that the plaintiff, the defendants, the apply to this case and whatever additional 11:54AM 13 13 guidance I think you may need for your 14 Court have each concluded each one of you 11:54AM **14** 11:53AM deliberations. You will then retire to the will be a fair and impartial juror, and 11:54AM 15 11:53AM **15** that really is a tribute to each one of jury room to deliberate and decide what 11:54AM 16 11:53AM you. There were a lot of people that we 11:54AM **17** your verdict will be. 17 11:53AM interviewed. At the end of the trial you must make 11:53AM 18 11:54AM 18 11:53AM 19 The services you render as jurors in 11:54AM 19 your decision based on what you recall of this case are as important to the 11:54AM **20** the evidence. You will not have a written 11:53AM **20** administration of justice as those rendered transcript to consult and it is difficult 11:53AM **21** 11:54AM **21** 11:53AM **22** by me as the judge and by the attorneys. 11:54AM **22** and time-consuming for our court reporter So please pay close attention to everything to read or play back lengthy testimony. I 11:54AM 23 11:53AM 23 11:53AM **24** that is said and done in this courtroom so 11:54AM 24 urge you, therefore, to pay chose attention that you may perform your duties well. 11:55AM **25** to the testimony as it is given. If at any 11:53AM **25** 

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Judge's Opening Remarks point in the trial you cannot hear or understand a witness, a lawyer, or myself or see an exhibit, please let us know in order that we may resolve it for you immediately.

It will get a little noisy because of

the air conditioning, but it gets extremely

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hot during the summer when the air conditioning isn't on. At times we may turn it off briefly, but if at any point you can't hear us, let us know. Unfortunately, although you may wish to question some of the witnesses yourself,

you are not permitted to do so. It is my responsibility as the judge to decide all questions of law during the trial. You must follow my rulings and instructions whether or not you agree with them. I am not, however, the judge of the facts. You, the jurors are the only judges of the facts. It will be your responsibility at the end of the trial when you deliberate to evaluate the evidence and from that evidence determine the facts.

Judge's Opening Remarks

You will apply the rules of law that I give you to the facts as you find them to decide whether the plaintiff has met her burden of proving the elements of the claim that will entitle her to relief.

In order to decide the facts of this case you're going to have to judge the credibility and weight of the testimony and other evidence. By credibility I mean the truthfulness or accuracy of what is being said or shown to you. By weight I mean the value or importance that you give to the testimony or evidence.

When you judge the credibility and weight of a witness' testimony or of evidence being presented, use your understanding of human nature and your common sense. Observe each witness as he or she testifies. Be alert for anything in the witness' testimony or behavior or for anything in the other evidence that might help you judge the truthfulness, accuracy and weight of the testimony. Neither

sympathy or prejudice is to influence your

Judge's Opening Remarks consideration of the evidence.

Each of you must keep an open mind 3 throughout the trial. You should avoid 4 forming opinions about any disputed 6 questions until the trial is over and you begin your deliberations. Do not talk with 7 each other about the evidence or any other matter relating to your verdict until I 9 11:56AM 10 send you to the jury room to deliberate 11:56AM **11** upon your verdict. Only then will you know enough about the case to discuss it 11:57AM **12** 11:57AM **13** intelligently and fairly.

You should also not talk with anyone else about the case until the case is completely over, including your family members, people at home, your friends, or with anyone on social media or Internet sites.

Do not try to get information relevant 11:57AM **20** 11:57AM **21** to the case on your own. Do not make any 11:57AM **22** investigation, do any research, visit any 11:57AM 23 scene or conduct any experiment. If there 11:57AM **24** is any media coverage of the case, you are 11:57AM **25** not to read, listen to, or watch anything

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Judge's Opening Remarks 1 about the case in newspapers, magazines, 3 radio, television, or Internet.

There are some people with whom you 11:57AM must avoid even casual conversations having 11:57AM nothing to do with the case again until the 6 11:57AN case is completely over. These people are 11:57AM 8 the parties, the lawyers, and the 11:57AM 9 witnesses. 11:57AM

11:57AM 10 Please do not feel hurt or insulted if during a recess or at any other time one of 11:57AM 11 11:57AM **12** them sees you in the hallway or an elevator 11:57AM 13 or anyone else and does not return your greeting. They simply are not permitted to 11:58AM 14 11:58AM **15** do so. I will continue to greet you whether I see you inside or outside the 11:58AM 16 11:58AM 17 courthouse, but we are not permitted to 11:58AM 18 discuss any aspect of the case.

> If you are approached by anyone or if you see or hear something you think that you should not have seen or heard, do not speak to the other jurors about it, but rather notify courtroom personnel about it and they will bring it to my attention.

Statements made by the attorneys are

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Judge's Opening Remarks
not evidence. The questions that they ask
of the witnesses are not evidence. It is
the answers to those questions by the
witnesses that provide the evidence for you
to consider. You should not speculate or
guess that a fact may be true merely
because one of the lawyers asks a question
which assumes or suggests that a fact is
true.

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Occasionally there will be objections to the questions that are asked by the attorneys. If I overrule the objection to the question, you may consider the answer. However, if I sustain the objection, that means I will not allow an answer to be given; and if an answer has already been given, I will most likely direct you to disregard the answer, and you must do so.

It is possible I might question some
of the witnesses myself. It won't happen
often, if at all. These questions are not
intended to reflect any opinion on my part
about the evidence or about the case. The
only purpose of doing so would be to

Judge's Opening Remarks inquire about matters that I think should be more fully explored or clarified for you out of fairness to both sides.

At different points during the trial the attorneys and I may need to deal with certain matters outside of your hearing. We generally call this sidebar. We will try to do it as infrequently as possible, but it's bound to happen several times during the trial.

Any time you need a convenience break of any type, just let us know. We'll be asking at regular intervals whether you'd like a convenience break. In particular, if you need water, just let Ms. Gyimesi or Ms. Wicclair know. You can do that, just raise your hand and get their attention.

If you haven't already been told, I think you have, you can bring in any nonalcoholic beverage of your choice while you're listening to the evidence.

We have notepads and pens for each of you in the event that you wish to take notes. We'll be passing them out when the

Judge's Opening Remarks

**2** first witness testifies. You are not

12:00PM 3 allowed to take notes during any of the

• 4 opening statements or closing arguments.

5 You are under no obligation to take notes

12:00PM **6** and it is entirely up to you whether you

**7** wish to take notes to help you remember

12:00PM 8 what witnesses said and to use them during

ъм **9** your deliberations.

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If you do take notes, remember that 12:00PM 10 12:00PM **11** one of your responsibilities as a juror is 12:00PM **12** to observe the demeanor of witnesses to 12:00PM 13 assess their credibility. Do not become so involved with note taking that it 12:00PM **14** interferes with your ability to observe a 12:00PM 15 witness or distracts you from hearing the 12:00PM 16 12:00PM 17 questions being asked the witness and the

answers being given by the witness.

Your notes may help you refresh your recollection of the testimony and it should be treated as a supplement to your memory, rather than a substitute for your memory. Your notes are only to be used by you as

12.00PM **24** memory aids and should not take precedence

25 over your independent recollection of the

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Judge's Opening Remarks

2 facts.

Those of you who do not take notes
should not be overly influenced by the

should not be overly influenced by thenotes of other jurors. Sometimes it is

12:00PM5 notes of other jurors. Sometimes it is12:01PM6 just as easy to write something down

12:01PM **7** incorrectly as it is to remember it

12.01PM **8** incorrectly, and your fellow jurors' notes

**9** are entitled to no greater weight than each

12:01PM **10** juror's independent memory.

Although you may refer to your notes during deliberations, give no more or no less weight to the view of a fellow juror just because that juror did or did not take notes. Although you are permitted to use your notes during deliberations, the only notes you may use are the notes you write in the courtroom during the proceedings on the materials that will be distributed by the court staff.

Each time that we adjourn, your notes will be collected and secured by the court staff. Your notes are completely confidential and neither I nor any member of the court staff will read your notes now

18 20 1 Judge's Opening Remarks 1 Judge's Opening Remarks 2 or at any time in the future. After you've You are not to conclude that the 2 12:03PM 12:01PM attorneys will necessarily be able to prove reached a verdict in this case, your notes 3 12:01PM 3 12:03PM will be destroyed immediately by court what they say they expect to prove, nor 4 12:01PM personnel. that the Court will permit such evidence to 12:03PM 12:01PM Our schedule will vary day to day. 6 be introduced. 6 12:03PM We'll normally have you arrive by 9:00 in 7 Counsel, you may address the jury. 12:03PM 12:01PM MS. BALDWIN: Thank you, Your Honor. the morning so we can start at 9:30. We'll 8 12:01PM 12:03PM normally take a one-hour lunch break THE COURT: If you need the lights 9 12:01PM starting somewhere between 12:30 and 1:30 12:03PM 10 dimmed at any point, just let us know. 12:02PM and we'll normally work somewhere between 12:03PM **11** MS. BALDWIN: I think we'll be okay, 11 4:30 and 5:00. 12 12:03PM **12** but if the jury has trouble, if they could 12:02PM Obviously, if the jury has a sort of 12:03PM **13** just raise their hands, we'll dim the 12:02PM **13** consensus that they want to start even lights when we put the slides up. 14 14 12:03PM 12:02PM earlier and work even later to shorten the 12:04PM **15** I guess it's appropriate to say good 15 12:02PM duration of the trial, we'll be amenable to afternoon. So good afternoon everyone. 16 12:04PM 16 12:02PM 17 that as well. 12:04PM 17 THE JURY: Good afternoon. 12·02PM 12:04PM **18** MS. BALDWIN: Thank you for bearing 18 Today we're going to hear one of the two opening statements, then take our lunch 12:04PM 19 with us for an entire week of jury 19 12:02PM break, and then have the other opening selection. It's a first for me, so 12:04PM **20** 20 statement and begin with our evidence. We hopefully things get better for you than a 12:02PM 21 12:04PM 21 12:02PM **22** will conclude some time between 4:00 and 12:04PM **22** couple days of sitting around. 23 5:00 this afternoon. 12:04PM **23** The defendants in this case are 12:02PM Ethicon and Johnson & Johnson. They put You've already been given instructions 12:04PM **24** 12:02PM **24** two defective products on the market, the I believe by court staff as to which 12:04PM **25** 12:02PM **25** 19 21 Judge's Opening Remarks Plaintiffs' Opening Statement 1 1 restrooms are appropriate to use in this TVT-Retropubic, which we're going to call 12·04PM 12·02PM case. It's important that you pay close just the TVT throughout the trial, and the 12:04PM attention to those instructions. TVT-Secur, which you will hear us call the 12:04PM 12:02PM TVT-S throughout the trial. 5 Please remember to wear your juror 5 12:02PM 12:04PM badges in a conspicuous place at all times Ella Ebaugh, my client -- please 6 6 12:02PM 7 during the course of the trial and while 7 stand, Ella. 12:04PM 12·02PM vou're either in the courtroom or in the 8 (Ella Ebaugh complies with request) 8 12:04PM MS. BALDWIN: And her husband Marvin. courthouse. 12:04PM 12:02PM It's now time for the attorneys to 12:04PM 10 Marvin, go ahead and stand. 10 give opening statements telling you what (Marvin Ebaugh complies with request) 11 12:04PM 11 12:02PM they expect to prove or not be proven 12:04PM **12** MS. BALDWIN: Thank you. 12 12:02PM during the trial. The opening statements, 12:04PM 13 Ella Ebaugh had each of these devices 13 implanted in her in 2007. Ethicon and 14 as with any statements by the attorneys, do 12:05PM 14 12:02PM 12:02PM **15** not constitute evidence and you are not to 12:05PM **15** Johnson & Johnson had information about consider these opening statements as both of these products before it ever put 16 12:05PM 16 17 established facts. 12:05PM 17 them on the market that they were dangerous 12:02PM The only purpose of the opening 12:05PM **18** and they presented an unreasonable risk of 12:02PM 18 12:02PM 19 statement is to give you a general outline 12:05PM 19 danger to women who had them implanted in of what the case is about so that you will 12:05PM **20** them. After the products were put out on 12:02PM **20** 12:03PM **21** have a better understanding of how each the market, Ethicon and Johnson & Johnson, 12:05PM **21** 12:05PM **22** 12:03PM **22** piece of evidence fits in, subject of who I'm just going to start calling Ethicon course to your evaluation of the evidence so I don't have to say that long name, got 12:05PM 23 12:03PM 23 12:03PM **24** as to its credibility, its accuracy, and 12:05PM **24** even more information about how dangerous the weight to be given to the evidence. these products were, but they kept them on 12:03PM **25** 12:05PM 25

22 1 Plaintiffs' Opening Statement 1 Plaintiffs' Opening Statement the market. 2 products and what they were created for. 12:05PM 2 12:08PM This is a normal pelvic anatomy. You In the case of this one, the 3 12:05PM 3 12:08PM have three primary organs, which would be TVT-Secur, they kept it on the market from 12:05PM 2006 until 2012. They still sell the TVT. the bladder here, the uterus, which is 12:08PM 12:05PM These defective products have literally 6 connected to the vagina for sex and 12:08PM mangled Ella Ebaugh's urethra. She has 7 childbirth, and the rectum for feces. 12:08PM 12:05PM almost no control of her bladder because of At the bottom of the bladder is a 12:06PM 8 12:08PM them, is completely incontinent, and lives four-centimeter tube called the urethra. 9 12:06PM in constant pain because they're permanent 12:08PM 10 The urethra is the tube that takes urine 10 12:06PM implants and you can never get them 12:08PM **11** from the bladder outside of the body. The 11 12 completely out of your body. She's going 12:08PM 12 urethra needs to remain closed, kind of 12:06PM to suffer with this for the rest of her 12:08PM **13** like my fist here, so that you don't drip 13 life. urine. When you have to urinate, you use 12:06PM 14 12:08PM 14 Johnson & Johnson is worth seventy your pelvic muscles, you open it ever so 12:06PM 15 12:08PM 15 billion, four-hundred-eighteen million slightly so the urine is expelled from the 16 12:08PM 16 12:06PM 17 dollars. Ethicon is worth two billion 12:08PM 17 blood and then you use your muscles to seven-hundred-sixty-two million dollars. 12:08PM 18 close the urethra. That's the normal way 18 I'm mentioning this right at the outset 12:08PM 19 things happen. 12:06PM 19 right now because these defendants 20 12:08PM **20** Women get older, men get older. We 12:06PM **21** collectively worth more than seventy-two all do, but in women when you age and the 12:09PM 21 12:06PM **22** billion dollars made every decision about 12:09PM **22** muscles of the pelvis weaken from having 23 these products with money in mind, how much 12:09PM **23** kids, other stressors, weight gain, these 12:06PM money they could make. pelvic muscles can weaken, and what happens 12:06PM **24** 12:09PM **24** is the urethra, that four-centimeter tube, 12:06PM **25** I didn't make this slide. I didn't 12:09PM **25** 23 Plaintiffs' Opening Statement Plaintiffs' Opening Statement 1 1 type this. Look at the logo on the top doesn't stay in the same place all the 12:09PM 12:06PM left corner. "Ethicon's Women's Health and 3 12:09PM

Urology. Show me the money." This is a 12:07PM presentation that was given in their 12:07PM 5 marketing department in 2007. This is what 6 12:07PM Ethicon was concerned about when it 12:07PM marketed its TVT line of products, which includes the two that are at issue in this 12:07PM 10 case. 12:07PM They didn't concern themselves with 11 12:07PM 12

things like patient safety, whether they were permanently injuring women like my client Ella Ebaugh. They didn't concern themselves with things like testing the products.

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In the case of the TVT they relied on tests that were inherently biased. They paid for the results and then they never verified the data underlying them.

In the case of the TVT-S they never tested it in humans in a robust study before they put it on the market.

12:07PM **24** Ella Ebaugh is a casualty of their reckless conduct. So let's talk about the 12:08PM **25** 

time, it starts to move around. The pelvic

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muscles can't hold it in place as much and 12:09PM

5 keep it as tight as it needs to be, so 12:09PM

something happens called stress urinary 6

7 incontinence. 12:09PM

8 I think a lot of you said you didn't 12:09PM know what that was earlier. All that is as 12:09PM 12:09PM 10 a woman ages and her pelvic muscles weaken, when she coughs or sneezes or maybe does a 11

12:09PM 12:09PM **12** couple jumping-jax couple drops come out.

12:09PM **13** Not the whole content of the urine, just a

12:09PM 14 drop here or drop there. Some women wear

12:09PM 15 panty liners or maxi pads because they don't like that feeling in their underwear. 12:09PM 16

12:10PM 17 This is the TVT-Secur, the TVT-S. I'm going to open it up for you just so you get 12:10PM 18 an idea of what it is. It's sold as a kit 12:10PM 19

in the box. And in the kit comes 12:10PM 20

Instructions For Use, an IFU pamphlet, and 12:10PM **21** 12:10PM **22** then the product itself.

12:10PM 23 The product consists of a very short 12:10PM **24** piece of mesh, only about eight centimeters long, and then it has this device, the 12:10PM 25

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1 Plaintiffs' Opening Statement metal attached to it called the arrowhead 2 introducer, which is the means of inserting 3 it into the space between the urethra and the vagina. So let me show you what that is. 6

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This is called a single incision approach because what it involves is going in through the vagina inserting a speculum to open it or a clamp to open it like you would during a normal OB/GYN appointment and then making an incision into the vagina. This is an invasive procedure. It does involve cutting through the vagina and then placing the sling here just beneath the urethra to support it.

So as a woman ages, in theory this mesh is left in there to support the urethra. These arrowhead introducers are removed so all that's left is the mesh.

Now, I described it relatively simply, but you need to know just how invasive it is. It doesn't just involve the one cut into the vagina. You cut open the vagina and you use scissors to tunnel into the

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Plaintiffs' Opening Statement 1 tissue behind the vagina, between the vagina and the urethra. These arrowhead 3 introducers are sharp so they can push aside the tissues that's there. It's an 5 intrusive device that affects the way the 6 7 tissues sit in the vagina. It's designed to be permanently implanted there so that 8 the mesh should not be removed.

As I said earlier, the TVT-S was taken 10 off the market in 2012. It's defective and you're going to hear all about how not only did it not work to relieve stress urinary 14 incontinence in women, but it also created 12:12PM **15** quite a few risks for them.

> This is the TVT Retropubic Sling, often called the TVT. Again it comes as a kit. You get an Instructions for Use, and you get a much longer piece of tape. I think it's about 18 centimeters.

12:12PM **20** 12:12PM **21** This device is also not implanted in noninvasive procedure. It is invasive. 12:12PM **22** You have to cut into the vagina again and 12:12PM 23 12:12PM **24** you use these tools. I measured them on my finger about eight centimeters. Insert 12:12PM **25** 

Plaintiffs' Opening Statement 1 2 them through the vagina and then literally create a tunnel from the space behind the vagina all the way out to the abdominal 4 wall on either side. And I used myself as 6 a demonstration because they come out in 7 the abdomen in approximately this area.

The surgeon then pulls to make the 12:13PM mesh taught around the urethra, cuts the 9 12:13PM 10 extra mesh off here, and then uses surgical 12:13PM **11** glue or sutures to close the incisions here 12:13PM 12 as well as the incision that's made in the 12:13PM **13** vagina. So this has -- this is more than one incision and it's what's known as a 12:13PM **14** retropubic approach because it lies behind 12:13PM **15** the pubic bone, the mesh. Again the mesh 12:13PM 16 12:13PM 17 is meant to be permanently implanted. It's 12:13PM 18 not designed to be able to be taken out of 12:13PM 19 the body should complications arise, which they knew would. 12:13PM **20** 

Ella Ebaugh had a TVT-S implanted in May of 2007, didn't work and then her doctor put in a TVT. The recommended cure if one of their devices doesn't work, just put in a second one. And she developed, as

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Plaintiffs' Opening Statement I said, a multitude of complications that 3 have left her in very bad shape today.

So let's talk a little bit about what 12:14PM the issues are with the products. Both the 5 12:14PM TVT and TVT-S, and now I'm talking just 6 about the mesh themselves, the blue stuff 12·14PM 8 you see, are made of plastic. It's called 12:14PM Prolene. That's the pretty name they give 12:14PM

12:14PM 10 to it, but it's plastic. It's made by

weaving together sutures, polypropylene 12:14PM **11** 12:14PM **12** 

sutures, stitches, into a mesh form. So 12:14PM **13** pores are the holes between the sutures,

12:14PM **14** and the easiest way for me to show you this 12:14PM **15** is with a basketball net.

If you picture the white here as 12:15PM 16 12:15PM **17** polypropylene sutures woven into a mesh to 12:15PM **18** form the neck, these spaces in between, 12:15PM 19 those are what are called pores. Pore size is very important in implantable devices. 12:15PM 20 It matters because you need something 12:15PM **21** 

12:15PM **22** that's called macroporous. You need to maintain big pores. Why? Because we all 12:15PM 23

12:15PM **24** are human and we all have human tissue that grows. So in order to get these 12:15PM **25** 

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Plaintiffs' Opening Statement integrated, we need the tissue to grow in and around the pore so the mesh is implanted safely.

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In the case of microporous mesh where the pores are smaller, the tissue is going to grow over the pores and encapsulate them, and this is a process that's called scar plating or bridging fibrosis. Fibrosis is a fancy word for scars. The scars bridge the pores and cover the mesh.

Ethicon knew that in its TVT line of products, including the two that we're talking about here, that the pores were too small and that they would collapse if any tension was put on them during the implant surgery.

The easiest way I can show you pore collapse is again with this net. If you tension it or pull on the mesh at all, the pores collapse and become smaller like this, but you need to tension those devices to get them under the urethra. You can't avoid collapsed pores which creates those scars. This is the first defect with the

Plaintiffs' Opening Statement products.

Ethicon had an offered a different mesh called Ultrapro in some of its other pelvic organ products. One of the meshes that it offered was called Ultrapro, which I said, and it was made half of polypropylene and half of something called Monocryl. I know that's a big word, but what you need to know is the Monocryl is absorbable. The body absorbs it. So after a few weeks the Monocryl disappears, the body's absorbed it. So you're left with half a mesh and the pore sizes are automatically bigger to avoid the scar plating and the bridging fibrosis.

Ethicon never offered that in any of its TVT line of products.

Ethicon also had a medium-sized pore mesh, Dynamesh, that's used in some of its other products. It also never tried to use it in its TVT line of products.

The second defect with the mesh is that it causes chronic inflammation. All surgical implants cause some level of

Plaintiffs' Opening Statement inflammation, you can't avoid it. You can't put foreign bodies into your own tissue. The problem with these devices is that the Prolene, the plastic, is not inert and the reaction, the inflammatory reaction won't fade over time like it would, say, if you had a metal rod in your leg.

That triggers a chronic foreign body response. It's identified by pathologists when they look at tissue under the slide.

12:18PM 12 It's something called a giant cell 12:18PM 13 reaction. If you have just one Prolene

12-18PM **14** suture in your body, no big deal, just one suture. The TVT-S, this little thing here

uith this little piece of tape, they call it a mini sling sometimes, has 30 to 40

12-18PM **18** feet of polypropylene in it. That's a lot of plastic to put in a tissue surrounding

your vagina just under your urethra. Thatchronic foreign body response is permanent

and your body will never stop fighting it.

Scarring in the pelvic region around the urethra, around the vagina, is a big, big problem. Scar tissue, for anyone who

25 big problem. Scar tissue, for anyone who 33

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Plaintiffs' Opening Statement

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 2 has one knows this already, is dense. It's
 12:18PM
 3 not as elastic as other human tissue. The

4 organs in the human body, specifically the

5 pelvis, specifically a woman's pelvis, need

6 to be elastic. And this might be common

7 sense, but when women have sex, a penis is

12:19PM 8 inserted in the vagina, it needs to be able

9 to expand. When women drink a lot of water, I drank a big one just before I got

12:19PM **11** up, the bladder needs to be able to expand

12:19PM **12** to accommodate and then get smaller.

12:19PM 13 If you've got scarring and scar
12:19PM 14 plating and bridging fibrosis and a chronic
12:19PM 15 inflammatory reaction, those organs can't
12:19PM 16 be as elastic as they need to be. They
12:19PM 17 can't expand when they need to. They can't
12:19PM 18 shrink down when they need to. And that
12:19PM 19 creates pain, chronic pain.

Now, a natural part of scar tissue formation is that scars themselves actually contract. When scars form around this Prolene mesh, it actually contracts with the mesh as much as 30%, so it doesn't stay in the same form when you implant it in the

9 of 31 sheets Page 30 to 33 of 74 08/07/2017 08:40:19 PM

34 1 Plaintiffs' Opening Statement human body. Not only does that make the 2 12:20PM mesh more rigid, which we're going to talk 12:20PM 3 about in a minute, but it can also cause 12:20PM 5 pain. 12:20PM 6 The pelvis is an innervated region. You've got nerves all over down there. 12:20PM Again, this might be common sense, but you 12:20PM 8 have nerves so that you can enjoy sexual 9 12:20PM experiences, you have nerves that tell you 10 12:20PM when you have to take a bowel movement, you 11 12 have nerves that tell you when you have to 12:20PM urinate. They need to be there and they 12:20PM **13** need to be intact. This is the fourth 14 12:20PM defect in the product. 15 12:20PM The TVT and the TVT-S also don't 12:20PM 16 remain soft after implantation. And this 17 12:20PM is because of that inflammatory reaction I 18 told you about. This is because of the 12:20PM 19 scar tissue that I told you about. And 20 12:20PM **21** 

also the way they're cut affects them. As a result, the mesh can migrate out of place from where it's supposed to be into organs that it's not supposed to be in.

Erosion is a term you'll hear a lot.

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Plaintiffs' Opening Statement 1 It's when the mesh migrates out of place and makes its way into an organ where it's 3 not supposed to be, like the urethra or the bladder. This is the fifth defect with the 5 mesh. And you're going to hear that Ella 6 Ebaugh has had three erosions with five 7 perforations to her urethra. 8 Now, the holes that Ella had are very

10 small. The urethra itself is only four centimeters. So it's about the size of a pen cap. It's a very small organ. Urethra 12:21PM **12** -- I'm sorry, Ella has had three erosions, 13 14 five perforations. That means the mesh has 12:21PM poked a hole in Ella's urethra five times. 12:21PM **15** The perforations were small, probably only 16 12:21PM a few millimeters because the organ is only 17

12:21PM four centimeters, but it's not meant to 12:21PM 18

12:21PM 19 have holes poked into it.

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Like the mesh here, if we look at 12:21PM **20** 12:22PM **21** this, this is the inside of Ella's urethra.

12:22PM **22** And I know the clarity isn't great.

Perhaps you can see to the side there. 12:22PM 23

12:22PM **24** This blue stuff, that's mesh inside her

12:22PM **25** urethra all the way down to here. This

1 Plaintiffs' Opening Statement 2 picture was taken in 2012 by one of Ella's 3 physicians.

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The urethra is also not meant to have calcium deposits in it. You've probably 12·22PM

6 heard of kidney stones and know how painful 12:22PM 7 they can be. This was Ella's urethra. And 12:22PM

perhaps I can just pull this over a bit. I 8 12·22PM

think I've got a little cord on it. This 9 12:22PM 10 is Ella's urethra in 2015.

12:22PM **11** Can the jurors in the back see? I'm 12:22PM **12** sorry. Could you see?

12:22PM **13** A JUROR: Yes.

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12:22PM

MS. BALDWIN: So that's the inside of 12:22PM **14** Ella's urethra in 2015. You can't see as 12:22PM **15** much blue there because now we've got --12:22PM 16 12:22PM 17 and I'll do it up here -- we've got calcium deposits inside of her little urethra 12:22PM **18** 12:23PM 19 that's four centimeters long covering the mesh that eroded into it. That's a big 12:23PM **20** 12:23PM **21** problem.

12:23PM **22** Now, the TVT-S is designed to stay in 12:23PM **23** place with what are called felt tips, these

little white pads you see here. These felt 12:23PM **24** 

tips are actually just absorbable suture 12:23PM **25** 

Plaintiffs' Opening Statement material which wouldn't go away. But what

3 you're going to hear in just a few days is 12:23PM

that the TVT-S, they don't work. So this 12:23PM

5 thing doesn't stay in place as implanted 12:23PM

and this little piece of mesh migrates all 6

around and can get out of place and there's 12:23PM 12:23PM

8 a greater risk of erosion and that

happening with the TVT-S. 12:23PM

12:23PM 10 Now, this device here, the TVT-S, is also made of something called laser cut 12:23PM **11** 

12:23PM **12** mesh. When they make the mesh, they form

12:23PM **13** big sheets and have it cut into strips.

12:23PM 14 They use a laser. Something called LCM,

12:23PM 15 laser cut mesh. You're going to hear that

laser cut mesh is three times as rigid than 12:23PM 16

12:24PM **17** the other way they cut the mesh, mechanical

cut mesh, which means this little tiny 12:24PM 18

12:24PM 19 piece of tape that's not held in place with

12:24PM **20** those felt tips is three times as rigid

than their other product, making it more 12:24PM **21** 

12:24PM **22** likely it's going to erode into the urethra 12:24PM 23 and you're going to have that.

12:24PM **24** For mesh erosion mesh removal surgery has to be done because it creates all sorts 12:24PM 25

It doesn't have to be this way. There 11 12 are other ways to treat stress urinary 12:24PM incontinence. There are noninvasive 13 options like Kegel exercises. I'm sure 14 12:24PM some of the women have heard of those where 12:25PM **15** you just practice tensioning the muscles in 12:25PM 16 your pelvic. They can give you a plastic 12:25PM 17 12:25PM **18** device called Hef3 that you can insert and take out yourself if it becomes 19 problematic. You can use bulking agents 12:25PM **20** 12:25PM **21** that they can just inject in there to 12:25PM **22** support the urethra. 12:25PM **23** 

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If your stress urinary incontinence is really bothersome, there are other surgical

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Plaintiffs' Opening Statement 1 put this stuff on the market. One of them 2 is called the Burch procedure. The Burch 3 procedure is invasive. It's a surgery. It involves making an incision in the lower 5 pelvis and then using a few sutures to 6 stitch up the vagina so your whole organs 7 support that urethra. The big problem with 8 it, it might not work. And if it doesn't work, no long-term problems. If those few 10 sutures give you a problem, they can easily be taken out. You're not going to get this 12:25PM **12** from a Burch procedure. You're not going 13 14 to met a mangled urethra from a Burch

options available long before Ethicon ever

12:26PM **15** procedure. There's another surgery you can do. You can do what's called an MMK procedure. This is where surgeons go in and they use 18 12:26PM 19 slings, but not mesh slings, not synthetic substances. They can use animal tissues, 12:26PM **20** sometimes called a porcine graft. They can 12:26PM **22** use cadaver tissue, which means a dead body that's been donated, or they can even

12:26PM 23 12:26PM **24** harvest tissue from other parts of your 12:26PM **25** body, from the inside of your thigh or

Plaintiffs' Opening Statement somewhere on your abdomen using a natural

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The big risk with the MMK, it's a big one, it might not work. And if it doesn't work, there's no problem. There's

You won't get this from an MMK procedure.

that were available, Johnson & Johnson 12:26PM 11 12:26PM **12** launched the TVT on the market in 1996. 12:27PM **13** They bought the device for \$24 million, paid its inventors millions more after the 12:27PM 14 sale. They paid the inventor himself to 12:27PM 15 test the product for them and they 12:27PM 16 12:27PM 17 conditioned the payment on the results of 12:27PM 18 his study. They never bothered to verify the results to see if what he was reporting 12:27PM 19 was true. Why? \$24 million was a good 12:27PM **20** 12:27PM **21** investment. By 2004 the TVT was worth \$100

> profit. In the mid-2000s other medical device manufacturers started getting on the

million to the company. They had a 91%

12:27PM **25** 

Plaintiffs' Opening Statement market, started entry of the synthetic

3 slings, that went into the obturator tape, 12:27PM

a slightly different area. Johnson & 12:27PM

Johnson didn't want to lose its share of 5 12:27PM

the market, so they put out an obturator 6

tape. You'll hear a little about it, the 12·27PM

8 TVT-O. They wanted to protect their share 12:27PM

of that cash cow industry. Not my words, 12:27PM

12:27PM 10 their words. You're going to see that

that's what they call the stress urinary 12:27PM 11

12:28PM **12** incontinence field.

12:28PM **13** Renee Selman, the president of 12:28PM 14 Ethicon, was given presentations on how 12:28PM **15** Ethicon was losing its market share and they had to come out with a new sling 12:28PM 16 12:28PM **17** because they weren't first in the market 12:28PM 18 with that obturator sling. So that's when 12:28PM 19 they decided to come out with the TVT-S. It was created by Dan Smith, an engineer, 12:28PM 20 not a doctor, and it was a single-incision 12:28PM **21** 

12:28PM **22** sling, as I told you earlier. The TVT-S was not effective, 12:28PM 23 12:28PM 24 unreasonably dangerous, barely looked at in humans before it was launched on the 12:28PM 25

42 44 Plaintiffs' Opening Statement Plaintiffs' Opening Statement 1 1 market, but they did it anyway. Why? referring to their TVT-S validation studies 2 2 12:30PM 12:28PM You're going to see company documents that as a big steaming pile of dot dot dot. 3 12:28PM 3 12:30PM You'll see the TVT-S referred to as a they thought it was quote, priceless, to 12:28PM get it on the market before their 5 failed product. 12·28PM 12:30PM competitors. 6 You'll see the data for the TVT-S 6 12:31PM Now, you'll hear a lot in this case 7 described as, quote, pretty awful. 12:31PM 12:28PM You'll see Power Points describe the about the types of studies you can do on 12:28PM 8 12:31PM things. The most robust study you can do launch without one year results as a risky 9 12:28PM is called a Randomized Controlled Trial. I 12:31PM 10 situation. 10 12:28PM shortened it to RCT. RCT looks at two 12:31PM **11** You'll see company employees saying 11 the world was overdue for a status check on 12 treatment methods to see which is better 12:31PM **12** 12:28PM and how safe they are. Ethicon was paying 12:31PM 13 the TVT-S, including the good, the bad, and 13 doctors millions to support its products. the ugly. 12:31PM 14 14 12:29PM These doctors they paid were called key 12:31PM **15** Ella just got up and I was going to 15 12:29PM opinion leaders. Ethicon had two key say this later, but I'll say it now. She 16 12:31PM 16 12·29PM opinion leaders tell it do an RCT on the 12:31PM 17 has to use the bathroom sometimes, so 17 12-29PM TVT-S before you put it on the market. please forgive her if you see her get up. 18 12:31PM 18 They didn't do one. Why? There's why. Good, bad, and ugly, we'll get back to 12:29PM 19 12:31PM 19 Budget constraints. \$72 billion and they this. You'll see Ethicon employees refer 12:31PM **20** 20 to the TVT-S as dead and weak. 12:29PM **21** had budget constraints. So they couldn't 12:31PM **21** 12:29PM **22** test the product in humans before they put 12:31PM **22** Now, when studies were done on their 23 it on the market. 12:31PM **23** products, they had input on that as well. 12:29PM The rest of this slide is interesting, I don't have time to put all the documents 12:29PM **24** 12:31PM **24** but we don't have time to go through it. up now, but let's just go through what they 12:29PM **25** 12:31PM **25** 43 45 Plaintiffs' Opening Statement Plaintiffs' Opening Statement 1 1 We'll do it later. said when they got data about their 2 12:31PM 12·29PM Instead of doing a RCT, they collected products that they didn't like. I'm using 3 12:31PM five weeks of data on 31 women. Now five their words again. One, they said, "How 12:31PM 12:29PM weeks is a short time. Many women haven't can we jazz it up?" Jazzing up scientific 5 5 12:32PM 12:29PM even gone back to an active lifestyle after 6 data. 6 12:29PM Two, "How can we spin it?" 7 getting an implant. The results were never 7 12:32PM 12·29PM published. They didn't share them with the 8 Three, "Let's probe the results." 12:32PM medical community. Why? Sixty percent Four, "Let's," quote, "tell doctors 12:29PM 12:32PM 10

complications at five weeks. Thirty percent of women it had failed within five weeks. They got this information just before they put it on the market and they launched it anyway.

For six years they got nothing but bad information about the product, didn't take it off the market. Some of the stuff you're going to see. In November of 2006 the top executive at Ethicon in Germany sent an e-mail to Axel Arnaud, U.S. medical director in the company, that literally said, let me get this right, "The more procedures," referring to the TVT-S

You'll see internal Ethicon documents

implant, "The more problems."

12:32PM **10** which complications they should report."

In 2007 one of their key opinion 11 12:32PM 12:32PM **12** leaders, the people they made millions of 12:32PM **13** dollars to support their products and teach 12:32PM 14 other doctors how to use them, had very 12:32PM **15** poor efficacy results with the TVT-S. He just couldn't get it to work. Ethicon 12:32PM 16 12:32PM 17 employees discussed an internal e-mail 12:32PM 18 whether they should review what patient 12:32PM 19 report results to report and they weren't going to report all the complications, 12:32PM **20** well, maybe they should just stop and not 12:32PM **21** 

12:32PM **22** publish the data. Now, a lot of what I just talked to 12:32PM 23 12:32PM 24 you is going to be shown through deposition testimony. Bear with me. You're going to 12:32PM 25

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46 48 Plaintiffs' Opening Statement 1 Plaintiffs' Opening Statement 1 have to watch it on a TV. I can't bring 2 done called a Hota Study, it was stopped 2 12:34PM 12:32PM these Ethicon folks in here and I don't early because of lower success rates than 12:33PM 3 12:34PM think they're going to bring anybody from anticipated, had a 50% failure rate and a 4 12:33PM Ethicon either. So please bear with me. 19% complication rate. 12:34PM 12:33PM Pay attention. It's just as important as 12:35PM 6 Most appalling of all of this, when a though it's live witnesses. We took their 7 woman suffered a complication and her 12:35PM 12:33PM implant didn't work, the recommendation was depositions under oath. They swore to tell 12:33PM 8 12:35PM the truth, just as important. put in another mesh, put in another implant 9 12:33PM Some other stuff you'll see. You'll 12:35PM 10 right on top of the one you got. So you 12:33PM see an internal e-mail from Dan Smith, the 12:35PM **11** got two slings, twice the mesh, twice the 11 gentleman who created the TVT-S, full with 12 12:35PM **12** scar plating, twice the inflammation, twice 12:33PM information about the TVT-S. The first 12:35PM **13** the risk of erosion, but Johnson & Johnson 13 words of the e-mail, "Do not forward, gets twice the sales. 12:35PM 14 14 please delete." Now, there are plenty of surgeons who 12:33PM 15 12:35PM 15 just won't use transvaginal mesh. They So what are they trying to hide? 12:33PM 16 12:35PM 16 Well, the TVT-S was pulled from the market 12:35PM 17 think it's dangerous, especially because 17 12:33PM in Australia in 2006 by their medical there are other treatment options that are 18 12:35PM 18 director there due to concerns of efficacy. 12:35PM 19 out there. 12:33PM 19 They continue to launch it in the U.S. and 20 12:35PM **20** Now, in this courtroom you're going to 12:33PM **21** sell it here without ever sending letters 12:35PM **21** hear Johnson & Johnson in a few minutes get 12:33PM **22** to doctors that they had this huge problem 12:35PM **22** up here and say it's the gold standard, 23 in Australia. 12:35PM **23** this product was the gold standard. Sure, One of their key opinion leaders, among doctors that use mesh it is the gold 12:33PM **24** 12:35PM **24** Professor Flam, told defendants very early 12:35PM **25** standard. Why? One, it's a simple 12:33PM **25** 47 49 Plaintiffs' Opening Statement Plaintiffs' Opening Statement 1 1 on that the TVT-S had defects and that he procedure, it only take 20 minutes. 12:35PM 12:33PM wouldn't demonstrate it or promote it until 3 If you want to do a Burch or an MMK, 12:35PM they addressed those defects. They never you need to be a skilled surgeon. So 12:35PM 12:34PM changed the design. Johnson & Johnson found a way that OB/GYNs 5 5 12:36PM 12:34PM Dr. Vincent Lucente is one of their could not refer out their patients that 6 12:34PM 7 key opinion leaders, he trained Ella's needed surgeries, they can do it 12:36PM 12:34PM implanter, was paid over \$2 million by the 8 themselves. It's all about the money. 12:36PM company, has horrible failure rates with Dr. Douglass, Ella's implanter, said, 12:34PM 12:36PM the device, 60% failure rates. In the 12:36PM 10 "Yeah, I like the TVT, I like to do it in 10 words of the company they were very outpatient centers because that way I could 12:36PM **11** 12:34PM 12 concerning. They never published this 12:36PM **12** put more products in in one day." data. 12:36PM 13 And Ethicon and Johnson & Johnson also 13 12:34PM **14** The defendants knew doctors were 12:36PM 14 paid a lot of money promoting its products. struggling on how to put it in properly, so 12:36PM **15** They had an \$800 million prelaunch 15 they came up with what's called cookbook. marketing budget for the TVT-S. It fought 16 12:36PM 16 17 They circulated that to doctors. The 12:36PM **17** hard against naysayers with its money. 12:34PM failure rates never got any better. The 12:36PM **18** In addition to paying key opinion 18 19 product is so dangerous, there's no fixing 12:36PM 19 leaders and doing its marketing, they would 12:34PM sponsor industry events. AUGS is the 20 12:36PM 20 12:34PM **21** By August of 2007 the key opinion American Urogynecologic Society, SUFU, 12:36PM **21** leaders who told them to do the randomized 12:36PM **22** 12:34PM **22** Society of Urodynamics, Female Pelvic controlled trials said we won't support the Medicine, and Urogenital Reconstruction. 12:36PM 23 12:34PM 23 12:34PM **24** product. When they finally did a 12:36PM **24** In 2014 they issued a position statement in randomized controlled trial, and one was support of these kind of products 12:34PM **25** 12:36PM 25 13 of 31 sheets Page 46 to 49 of 74 08/07/2017 08:40:19 PM

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Plaintiffs' Opening Statement midurethral slings.

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You're going to hear from Charles Nager. He was the president of AUGS and a member of the task force that wrote this statement. He had a relationship with mesh manufacturers. He was paid by mesh manufacturers. In the notes from the first meeting of this task force where they wrote this statement, they said we want our members to use this position statement at legal proceedings, like this. Guess who can joined AUGS? Medical device manufacturers. Guess who was a member? Ethicon. Guess who is going to stand up and show you that AUG statement? Ethicon and Johnson & Johnson.

You're going to hear Ethicon's lawyers say we didn't have to do an RCT, we could rely -- RCT on the TVT-S, that study I told you about, because we could rely on the data of the TVT, it had been on the market for a very long time. The TVT-S was, in Ethicon's own words, a revolution. It was a shorter mesh life. The felt tips were

Plaintiffs' Opening Statement different. The arrowhead introducer was different. It was laser cut mesh.

Their own internal people recognized they couldn't rely on the TVT data. And 5 you're going to hear about how biased that 6 TVT data is about them paying for the results and then never bothering to verify 9 them.

You'll see Ethicon recognized the mistakes it made with the TVT-S. Their slide, not my words, Ethicon is guilty of two cardinal sins, a rush to market in the absence of sound data, TVT-Secur.

What they did was wrong. The bottom line is that TVT and TVT-S are defective. 16 They didn't meet the expectations of Ella or her doctor. Dr. Douglass testified in 12:38PM 19 deposition, again he's going to be on video, saying I love the TVT, I used it all 20 the time, it was great. I knew there were risks. I knew there was a risk of erosion.

12:38PM **22** There's a risk of erosion for all 12:38PM **23** 

12:38PM **24** surgically implanted materials. I knew you

could have urinary retention, bladder 12:39PM **25** 

Plaintiffs' Opening Statement

spasm, urgency, infection, bleeding, and it

might not work. I told all that to Ella, 3 12:39PM

no problem, show you the consent form. But 4

he testified he thought the risks were 12:39PM

6 exceedingly low, it almost never happened, 12:39PM

7 and if those problems developed, that 12:39PM

they'd be easily treatable. That's why he 8 12:39PM

was putting it in women. 9

12:39PM 10 Now, he retired in 2011. He wasn't 12:39PM **11** around long enough to follow up with all of 12:39PM **12** his patients to know the true harm that it 12:39PM **13** was doing to women like Ella Ebaugh. He had no idea that her urethra was mangled 12:39PM **14** 12:39PM **15** and all the urinary problems she had. He stopped practicing. He was not aware of 12:39PM 16 12:39PM 17 and did not warn her of the serious nature, the frequency, severity, and permanency of 12:39PM 18 12:39PM **19** the true risks. He couldn't tell her. She never knew about them because Ethicon 12:39PM **20** 

12:39PM 21 didn't let it out. 12:39PM **22** Dr. Douglass testified he relied on 12:39PM **23** his own training, his colleagues, and the 12:39PM **24** literature that was out there in the field.

12:39PM **25** But he never got any letters from Ethicon,

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Plaintiffs' Opening Statement 1

which they could do, dear doctor letters 12·40PM 3 saying, hey, we pulled it from the market 12:40PM

in Australia; hey, we're seeing higher 12:40PM

erosion rates in women; hey, you might want 5 12:40PM

to be careful. Nothing. No communications 6

7 from the company. 12:40PM

8 There were no long-term studies on the 12:40PM TVT-S when Ella had it implanted in May of 12:40PM 12:40PM **10** 2007. When the defense lawyers get up here and they put up studies about problems with 12:40PM **11** 

12:40PM **12** mesh to suggest that Ella should have

12:40PM 13 known, look at what year they were

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published and what they were really

12:40PM **15** studying. Were they studying the products

at issue in this case? Was the information 12:40PM 16

12:40PM 17 really available to Dr. Douglass? Did

12:40PM **18** Ethicon have a say in jazzing up the data?

12:40PM 19 The risks of the TVT-S and TVT far 12:40PM **20** outweighed the benefits. They're not minimal and they're not temporary. They're 12:40PM **21** 12:40PM **22** 

severe, frequent, and permanent. 12:40PM **23** Plaintiffs also have a negligent 12:40PM **24** design claim. Quite simply, a medical

device manufacturer must act in a 12:40PM 25

reasonably careful manner to avoid injuring
others. Ethicon and Johnson & Johnson
didn't do that.

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Defense counsel speaks after me and I'm really sure they're going to address almost none of this about their products or any of these internal documents. I'm probably the only one who is going to show them to you. They're going to focus on Ella and Ella's life.

Ella has had a tough life. She's had some problems. But we're not here because of her problems. We're here because of her mangled urethra and her permanent urinary dysfunction and her pain.

A little bit about Ella. And I'm just looking at the clock, so if you see me turn my head at all, don't think I'm ignoring you.

Ella is 51 years old. She's married to her husband Marvin since December of 2012. They live in, Manchester, which is just outside of York. She has four children from her first marriage, Jamie

Plaintiffs' Opening Statement

Joseph, Jennifer, and Jacob. Jacob is in high school, still lives at home with them.

Marvin has two children from his first marriage. His daughter Sarah lives at home with them. So there's a family of four in

7 the house right now.

Ella is a proud, proud grandmother.

She has four grandchildren and a little

10 boy -- am I getting that right -- a little

1 boy grandchild on the way, so soon to be

12:42PM **12** five grandchildren. The things she enjoys

2PM 13 most in life is spending time with her

12.42PM 14 family. She babysits her grandchildren

15 when she can.

Every Sunday her mom makes dinner and her whole family, all her siblings come.

She's got nine siblings. Big family dinner

12:42PM **19** every Sunday night, she tries to get there.

She used to be an avid athlete, played

12:42PM **21** a lot of sports. She's had some hip 12:42PM **22** issues. She can't do that anymore, but she

22 issues. She can't do that anymore, but she

12:42PM **23** likes to go to her son Jacob's baseball and football games.

12:42PM **24** football games. 12:42PM **25** She had a

She had a history of urinary problems.

She started getting urinary tract
 infections when she first started having
 sex. She's had them through the years.
 That's not why we're here.

Pre-implant she had urgency issues.

When she felt like she had to go to the
bathroom, she had to go quick. She would
get up one to two times a night to go to
the bathroom. That's called nocturia.

12-43PM 11 In 2005 she was diagnosed with urethral stenosis, a constriction of the urethra. Her doctor dilated it. No evidence it's ever been a problem after.

And she's also had stress urinary 12:43PM 15 incontinence. Couple drops here and there 12:43PM 16 12:43PM 17 after she had kids. Got worse as she was playing softball. She would be sliding 12:43PM 18 into base and losing a lot more than a 12:43PM 19 couple drop. Started wearing a maxi pad 12:43PM **20** all the time. And that's why she went to 12:43PM 21 12:43PM **22** see Dr. Douglass to talk about treatment 12:43PM **23** options for it.

When she went to see Dr. Douglass in 2005 her primary complaint was having to

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Plaintiffs' Opening Statement wear that maxi pad all the time.

12.43PM **3** In 2005 she actually scheduled a TVT-O implant surgery, but didn't get it. Her

5 daughter was in a Junior Miss, a little

6 beauty pageant, she wanted to focus on her

7 daughter. Her stress urinary incontinence

8 was so minimal that she didn't need to get

12:43PM **9** surgery right away.

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In 2007 a new product was on the market, the TVT-S, and Dr. Douglass said let's do the new one. She agreed to have her implant May 31st, 2007. Two weeks after the implant Ella told her doctor it didn't work. July 12th, 2007, he puts in the TVT.

She had some urinary tract infections in '08, not unusual for her.

In 2009 she started to get more complaints of frequency, meaning she has to go to the bathroom more than normal.

Another UTI, not unusual for her.

But in 2011 things got markedly worse.

She started getting urgency much worse and nocturia frequency and a pain and a burning

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But in 2011 things got markedly worse.

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58 1 Plaintiffs' Opening Statement 1 2 region in her pelvis. She was sent to a 2 12:46PM 12:44PM urologist and he had to do a cystoscopy. 12:44PM 3 12·46PM This is not a pleasant procedure. You take a tube with a camera and insert it into he could. 12·46PM 12·44PM vour urethra to look up into it. Dr. 6 12:46PM Shrine did it and he saw that mesh had 12:46PM 12:44PM eroded into her urethra. He didn't do mesh 12:44PM 12:46PM surgery, so he sent her to someone else, 10 Dr. Mirsky. 12:46PM 10 12:44PM

Dr. Mirsky did another cystoscopy 11 12 putting a camera into her urethra. He saw the mesh had eroded right through the 13 urethra, and I'm quoting his words, it 12:45PM 14 looked like the sling was a gate 15 12:45PM obstructing urethra.

16 12·45PM 17 Dr. Mirsky did a mesh removal June 12:45PM 18 14th, 2011, very simple mesh removal, the kind of thing she had been warned about. 19 12:45PM

Another cystoscopy, snip the mesh out, left 20 the sling in place to treat her SUI, her 12:45PM 21

22 stress urinary incontinence. He did see

12:45PM **23** that the mesh had perforated, though, poked

holes in two places in her urethra, so he 12:45PM **24** 

tried to fix those. 12:45PM **25** 

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Plaintiffs' Opening Statement

She got better. She thought things were on the up and up, but then after a few months the problems came back. He did another cystoscopy and saw more mesh in her urethra. The mesh had created what he called a large, almost false passage. He thought she might need all of the mesh taken out, so he sent her to see Dr. Chai

at the University of Maryland. 10 Dr. Chai did another cystoscopy, saw 11 the mesh. She had to have six of these cystoscopies since she got her mesh 13 14 implanted, never had one prior. He saw the 12:46PM **15** mesh in her urethra and on top of her bladder. So this, as I said, is a serious 16 operation. He made an abdominal incision. 17 He told Ella he was cutting her open from 12:46PM 18 12:46PM 19 hip to hip. He dissected the tissue all the way around the bladder. He couldn't 12:46PM **20** 12:46PM **21** find the mesh on the bladder. He thinks

that perhaps it migrated when he did the

dissection, meaning cutting all the tissue

He went in vaginally, made another

Plaintiffs' Opening Statement incision vaginally, sliced up into those tunnels that were cut for the TVT and the TVT-S, and got out as much of the mesh as

The problems got a little better, but then they came back with a vengeance.

Frequency, pain with urination,

incontinence. A cystoscopy in August shows

that there was still a little bit of a mesh 12:46PM **11** on the one side. But he didn't want to

take it out because of the risk of the 12:46PM **12** 

12:46PM **13** procedure at this point. Ella was scared.

She didn't really want to undergo another 12:46PM **14** 

12:46PM **15** surgery.

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But things kept getting worse. She 12:46PM 16 started losing the full contents of her bladder with little provocation. She was in pain all the time. She was in pain when she had sex. She had trouble emptying her bladder at times, a condition known as 12:47PM **22** urinary retention.

12:47PM **23** 2015 she saw another doctor, Dr. 12:47PM **24** Drolet. She did another cystoscopy, saw a

mesh in the urethra and diagnosed Ella with 12:47PM **25** 

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1 Plaintiffs' Opening Statement urgency and cystitis. Cystitis is an 3 inflammation of the bladder.

Ella went to see another specialist, 12:47PM this time at Johns Hopkins, and he 5 12:47PM performed her third mesh removal surgery.

This is in 2016. He removed the mesh as 12·47PM 8 best as he could and tried to fix the 12:47PM

urethra, but it's very, very scarred. 12:47PM

12:47PM **10** You're going to hear it's mangled.

After the surgery the mesh was sent 12:47PM **11** 12:47PM **12** down to a pathology lab. They looked at 12:47PM 13 it. They saw fibrous tissue, that's that scar tissue, and a giant cell reaction. 12:47PM **14** 

12:47PM **15** Her body is still fighting the mesh.

Today Ella's urethra is mangled. It 12:47PM **17** covers in scar tissue distally near the 12:48PM **18** opening and in the middle. In one place the scar tissue has propped the urethra 12:48PM 19 12:48PM **20** open like this, which is why she has almost no control. 12:48PM **21** 

She no longer has stress urinary incontinence. She has something now called Intrinsic Sphincter Deficiency. She's got uncontrolled spasms of the bladder. She

away from the bladder.

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Plaintiffs' Opening Statement 1 can't control the muscles down there. She 2 12:48PM wakes up in the middle of the night four to 12:48PM 3 five times. She keeps a commode next to her bed so that she can hopefully make it 12·48PM in time. It's still possible for her to get a good night's sleep and a lot of 12:48PM nights she still can't make it in time and 12:48PM 8 she ends up sleeping on wet towels because 12:48PM she's too tired to change all the sheets. 10 12:48PM 11

Her husband's got to live with all of this and try to get a good night's sleep as best he can. When she does feel the urge, she gets up quickly and tries to make it. That's often not good enough.

Everywhere she goes she's got a bag with spare clothes in it. She wears nighttime Poise pads everywhere she goes in the event she can't get there in time.

She's in pain, constant pain in her pelvis, pain with the bladder filling, pain with sex. The pain is so bad, she and her husband almost never are intimate with each other anymore.

She still goes to her son's baseball

Plaintiffs' Opening Statement games, but she has to plan her route so she can sit near a bathroom. Otherwise she can't go.

Everything she does has limit. She's literally chained to a toilet, will be for the rest of her life, all because of these defective devices.

In a few minutes defense counsel is going to get up. They're going to say she didn't file a lawsuit on time.

12:49PM 12 Pennsylvania had two years from the date you knew or should have known your injury

14 was caused by another's conduct. Dr.

12-49PM **15** Douglass thought the risk of erosion was

12-49PM **16** rare. He thought all the risks were rare.

17 He thought the mesh was safe, and he's

12-49PM 18 going to tell you that in his deposition;

12:49PM **19** as are all of our other doctors, we thought the mesh was fine.

She had no idea everything I just told you about the problems with the mesh

12.49PM **23** because Ethicon didn't warn anybody.

24 Ethicon influenced the literature that was12.49PM 25 out there. Ethicon never sent letters out

Plaintiffs' Opening Statement to doctors. Ethicon never sent letters out to patients about all the things it knew.

Defendants are going to get up here

and say Ella's problems were there before 12:50PM the mesh and now that the mesh has been 12:50PM removed, it can't be the mesh. Come on. 12:50PM Nothing else mangled her urethra other than 12:50PM the mesh. There's no evidence of her 9 12:50PM 10 having a scarred mangled urethra that was 12:50PM **11** propped open like a train tunnel until she got the mesh. 12:50PM **12** 

She had preexisting problems, I told you about it. They were minimal, so minimal she put off her surgery for almost two years before she decided to have one. But she did have some issues. They're not why we're here.

She has a life-altering injury. She loses the entire contents of her bladder with seconds' warning.

When they get up here and talk about warnings, think about all the things that Ella has that she wasn't warned about,

12:51PM **25** chronic intrinsic sphincter deficiency,

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Plaintiffs' Opening Statement
urethral stones, calcium deposits in her
urethra, permanent deformation of her
urethra. By the way, her urethra is not
straight anymore. It's kind of bent and
crocked because of all the scar tissue too.
She can't aim her urine and often will

7 She can't aim her urine and often wi urinate on the wall behind her.

9 She's had urethral diverticulum,
12.51PM 10 outpouchings of the urethra, and cystitis,
12.51PM 11 an inflammation of her bladder. Three
12.51PM 12 erosions, five perforations, all because of the mesh.

12:51PM **14** Their expert found something called 12:51PM **15** levator muscle spasm. It's when the pelvic floor muscles spasm. She never had this 12:51PM 16 12:51PM 17 before she got her mesh. She may have it 12:51PM **18** now. Our expert couldn't find it in her. Levator muscle spasms comes from injury of 12:51PM 19 12:51PM **20** the pelvis. Sure she's had injury. She's had five surgeries in her pelvis because of 12:51PM **21** 12:51PM **22** this mesh. She's had five perforations of her urethra, three erosions, and doctors 12:51PM 23

literally dissecting the tissue around

every organ in her vagina and her bladder

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Plaintiffs' Opening Statement trying to get the mesh out.

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Interestingly, their expert -- we have to consent they're allowed to do a medical exam of Ella -- didn't even bother to do a cystoscopy to take a peek at her urethra. You can't find scarring of the problems

that you're not looking for. The defendant is going to say she has chronic pain, fibromyalgia. She never had that before and fibromyalgia does not cause pain specifically in one region of the body.

12:52PM **13** They're going to blame all the 12:52PM **14** problems on everything else she's had. 12:52PM **15** Ella's had a hip implant. It was recalled. 16 She had to get a replacement hip. That hip 17 implant was excruciating before she got it 12:52PM 18 out. She testified previously it ruined 12:52PM 19 her life. That pain has since gone away. 20 She's rehabbed. She has pain in her hip

12:52PM **21** 12:52PM **22** and it runs down the front of her leg.

23 That has nothing to do with the pain in her 12:52PM **24** 

pelvis from the mesh. She can make

12:52PM **25** accommodations for that.

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In her life Ella has had some stuff happened. She divorced her first husband. They're a blended family. They have stepkids. They got in a fight before. She's had fibroid problems. She's a little overweight. She has arthritis. She has problems with her knee and her Achilles

Plaintiffs' Opening Statement

tendon. None of this is why we're all here. They're going to want to talk all 10 about it. 11

What she wants is a normal life now. When she had her hip problem, she could make accommodations. Instead of taking walks, they could ride bikes. They could do things together. They could get out of the house. She's a prisoner in her house or very close to it. She has to go where there's a bathroom within feet at all the

12:53PM **20** time. 12:53PM **21** They used to go walk around festivals, they can't do that, like a local apple 12:53PM **22** picking festival, because there's no 12:53PM 23 12:53PM **24** Porter-Potty and it's impossible for her to get changed in a Porter-Potty or to get 12:53PM **25** 

Plaintiffs' Opening Statement everyone else out of the line when you're waiting for a Porter-Potty.

She would really like her husband Marvin just to be able to drive her places. 12:53PM Right now she has to drive for fear that 12:53PM someone else won't pull over in time. She 12:53PM needs control because she's so scared she's 12:53PM going to lose the contents of her bladder 12:53PM 10 in the car.

12:53PM **11** She goes to her mom's house on 12:54PM **12** Sundays. It's fun, but it's also 12:54PM **13** mortifying. Her mom went out and bought her a special chair that has a special pad 12:54PM **14** 12:54PM **15** that she can unzip and wash because everyone in her family, all of her nine 12:54PM 16 siblings, know that Ella wets her chair 12:54PM 17 almost every week. 12:54PM **18** 

She wants to live her life not having 12:54PM 19 to wear adult diapers and looking for a 12:54PM **20** bathroom. She's 51 years old. She wants 12:54PM 21 12:54PM **22** to be normal, and she can't because of the 12:54PM **23** TVT-S and the TVT.

Real guickly. I'm going to bring you 12:54PM **24** two experts who are going to talk about the 12:54PM **25** 

Plaintiffs' Opening Statement 1 problems. One, Bruce Rosenzweig from

Chicago, urogynecologist. He used mesh for 12:54PM

many years. Stopped using it. He was 12:54PM

trained by Ethicon because he saw problems 5 12:54PM with his own patients. He's going to go

through all those details. He'll tell you 12:54PM

the risks are exceptionally high. His 12:54PM

testimony is long. Bear with me. They're 12:54PM

12:54PM **10** on video.

12:54PM

He went through all of those Ethicon 12:54PM **11** 12:54PM **12** documents. He spent a lot of time and he's 12:55PM **13** going to show you all about them. They're 12:55PM **14** not going to ask him one question about 12:55PM **15** those company documents, about jazzing, or spinning up, or hiding the data. 12:55PM 16

12:55PM 17 I'll bring you Dr. Tom Margolis, he's 12:55PM **18** from California, urogynecologist. He did a 12:55PM 19 cystoscopy when he saw Ella. He saw her once, he gave me a call, he said I need to 12:55PM **20** take a look at her urethra, we sent her 12:55PM **22** back, he looked, it's mangled. He'll explain to you all the problems that she's 12:55PM 23 12:55PM **24** got.

12:55PM 25 Defendants are going to cite to the

12:55PM **21** 

	70		72
1	Plaintiffs' Opening Statement	1	Plaintiffs' Opening Statement
12:55PM <b>2</b>	physician statements and the literature.	12:57PM <b>2</b>	say.
12:55PM <b>3</b>	Don't forget about bias. Don't forget	12:57PM <b>3</b>	At the end of the case I'm going to
12:55PM <b>4</b>	about who is issuing these statements.	12:57PM <b>4</b>	ask you to make a monetary award to fairly
12:55PM <b>5</b>	Don't forget about Johnson & Johnson	12:57PM <b>5</b>	compensate Ella and Marvin for the injuries
12:55PM <b>6</b>	spinning and jazzing and probing.	12:57PM <b>6</b>	they've suffered and I'm going to ask you
12:55PM <b>7</b>	When they brag about the years of data	12:57PM <b>7</b>	to make an award for punitive damages, to
12:55PM <b>8</b>	they have, think about where it's coming	12:57PM <b>8</b>	punish these companies for their reckless
12:55PM <b>9</b>	from and whether it's reliable or whether	12:57PM <b>9</b>	conduct that permanently disabled my client
12:55PM <b>10</b>	they should have verified the results. And	12:57PM <b>10</b>	Ella Ebaugh.
12:55PM <b>11</b>	ask yourself if they address any of this.	12:57PM <b>11</b>	Thank you very much.
12:55PM <b>12</b>	As the evidence comes in, think of all	12:57PM <b>12</b>	THE COURT: All right. Thank you,
12:55PM <b>13</b>	of Johnson & Johnson and Ethicon's	12:57PM <b>13</b>	counsel.
12:55PM <b>14</b>	motivation for everything they did with the	12:57PM <b>14</b>	Members of the jury, we're going to
12:55PM <b>15</b>	TVT and the TVT-S, their cash cow products,	12:57PM <b>15</b>	take a lunch break. Please remember not to
12:56PM <b>16</b>	their motivation for paying 24 million in	12:58PM <b>16</b>	discuss the case with anyone. We'll ask
12:56PM <b>17</b>	the first place when there were other	12:58PM <b>17</b>	you to be back in the jury room at 2
12:56PM <b>18</b>	treatment options out there; their	12:58PM <b>18</b>	o'clock.
12:56PM <b>19</b>	motivation for being a corporate member of	12:58PM <b>19</b>	THE LAW CLERK: Please stand as the
12:56PM <b>20</b>	AUGS; their motivation for paying key	12:58PM <b>20</b>	jury exits the courtroom.
12:56PM <b>21</b>	opinion leaders millions of dollars; their	12:58PM <b>21</b>	(Jury leaves courtroom)
12:56PM <b>22</b>	motivation for launching a product on the	12:58PM <b>22</b>	THE COURT: All right. We'll see
12:56PM <b>23</b>	market having only tested it in 31 women	12:58PM <b>23</b>	everyone at 2:00.
12:56PM <b>24</b>	for five weeks when they budgeted \$800	12:58PM <b>24</b>	(Luncheon recess)
12:56PM <b>25</b>	million for prelaunch marketing on that	25	
	71		70
	71 Plaintiffs' Opening Statement	4	73
1	Plaintiffs' Opening Statement	1	
12:56PM <b>2</b>	Plaintiffs' Opening Statement same product; their motivation for not	2	(Afternoon session reported by Sharon
12:56PM <b>2</b>	Plaintiffs' Opening Statement same product; their motivation for not using Ultrapro or even trying other	_	
12:56PM <b>2</b>	Plaintiffs' Opening Statement same product; their motivation for not using Ultrapro or even trying other formulations for mesh and TVT line of	2 3 4	(Afternoon session reported by Sharon
12:56PM 2 12:56PM 3 12:56PM 4 5	Plaintiffs' Opening Statement same product; their motivation for not using Ultrapro or even trying other formulations for mesh and TVT line of products if they tried a different	2	(Afternoon session reported by Sharon
12:56PM <b>2</b>	Plaintiffs' Opening Statement same product; their motivation for not using Ultrapro or even trying other formulations for mesh and TVT line of products if they tried a different method, there would have to be more	2 3 4 5	(Afternoon session reported by Sharon
12:56PM 2 12:56PM 3 12:56PM 4 5	Plaintiffs' Opening Statement same product; their motivation for not using Ultrapro or even trying other formulations for mesh and TVT line of products if they tried a different method, there would have to be more tests the motivation for keeping this	2 3 4 5 6	(Afternoon session reported by Sharon
12:56PM 2 12:56PM 3 12:56PM 4 5 6 12:56PM 7	Plaintiffs' Opening Statement same product; their motivation for not using Ultrapro or even trying other formulations for mesh and TVT line of products if they tried a different method, there would have to be more tests the motivation for keeping this thing on the market for six years when they	2 3 4 5 6 7	(Afternoon session reported by Sharon
12:56PM 2 12:56PM 3 12:56PM 4 5 6 12:56PM 7 12:56PM 8	Plaintiffs' Opening Statement same product; their motivation for not using Ultrapro or even trying other formulations for mesh and TVT line of products if they tried a different method, there would have to be more tests the motivation for keeping this	2 3 4 5 6 7 8	(Afternoon session reported by Sharon
12:56PM 2 12:56PM 3 12:56PM 4 5 6 12:56PM 7 12:56PM 8 12:56PM 9	Plaintiffs' Opening Statement same product; their motivation for not using Ultrapro or even trying other formulations for mesh and TVT line of products if they tried a different method, there would have to be more tests the motivation for keeping this thing on the market for six years when they knew it was a failed product in the face of	2 3 4 5 6 7 8 9	(Afternoon session reported by Sharon
12:56PM 2 12:56PM 3 12:56PM 4 5 6 12:56PM 7 12:56PM 8 12:56PM 9 12:56PM 10	Plaintiffs' Opening Statement same product; their motivation for not using Ultrapro or even trying other formulations for mesh and TVT line of products if they tried a different method, there would have to be more tests the motivation for keeping this thing on the market for six years when they knew it was a failed product in the face of horrific news about it; their motivation	2 3 4 5 6 7 8 9	(Afternoon session reported by Sharon
12:56PM 2 12:56PM 3 12:56PM 4 5 6 12:56PM 7 12:56PM 8 12:56PM 9 12:56PM 10 12:56PM 11	Plaintiffs' Opening Statement same product; their motivation for not using Ultrapro or even trying other formulations for mesh and TVT line of products if they tried a different method, there would have to be more tests the motivation for keeping this thing on the market for six years when they knew it was a failed product in the face of horrific news about it; their motivation for still selling that when this trial was	2 3 4 5 6 7 8 9 10	(Afternoon session reported by Sharon
12:56PM 2 12:56PM 3 12:56PM 4 5 6 12:56PM 7 12:56PM 8 12:56PM 9 12:56PM 10 12:56PM 11 12:56PM 12	Plaintiffs' Opening Statement same product; their motivation for not using Ultrapro or even trying other formulations for mesh and TVT line of products if they tried a different method, there would have to be more tests the motivation for keeping this thing on the market for six years when they knew it was a failed product in the face of horrific news about it; their motivation for still selling that when this trial was going on; the motivation for encouraging	2 3 4 5 6 7 8 9 10 11	(Afternoon session reported by Sharon
12:56PM 2 12:56PM 3 12:56PM 4 5 6 12:56PM 7 12:56PM 8 12:56PM 9 12:56PM 10 12:56PM 11 12:56PM 12	Plaintiffs' Opening Statement same product; their motivation for not using Ultrapro or even trying other formulations for mesh and TVT line of products if they tried a different method, there would have to be more tests the motivation for keeping this thing on the market for six years when they knew it was a failed product in the face of horrific news about it; their motivation for still selling that when this trial was going on; the motivation for encouraging TVT implants when TVT-S fails.	2 3 4 5 6 7 8 9 10 11 12	(Afternoon session reported by Sharon
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12:56PM 2 12:56PM 3 12:56PM 4 5 6 12:56PM 7 12:56PM 8 12:56PM 10 12:56PM 11 12:56PM 12 12:56PM 12 12:57PM 14 12:57PM 15 12:57PM 16 12:57PM 17	Plaintiffs' Opening Statement same product; their motivation for not using Ultrapro or even trying other formulations for mesh and TVT line of products if they tried a different method, there would have to be more tests the motivation for keeping this thing on the market for six years when they knew it was a failed product in the face of horrific news about it; their motivation for still selling that when this trial was going on; the motivation for encouraging TVT implants when TVT-S fails.  I just want to say thank you all for being here. I really do appreciate it. It's a Friday on a hot August day. I know you all probably want to be somewhere else.	2 3 4 5 6 7 8 9 10 11 12 13 14	(Afternoon session reported by Sharon
12:56PM 2 12:56PM 4 5 6 12:56PM 7 12:56PM 8 12:56PM 10 12:56PM 10 12:56PM 11 12:56PM 12 12:56PM 13 12:57PM 15 12:57PM 16	Plaintiffs' Opening Statement same product; their motivation for not using Ultrapro or even trying other formulations for mesh and TVT line of products if they tried a different method, there would have to be more tests the motivation for keeping this thing on the market for six years when they knew it was a failed product in the face of horrific news about it; their motivation for still selling that when this trial was going on; the motivation for encouraging TVT implants when TVT-S fails.  I just want to say thank you all for being here. I really do appreciate it. It's a Friday on a hot August day. I know you all probably want to be somewhere else. I wish I wasn't working. But jury service	2 3 4 5 6 7 8 9 10 11 12 13 14 15	(Afternoon session reported by Sharon
12:56PM 2 12:56PM 3 12:56PM 4 5 6 12:56PM 7 12:56PM 8 12:56PM 10 12:56PM 11 12:56PM 12 12:56PM 15 12:57PM 15 12:57PM 16 12:57PM 17 12:57PM 18 12:57PM 19	Plaintiffs' Opening Statement same product; their motivation for not using Ultrapro or even trying other formulations for mesh and TVT line of products if they tried a different method, there would have to be more tests the motivation for keeping this thing on the market for six years when they knew it was a failed product in the face of horrific news about it; their motivation for still selling that when this trial was going on; the motivation for encouraging TVT implants when TVT-S fails.  I just want to say thank you all for being here. I really do appreciate it. It's a Friday on a hot August day. I know you all probably want to be somewhere else. I wish I wasn't working. But jury service is extremely, extremely important. So	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	(Afternoon session reported by Sharon
12:56PM 2 12:56PM 3 12:56PM 4 5 6 12:56PM 7 12:56PM 8 12:56PM 10 12:56PM 10 12:56PM 12 12:56PM 12 12:57PM 14 12:57PM 15 12:57PM 16 12:57PM 17 12:57PM 18 12:57PM 19 12:57PM 20	Plaintiffs' Opening Statement same product; their motivation for not using Ultrapro or even trying other formulations for mesh and TVT line of products if they tried a different method, there would have to be more tests the motivation for keeping this thing on the market for six years when they knew it was a failed product in the face of horrific news about it; their motivation for still selling that when this trial was going on; the motivation for encouraging TVT implants when TVT-S fails.  I just want to say thank you all for being here. I really do appreciate it. It's a Friday on a hot August day. I know you all probably want to be somewhere else. I wish I wasn't working. But jury service is extremely, extremely important. So please pay attention to every detail, do	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	(Afternoon session reported by Sharon
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12:56PM 2 12:56PM 3 12:56PM 4 5 6 12:56PM 7 12:56PM 8 12:56PM 10 12:56PM 10 12:56PM 12 12:56PM 12 12:57PM 14 12:57PM 15 12:57PM 16 12:57PM 17 12:57PM 18 12:57PM 20 12:57PM 21 12:57PM 22	Plaintiffs' Opening Statement same product; their motivation for not using Ultrapro or even trying other formulations for mesh and TVT line of products if they tried a different method, there would have to be more tests the motivation for keeping this thing on the market for six years when they knew it was a failed product in the face of horrific news about it; their motivation for still selling that when this trial was going on; the motivation for encouraging TVT implants when TVT-S fails.  I just want to say thank you all for being here. I really do appreciate it. It's a Friday on a hot August day. I know you all probably want to be somewhere else. I wish I wasn't working. But jury service is extremely, extremely important. So please pay attention to every detail, do your best.  This case is very, very important to	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	(Afternoon session reported by Sharon

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1		
03:35PM <b>2</b>	<u>CERTIFICATE</u>	
3		
4	I HEREBY CERTIFY THAT THE PROCEEDINGS	
5	AND EVIDENCE ARE CONTAINED FULLY AND	
6	ACCURATELY IN THE NOTES TAKEN BY ME ON THE	=
7	TRIAL OF THE ABOVE CAUSE, AND THIS COPY IS	
8	A CORRECT TRANSCRIPT OF THE SAME.	
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