APPELLATE CASE NO B286283

COURT OF APPEAL OF THE STATE OF CALIFORNIA
SECOND APPELLATE DISTRICT
DIVISION FOUR

Elisha Echeverria, Acting Trustee of the
2017 Eva Elaine Echeverria Living Trust,
Plaintiff and Appellant,
v.
Johnson & Johnson *et al.,*
Defendants and Respondents.

Appeal from a Judgment and Order of the
Superior Court of Los Angeles
Civil Case No.: BC628228
The Honorable Maren E. Nelson, Judge Presiding

APPELLANT'S OPENING BRIEF

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TO BE FILED IN THE COURT OF APPEAL **APP-008**

COURT OF APPEAL 2nd APPELLATE DISTRICT, DIVISION	COURT OF APPEAL CASE NUMBER: B286283
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APPELLANT/ PETITIONER: Elisha Echeverria, acting Trustee of the 2017 Eva Elaine Echeverria Living Trust RESPONDENT/ REAL PARTY IN INTEREST: Johnson & Johnson, et al.	

CERTIFICATE OF INTERESTED ENTITIES OR PERSONS

(*Check one*): [X] INITIAL CERTIFICATE [ ] SUPPLEMENTAL CERTIFICATE

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1. This form is being submitted on behalf of the following party (*name*): Elisha Echeverria

2. a. [X] There are no interested entities or persons that must be listed in this certificate under rule 8.208.
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(1)		
(2)		
(3)		
(4)		
(5)		

[ ] Continued on attachment 2.

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Date: July 18, 2018

Mark P. Robinson, Jr.
(TYPE OR PRINT NAME)

▶ Mark P. Robinson, Jr.
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APPELLANT'S OPENING BRIEF

This was the first trial in a coordinated proceeding on behalf of women who developed ovarian cancer after decades of daily perineal use of Johnson's Baby Powder and Shower to Shower, talcum powder products manufactured and sold by Defendants and Respondents Johnson & Johnson, Inc. ("J&J") and its subsidiary Johnson & Johnson Consumer Inc. ("JJCI"). 52AA23470. Eva Echeverria, who used these products for over 50 years, was diagnosed with high grade serous epithelial ovarian cancer in 2007. She sought compensatory as well as punitive damages based on Defendants' despicable conduct in failing to warn consumers about the known risk of ovarian cancer.

Ms. Echeverria began using Johnson's Baby Powder twice daily (three times during her period) in 1965, when she was eleven. 27RT7521:8-7522:2, 7526:6-11, 7527:21-7528:15. She applied Johnson's Baby Powder in her perineal area, on sanitary napkins and on her undergarments two and sometimes three times daily from 1965 to 2016. 27RT7528:6-7529:21, 7535:13-22, 7569:25-7571:16. If she had seen an ovarian cancer warning, she would not have used the product. 27RT7540:1-18. She used Johnson's Baby Powder continuously through January of 2016, with the exception of 1979-1980, when she used Shower to Shower. 27RT7527:21-7530:20. Ms. Echeverria unwittingly continued using Johnson's Baby Powder for nine years after her ovarian cancer diagnosis. 27RT7638:26-7640:24. She only stopped in late January 2016 when she saw

something on television about a woman who had ovarian cancer who had been using it. 27RT7529:17-7530:20.

The court ordered an expedited trial in light of Ms. Echeverria's terminal illness. In 2017, the jury awarded $417,000,000 against J&J and JJCI: compensatory damages of $68,000,000 and punitive damages of $340,000,000 against J&J, plus compensatory damages of $2,000,000 and punitive damages of $7,000,000 against JJCI. 52AA2355-023552. The trial court granted a new trial and judgment notwithstanding the verdict to both Defendants. 52AA23469-23519.

Eva Echeverria passed away one month after the verdict. Her daughter, Elisha Echeverria, Acting Trustee of the 2017 Eva Elaine Echeverria Living Trust, was substituted as the plaintiff. She appeals, asking this Court to reinstate the judgment on the jury verdict. If the Court believes the amount of damages is excessive, Plaintiff respectfully asks that the Court remit the judgment to the amount it deems appropriate in light of the evidence.

I. Introduction: The Trial Court Granted New Trial and JNOV Based on Legal Errors and Factual Findings Unsupported by Any Evidence

The trial court did a complete about-face when it granted a new trial and both JNOV motions. When Defendants moved for nonsuit and for directed verdict, the court had held there was sufficient evidence to go to the jury on whether both J&J and JJCI acted with conscious disregard for safety in failing to warn Ms. Echeverria about the risk of ovarian cancer, but after the verdict, the

court reached the opposite conclusion. Likewise, repeatedly before and during trial, the court had ruled that the causation opinion of Ms. Echeverria's treating gynecological oncologist, Dr. Annie Yessaian M.D., was admissible and sufficient to go to the jury. AA24:11865, 11858; 29RT8101:15-8126:24; 31RT8742:15-8743:10.

While a trial court retains inherent authority to change its preliminary determinations (*Shaw v. County of Santa Cruz* (2008) 170 Cal.App.4th 229, 268), its eventual rulings must be based upon correct interpretations of the law, and on factual findings that find a basis in the evidence. "[E]videntiary rulings which are based on a misunderstanding of the law are an abuse of discretion." *Hernandez v. Amcord, Inc.* (2013) 215 Cal.App.4th 659, 678. A trial court abuses its discretion when it applies the wrong legal standard or its factual findings are not supported by substantial evidence. *Palmer v. Superior Court* (2014) 231 Cal.App.4th 1214, 1224.

After the verdict the court held not only that Dr. Yessaian's causation opinion was insufficient to support the verdict, but that it should have been stricken. 52AA23495; 23509-23510. This post-trial turnabout was an abuse of discretion in that it was premised upon not only a misinterpretation of controlling law, but also on factual findings that are demonstrably unsupported and contradicted by the record. *Global Modular, Inc. v. Kadena Pacific*, Inc. (2017) 15 Cal.App.5th 127, 150 ("A trial court abuses its discretion if it misinterprets the law or makes a factual finding not supported by substantial evidence"); *Sukumar v. City of San Diego* (2017) 14 Cal.App.5th 451, 464 ("[A] trial court abuses its discretion when

factual findings critical to its decision are not supported by substantial evidence.")

In ordering a new trial, the trial court misunderstood this Court's holding in *Cooper v. Takeda Pharmaceuticals America, Inc.* (2015) 239 Cal.App.4th 555. Contrary to what the court thought (52AA23496; 23498-99.), *Cooper* **does not** require an expert witness testifying to causation to completely rule out all other possible causes. 239 Cal.App.4th at 571 (plaintiff's expert "not required to rule out all other possible causes of [] cancer before his testimony could be deemed admissible. The trial court's ruling to the contrary contravened California law"); see also, *id.* at 578 ("it is not necessary for a plaintiff to … exclude every other possible cause of a plaintiffs illness"); please see further discussion in section V.A., below. Compounding this legal error, the court misstated Dr. Yessaian's testimony, mistakenly believing that Dr. Yessaian opined that it was probable that Plaintiff's cancer was caused by some unknown factor, when in fact Dr. Yessaian repeatedly testified to the contrary. Please see, pp. 78-79, below.

The trial court similarly abused its discretion in granting a new trial on other grounds, which, as will be shown below, were also based upon errors of law and factual findings which find no support in the record. Likewise, the trial court erred in granting both JNOV motions. As to causation, the JNOV ruling was in large part based upon the same legal errors and mistaken reading of the record that require reversal of the new trial ruling. Additionally, the court erred

in failing to consider substantial evidence demonstrating J&J's direct liability for failure to warn.

These various errors require the Court to reverse the order granting a new trial as well as the judgments resting on the order granting JNOV.

II. Statement of Facts and Procedural History

Since this appeal is in part from a JNOV, in subsections A., B., C., and E. below, Plaintiff presents the evidence in the light most favorable to her. (*Clemmer v. Hartford Insurance Co.* (1978) 22 Cal.3d 865, 878.) Subsection D. presents facts that Defendants believe entitled them to a new trial.

A. J&J was involved in concealing the risk of ovarian cancer associated with the perineal use of Johnson's Baby Power from 1964 onward

J&J first sold Johnson's Baby Powder in 1893. 27RT7657:19-27. The product is nearly 100 percent talc with fragrance added. 16RT4407:9-27; 21RT5796:27-5797:1. Imerys Talc America ("Imerys"), previously known as Luzenac America, is J&J's talc supplier. 25RT6914:28-6915:8; 16RT4372:18-4373:6. Imerys mines raw talc and processes it to J&J's specifications. 25RT6916:8-6917:2.

J&J manufactured Johnson's Baby Powder until 1967. Thereafter, the product, as well as a similar product called Shower to Shower, was manufactured by JJCI, a new, wholly owned subsidiary of J&J. 52AA23470; 27RT7657:7-7658:10. Although J&J transferred manufacturing to its subsidiary, J&J remained involved in the efforts

to prevent disclosure of cancer risk associated with genital use of talcum powder.

1. Memos from 1964 onward demonstrate that both J&J and JJCI knew that genital use of talcum powder posed a risk of ovarian cancer, and worked to hide the danger from consumers

Decades ago J&J became aware that talc could not be safely absorbed into the vagina, and was considering replacing the mineral with cornstarch. In 1964, William Ashton, a "manager or director" (17RT4592:10-4593:2) of J&J wrote a memo noting that Dry-Flo, a "low substituted A1 salt of mildly treated cornstarch, had been used to replace talc as a condom lubricant "because it was found to be **absorbed safely in the vagina** whereas, of course, **talc was not**." 31AA14294 (P-343, emphasis added.) Mr. Ashton's memo pointed out that the cornstarch product offered a "very appealing" alternative to talc "because it will open the door to a merchandising advantage [as] an all-starch product with no added inorganics." 17RT4541:15-4544:25, 4592:10-4593:2. Mr. Ashton, and his employer J&J, continued learning about the ovarian carcinogen risk of talc from 1964 through 2004. 30AA14091 (P-396).

By 1975, J&J referred to "the talc/ovary problem" in connection with cancer research. 31AA14305. The memo of Dr. Gavin Hildick-Smith, of J&J, "Talc in the Ovaries," informed his superiors he had sent "a small donation" … to the Tenovus Institute for Cancer Research in Wales "with the main objective of trying to determine what research is in actual fact being conducted at the Tenovus Institute." He continued, "[i]t might be of value to identify

the precise scientific data available to Tenovus **concerning talc and ovarian cells.** We are not budgeted to support the research outlined and shall so inform [Tenovus Director] Griffiths if this meets with your approval." 31AA14305 (P-55), emphasis added; 17RT4545:4-4546:20. One recipient handwrote on the memo: "It would be wise to know ahead of time just what Gavin intends doing. … It has certainly given Griffiths the opening to **put us on notice re the talc/ovary problem.**" 31AA14305(P-55), emphasis added; 17RT4546:21-4548:12.

J&J's knowledge of a link between talc and ovarian cancer kept accumulating. J&J produced a 1986 document from its company files titled "Technological Forecast – Powders." 31AA14340-41 (P-9). The forecast, which repeatedly referred to "J&J" alone and not to JJCI, acknowledged that "safety of cosmetic powders has been a concern, especially among health professionals. They have decided that powders provide no health benefit" and that "[m]others are now being advised not to use baby powder, especially talc baby powders." **"[S]tudies have implicated talc use in the vaginal area with the incidence of ovarian cancer."** *Id.*, emphasis added. "[W]hile a CTFA-sponsored animal study has shown that talc does not migrate, this concern does affect use of powders by adult women." 31AA14340-41(P-9).[1] The document hypothesized that "pursuit of technologies which would create talc

[1] CTFA refers to the Cosmetic Toiletries, and Fragrance Association, of which J&J was a member. J&J was part of the CFTA's "Talc Interested Party Task Force." 17RT4552:24-4553:1. *See also* 31AA14306 (P-57).

based powders of higher interest (than JBP) to adults could be profitable. – major effort should be expended to prove a health benefit for 'cosmetic' dusting powders. Effort should probably be directed at cornstarch technologies since the limits of market penetration and potential benefit have not been approached. – **technologies which control or prevent potential safety hazards must be pursued to stifle the negative recommendations of health professionals**." 31AA14353 (P-9) (emphasis added), 17RT4532:17-4533:3, 4534:19-4535:12, 4548:13-4555:9.

In 1992, Obstetrics and Gynecology published an epidemiological study of ovarian cancer by Harlow, et al., of Brigham and Woman's Hospital, Harvard Medical School recommending against genital talc use. 18RT4812:11-4813:4. The authors estimated the proportion of ovarian cancer attributable to 10,000 lifetime exposures to be ten percent, and recommended that "**given the poor prognosis for ovarian cancer, any potentially harmful exposures should be avoided. For this reason, we discourage the use of talc in genital hygiene, particularly as a daily habit**." 33AA14867, 74, emphasis added.

A 1992 J&J document titled "Johnson's Baby Powder" discussed "major obstacles" and "major opportunities." 31AA14263, 64 (P-10). One of the "major obstacles" listed was that "Negative publicity from the health community on talc (inhalation, dust, negative doctor endorsements, cancer linkage) continues." 31AA14263, 64 (P-10), 17RT4555:10-4556:3, 4556:21-4557:21.

In 1993, Donald Jones of JJCI wrote to John Hopkins, a research and development director at J&J, discussing an upcoming talc safety symposium to be conducted by The International Society of Regulatory Toxicology & Pharmacology (ISRTP), an industry-friendly organization of scientists (20RT5465:16-5466:13), and the National Toxicology Program (NTP), a federal government body that researches toxicity of compounds. 17RT4693:17-27.17RT4612:14-18. The symposium was in response to the "1992 NTP finding regarding talc and the 1992 Harlow paper **resurfacing the ovarian cancer connection to cosmetic talc use** first proposed by Cramer." 17RT4559:13-19; 31AA14279 (P-238) (emphasis added.) Mr. Jones wanted Mr. Hopkins to attend because of his "leverage with the ISRTP," which was considered important "as part of a strategy to keep J&J at the forefront of cosmetic talc, and to ensure" that J&J had "worldwide oversight on talc issues." 31AA14279 (P-238), 17RT4558:16-4563:2. Mr. Jones stated that Mary Ann Cook (another J&J research and development director) and he were "organizing a Worldwide Talc Steering Committee." 31AA14279 (P-238), 17RT4562:17-4563:10.

In 1994, Mr. Jones prepared J&J's "Talc Questions and Answers" to answer potential media or public relations inquiries. 31AA14326 (P-764), 17RT4563:11-4564:27. It acknowledged that studies had "**linked the use of talcum powder to ovarian cancer**" and that scientists had reported that "**there may be a link between the use of talc and increased risk of ovarian cancer**." 31AA14326-7 (emphasis added). The document denied

that the switch to cornstarch was because "talc is not safe," yet acknowledged that surgeons no longer used gloves with talc because "some of the powder on the surgeon's gloves could be left in the body cavity or tissues." 31AA14338; 17RT4565:5-4571:2. "Talc Questions and Answers" repeatedly referenced "Johnson & Johnson" without mentioning JJCI. 31AA14329, 14333, 14335, 14336 and 14338.

Also in 1994, J. Neal Matheson, an Executive Vice President at JJCI, signed an agreement with the CTFA on behalf of "Johnson & Johnson," guaranteeing J&J's support of the CTFA's Talc Interested Party Task Force activities. 31AA14306 (P-57), 17RT4584:23-4586:25.

Later in 1994, Dr. Alfred Wehner, a J&J consultant, wrote to Michael Chudkowski, a manager at JJCI, about contemplated studies concerning talc and ovarian cancer risk, and recommended that J&J not object, even though he believed conducting the studies "would be like continuing to fish for small fish with a wide-mesh net." 31AA14265(P-16); 17RT4571:3-4578:17, 4580:27-4584:22.

2. As J&J tried to "deal[] with negative press reports on talc safety," its consultant cautioned J&J against "denying the obvious in the face of all evidence to the contrary"

In 1995, Mr. Hopkins wrote a memo to several people, including Margaret Aleles, a J&J vice-president, specifying various ways of "dealing with negative press reports on talc safety issues" 31AA14307-8 (P-59); 17RT4586:28-4591:4. Ms. Aleles responded by agreeing and suggesting more effort in what Hopkins had called

"Pattern 3": "Take a more pro-active stance in educating opinion leaders that cosmetic talc is safe when used properly." 17RT4590:20-4592:9.

In 1997, J&J's consultant Dr. Wehner critiqued CTFA "response statements." He warned Mr. Chudkowski that "[s]everal investigators have independently reported talc particles in ovarian tissue" and that "[s]imply citing the Battelle study and stating that it 'demonstrated that talc does not translocate through the cervix to the uterine cavity and beyond' does not address the problem, does not refute these findings." 40AA17750 (P-20). Dr. Wehner also criticized a November 17, 1994 CTFA statement that said: "although some of these studies suggested a weak association might exist, when taken together the results of the studies are insufficient to demonstrate any real association," characterizing it as "**inaccurate, to phrase it euphemistically" because, "[a]t that time there had been about 9 studies (more by now) published in the open literature that did show a statistically significant association between hygienic talc use and ovarian cancer."** *Ibid.,* emphasis added. Wehner warned J&J: "Anybody who denies this risks that the talc industry will be perceived by the public like it perceives the cigarette industry: **denying the obvious in the face of all evidence to the contrary.**" *Ibid.*, emphasis added. The letter noted: "[A] 'real' statistically significant association has been undeniably established independently by several investigators, which without doubt will be readily attested to by a number of reputable scientists/clinicians." *Ibid.*

In 1999, a large meta-analysis by Cramer, et al. concluded that "avoidance of talc in genital hygiene might reduce the occurrence of this highly lethal form of cancer by at least 10%" and that "**appropriate warnings should be provided to women about the potential risks of regular use of talc in the genital area."** 33AA 14866; 18RT4813:5-4814:19, emphasis added.

3. Defendants continued to "defend talc" as evidence of cancer risk mounted

In 2002, Richard Zazenski, Director of Product Safety at talc supplier Luzenac, faxed Bill Ashton, the manager or director at J&J who authored the 1964 Dry-Flo memo, boasting that they had "been successful this far in fending off the NTP classification of talc as being a potential human carcinogen." Mr. Zazenski also warned J&J that "we must also keep an eye out for IARC…Unlike NTP, IARC is answerable to no one politically… You might want to counsel your management on this potential (and not to be too complacent about the status of talc)." 40AA017752 (P-27); 16RT4375:4-4380:1.

In 2003, Steven Mann, "Director, Toxicology, Johnson and Johnson Consumer Personal Products Worldwide," wrote to Mr. Zazenski, advising that "management [was] willing to support the Huncharek/Muscat narrative on ovarian cancer and talc," but first "J&J management wanted to know how strong Mike [Huncharek] and Joshua [Muscat] felt the case was likely to be." 31AA14283 (P-262), 17RT4593:3-4598:11. (Dr. Huncharek and Dr. Muscat were researchers hired by J&J. 17RT4594:21-4595:11.) Mr. Mann asked the talc supplier about "any news on NTP backing away as you

expected you might hear by the end of January?" 31AA14283 (P-262); 17RT4598:4-11.

In 2004, Mr. Zazenski sent another fax to Mr. Ashton at J&J about a recent study that "offers some compelling evidence in support of the 'migration' hypothesis." 30AA14091 (P-396), 16RT4380:2-4382:14.[2] The 2004 fax stated that this evidence combined "with the theory that talc deposition on the ovarian epithelium initiates epithelium inflammation – which leads to epithelium carcinogenesis – and you have a potential formula for NTP classifying talc as a causative agent in ovarian cancer." *Ibid.* 16RT4382:22-4384:5.

In 2005, a "string of email correspondence … between various persons at Johnson & Johnson" discussed Defendants' ongoing "project to defend talc," which was a "significant business globally" for the corporation. 31AA14284 at 14285 (P-263); 17RT4598:16-4601:9. Mr. Mann wrote to Joan Casalvieri, a senior J&J director, noting that the company was aware the NTP was considering listing cosmetic talc in its report on carcinogens "on the basis of epidemiological data related to talc and ovarian cancer," and that Mr. Mann was "working on several fronts," including the CTFA, Luzenac and their Washington, DC legal team "to assure a good outcome." *Id.* Mr. Mann reported: "[the company's] most recent intelligence indicate[d]" the NTP might delay or defer its classification for some time, that "[he was] working with Luzenac

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[2]The parties stipulated that J&J received this fax in 2004. 44AA19052; 27RT7654:16-7655:1.

and outside epidemiology experts to develop documents that scientifically support the lack of a relationship of talc and ovarian cancer," and that such "documents [would] be submitted to NTP and for publications in the scientific literature." 31AA14284 (P-263); 17RT4601:10-4604:2. In February 2005, Gerd Ries, a J&J employee in the Regulatory Department in Europe, wrote to his colleagues, including Mr. Mann, about the NTP review of talc as a human carcinogen: "The critical question that determines how we need to handle this case internally is what the chances are that we can prevent this classification." 31AA014280 (P-261); 17RT4604:28-4608:9.

In June 2005, Mr. Mann expressed frustration to other executives and directors, including Neal Matheson of JJCI, about how "it [wa]s VERY difficult to have any impact on IARC" (the International Agency for Research on Cancer) and how the CTFA and J&J were trying to get their consultants, Drs. Muscat and Huncharek, on the IARC panel and to write "white papers for NTP." J&J anticipated that IARC was likely to classify "talc as either 2A [probable] carcinogen or 2B [possible] carcinogen," which would result in the NTP then "listing talc on the Report on Carcinogens." J&J was also aware that a group of scientists within the NTP believed that talc was carcinogenic, but another "camp may gain the political upper hand." 31AA14286-14287 (P-264); 16RT4402:15-4404:28, 17RT4608:10-4611:10. J&J executive Susan Nettesheim responded that it was "Good news that we may be able to have John

Hopkins work with IARC." 31AA14286 (P-264); 16RT4403:3-21, 17RT4611:11-4612:18.

By at least 2009, Defendants' talc supplier, now called Imerys, was sending a Material Safety Data Sheet with every shipment of talc that warned "IARC: (2006 in preparation) Has concluded that perineal use of talc-based body powder is possibly carcinogenic to humans (Group 2B)." 40AA017757 (P-37); 16RT4388:14-4391:17.

In 2014, the FDA denied two Citizens Petitions to require a cancer warning on cosmetic talc products, stating that the FDA did not find that the data submitted presented "conclusive" evidence of a causal association between talc use and ovarian cancer. 46AA19654; 28RT7940:1-10. Nevertheless, the FDA recognized the plausibility of perineal talc progressing to ovarian cancer: "the potential for particulates to migrate from the perineum and vagina to the peritoneal cavity is indisputable. It is, therefore, plausible that perineal talc (and other particulate) that reaches the endometrial cavity, Fallopian Tubes, ovaries and peritoneum may elicit a foreign body type reaction and inflammatory response that, in some exposed women, may progress to epithelial cancers." 46AA19658. The FDA continued, **"[T]he best evidence for an association or causal relationship between genital talc exposure and ovarian cancer comes from epidemiologic data which show a statistically significant but modest increased risk of epithelial ovarian cancer, especially with serous histology, among women with a history of genital dusting with talcum powder.**" *Id.*, emphasis added.

At the end of 2014, J&J's net worth was $68.2 billion, and JJCI's net worth was $1.5 billion. 30RT8604:24-8605:5.

B. Defendants' products caused Ms. Echeverria's ovarian cancer

1. Annie Yessaian, M.D. testified that Defendants' talcum powder more probably than not caused Ms. Echeverria's cancer

Dr. Annie Yessaian is a gynecological oncologist, cancer surgeon, and professor at the University of Southern California Medical School. She specializes in women's cancers, performing more than 150 female cancer surgeries annually. 25RT6933:21-6935:16. She is double board-certified in general obstetrics and gynecology, and in gynecologic oncology. 25RT6942:20-6943:20. Her post-residency research at Sloan-Kettering Cancer Hospital and UC Irvine included work on how ovarian cancer cell lines become resistant to chemotherapy. 25RT6937:21-6941:22. Dr. Yessaian's training required study in advanced statistics, epidemiology and biostatistics. 24RT6941:23-6942:14.

This case was the first time Dr. Yessaian had ever testified in a courtroom. 25RT6933:8-10. By the time of trial she had been treating Ms. Echeverria for over ten years. 25RT6943:25-6944:5.

Ms. Echeverria suffered from serous, high-grade ovarian cancer that started in her left ovary. 25RT6944:6-9; 6945:18-28. Dr. Yessaian operated on her in 2007, found multiple tumors and diagnosed her with Stage IIIC ovarian cancer. 25RT6952:9-6953:11; 6955:9-6958:5. She started Ms. Echeverria on chemotherapy that

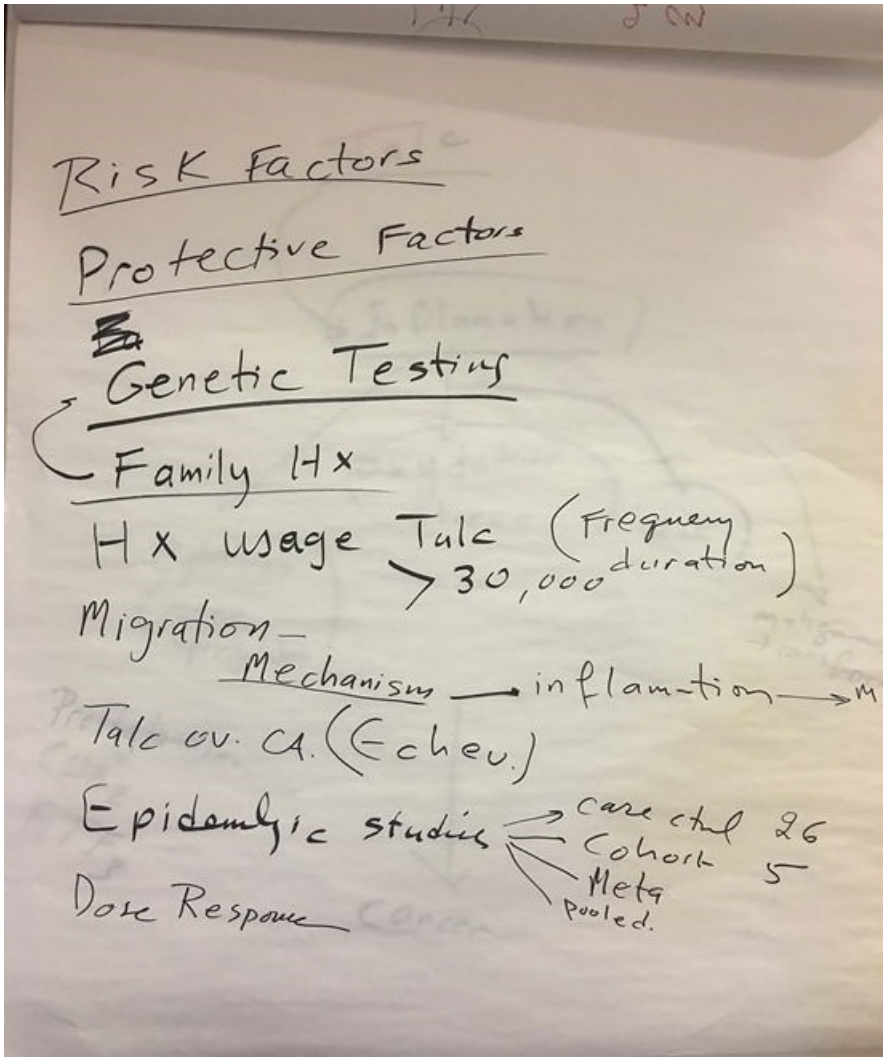
continued through 2017, when a PET scan showed recurrences of the tumors and the prognosis was terminal. 25RT6976:24-6981:3, 6961:11-6968:2.

Dr. Yessaian opined that talc more probably than not caused Ms. Echeverria's ovarian cancer, and that it is more probable than not that Ms. Echeverria would not have developed the cancer but for her use of talc. 25RT7057:8-7058:19; 26RT7392:21-7393:1. To form this opinion, Dr. Yessaian performed a differential diagnosis, investigating and ruling in and ruling out potential causes. 25RT6991:3-6993:15; see also *Cooper, supra*, 239 Cal.App.4th 565, and please see discussion in Section V.A., below.

a. Dr. Yessaian's differential diagnosis evaluated all relevant medical factors

Dr. Yessaian analyzed many factors to form her opinion. 25RT6992:25-7012:6, 7033:10-7041:15; 40AA17748.

i. Risk factors and protective factors



Dr. Yessaian "first looked at … her possible risk factors." 25RT6992:25-6993:23. She considered factors that increased Ms. Echeverria's risk as well as risk-reducing "protective" factors (number of children delivered to term, oral contraceptive pills, tubal ligation, and breastfeeding). 25RT7028:15-7033:15.

ii. Genetic testing, family history and obesity

Dr. Yessaian evaluated Ms. Echeverria's genetics, family history for cancer, age at cancer diagnosis, age at menarche, age at menopause, hormone usage, infertility and fertility drug usage, obesity, endometriosis, polycystic ovarian syndrome, tobacco use, alcohol use and use of talcum powder. 25RT6993:24-6994:6, 7003:21-7011:23.

Post-surgery genetic testing of the tumor showed no evidence of abnormality, meaning any mutation in mismatch repair genes could not have been a likely cause. 25RT6960:5-6961:6. Two years before this lawsuit was filed, testing of Ms. Echeverria's blood found no genetic mutations, including the BRCA genes associated with ovarian cancer. 25RT6984:6-6988:11. A special genetic counselor reviewed the blood and tumor tests and concluded genetics were not an implicating factor in Ms. Echeverria's cancer. 25RT6989:27-6990:22. Dr. Yessaian also ruled out other risk factors for ovarian cancer, including Lynch Syndrome, BRCA1 and BRCA2, estrogen-only hormone replacement therapy and use of fertility drugs 26RT7381:19-7382:5.

Dr. Yessaian considered family history, including family members who had various types of cancer, and ruled out that cause. 25RT7003:6- 7007:4; 25RT7033:26-7035:7. Dr. Yessaian also took into account Ms. Echeverria's age at the time of her first period, her age at menopause and her age at ovarian cancer diagnosis, each of which were average. 25RT7007:17-7008:25. Dr. Yessaian ruled out endometriosis, polycystic ovarian syndrome, fertility medication,

alcohol and tobacco. 25RT7009:25-7011:19; 25RT7008:26-7009:3. Defense expert Dr. Saenz admitted that neither alcohol nor smoking contributed to Ms. Echeverria developing serous ovarian cancer. 29RT8317:11-8322:2.

The data Dr. Yessaian reviewed for serous ovarian cancer showed no correlation with weight or obesity. 25RT7009:4-24.

iii. History of talc use

Dr. Yessaian reviewed Plaintiff's history of talc use, including frequency and duration. She learned that Ms. Echeverria used talc twice daily as a body freshener, and three times daily during menstruation, for over 50 years, from 1965 through 2016, which. amounted to "more than 30,000 lifetime applications." 25RT6995:2-4, 6994:7-6995:4, 7035:8-7036:1, 27RT7521:8-15, 7526:6-11, 7527:21-7528:3

iv. Talc found in Ms. Echeverria's ovarian tissue

Dr. Yessaian also relied on Dr. Godleski's findings identifying talc in Ms. Echeverria's cancerous tissue. 25RT6995:16-6996:1, 6911:17-20, 7038:21-7039:11.

b. Dr. Yessaian considered relevant scientific evidence

Besides considering Ms. Echeverria's history, Dr. Yessaian analyzed scientific information about talc and ovarian cancer.

i. Migration

To determine biological plausibility, Dr. Yessaian considered studies in both animals and humans showing compelling evidence that talc applied externally can migrate to the peritoneal cavity. 25RT6994:28-6996:1, 7036:15-7038:20, 6950:16-6951:11. Defense expert Dr. Saenz agreed that particulates could migrate upward towards the ovaries. 29RT8315:21-27.

ii. Inflammation mechanism

Dr. Yessaian reviewed the literature relating to "how do we go from talc sitting in the peritoneal cavity to talc participating in that whole cascade … process from inflammation to malignant transformation to leading to cancer." 25RT6995:16-6996:11. It shows that inflammation leads to malignancies or malignant transformation, meaning when the cell transforms from being "noncancer to cancer." Dr. Yessaian explained how talc causes inflammation resulting in cancer. 25RT6997:16-6998:6. When cells get inflamed they produce oxidative stress that can induce malignant transformation, the opposite of eating antioxidants like blueberries to prevent cancer. Inflammation can also induce secretion of cytokines like COX-2 and ATF3 that essentially push the gas pedal on the cell and it starts dividing and dividing. Inflammation can lead the cell to go from normal cell division to a "rapid crazy division, which is really what cancer is;" "[t]here are no brakes on the cancer process. The gas pedal is right on all the mechanism of replication, and the cells keep growing and growing and growing into large tumors." 25RT7000:3-7002:25.

The National Cancer Institute identified "use of talc" as a potential cause for ovarian cancer. 26RT7380:18-7382:8; 34AA15496. Ohio State University and Emory University both list talc as a potential cause of ovarian cancer on their websites. 26RT7383:22-7384:1.

iii. Relative risk

Relative risk (RR) is a commonly used approach for expressing the magnitude of the association between an agent and disease. It is the ratio of the incidence of disease in exposed individuals to the incidence rate in unexposed individuals. Ref. Guide on Epidemiology, Ann. Ref. Manual on Sci. Evid. 333 (2d ed.) 2004 WL 48155, 18; see also, 24AA 11857.

Dr. Yessaian looked at "multitudes of epidemiological studies … in the literature that studied these factors of the association between talc and the increased risk for developing ovarian cancer." 25RT6996:14-6997:8. These included 26 case-control studies, five cohorts, six statistically significant meta-analyses and a statistically significant pooled analysis. (Case control studies take people who have the disease in question and look backwards at what exposures they had. 25RT7047:20-7048:22. Cohort studies, on the other hand, follow a group into the future to see if they develop the disease. *Id.*)

Six meta-analyses and a pooled study support Dr. Yessaian's opinion that talc can cause ovarian cancer, and caused Ms. Echeverria's ovarian cancer. All seven studies had statistically

significant odds ratios between 1.22 and 1.39, showing a consistency among results demonstrating causation. 26RT7385:22-7386:14. Some of the cohort studies were not statistically significant, but they either did not have data on duration or did not record frequency of use, causing Dr. Yessaian to believe the methodology was flawed, which might explain why no statistically significant association was found in those studies. 25RT7042:18-7047:19. The 2008 Gates cohort study, which collected both duration and frequency of use data, reported a statistically significant association between perineal talc use and ovarian cancer. 25RT7049:15-7050:11. Gertig 2000, another cohort study, showed a statistically significant relative risk of 1.40, meaning a 40% increased risk of developing serous invasive cancer, the same type which Ms. Echeverria had. 25RT7050:12-7051:19. Likewise, the 2008 Gates study showed a total relative risk of 1.36, and a relative risk of 1.60 for serous histology (Ms. Echeverria's tumor type), indicating a sixty percent increase for those with talc exposure. 25RT7051:20-27. Dr. Yessaian also looked at Terry 2013, a pooled study showing a 1.20 statistically significant odds ratio for serous ovarian cancer. 25RT7051:28-7052:15.

Dr. Yessaian also relied upon four case-control studies evaluating use of talc in the genital area and ovarian cancer that showed statistically significant relative risks or odds ratios above 2.0. 25RT7052:16-23. Those included:

- Cramer 1982, a Harvard study of 200 patients with ovarian cancer and 200 matched controls, showed a relative risk for ovarian cancer of 3.28, with a confidence interval of

1.68 to 6.42 where talc was applied to both sanitary napkin and genitals, similar to Ms. Echeverria's use. 25RT7052:24-7053:19; 26RT7390:12-25; 11AA5411.

- Rosenblatt 1992, a Johns Hopkins study, found a relative risk for ovarian cancer of 4.8 and the confidence interval was statistically significant, where talc was applied to sanitary napkin. 25RT7053:20-7054:4; 26RT7390:26-7391:1; 41AA17804-5.
- Cramer 1999, another Harvard study with more than a thousand ovarian cancer patients and a large number of matching controls, found an odds ratio for ovarian cancer of 2.15 in the statistically significant range, with an odds ratio of 1.70 for serous invasive ovarian cancer. 25RT7054:5-20; 26RT7391:2-9; 33AA14861.
- Wu 2009, a USC study, resulted in a statistically significant relative risk of 2.08 for epithelial ovarian cancer, with a relative risk of 1.70 for serous invasive ovarian cancer. 25RT7054:21-7055:9. The Wu study had a confidence interval of 1.34 to 3.23. This L.A. County study involved 609 women who had been diagnosed with epithelial ovarian cancer and 688 control women. It found that "Risk of ovarian cancer increased significantly with increasing frequency and duration." 41AA17810, emphasis added.

Dr. Yessaian testified that the relative risk in the Wu study of 2.08, with a confidence interval of 1.34-3.23, is a conservative estimate as to Ms. Echeverria's risk. The highest duration of use the Wu study evaluated was 20 years, and the highest frequency of use

in the Wu study was "more than 30 times per month." 26RT7386:16-7388:14; 41AA17810. Because Ms. Echeverria used talc for more than 40 years and more than 60 times per month, Dr. Yessaian explained, "if anything, she should fall on the higher end of that confidence interval, [at] 3.23. That is conservative." 26RT7368:23-7375:26; 26RT7387:4-7389:3.

Although Dr. Yessaian relied upon the studies that showed an association of 2.0 or higher, she explained that in determining the relationship between talc use and Ms. Echeverria's developing ovarian cancer, she did not look at any single study, factor, element, or exposure. "It is the totality of all the evidence and the factors that [she] included." 25RT7055:10-7056:8. The four 2.0 studies are among the other things Dr. Yessaian relied upon, using the "analogy of the table and the 50 legs it stood on." 26RT7283:6-17.

Dr. Yessaian testified that epidemiology was just one facet of evaluating the totality of the evidence she considered, which included more than 75 publications. 25RT7039:25-7040:12, 7042:3-20, 7055:10-7056:8. She looked at 70 to 80 studies examining the association between talc and increased risk for developing ovarian cancer. 25RT6996:12-6997:17. She also reviewed literature showing how talc can cause inflammation, and how inflammation leads to malignancies. 25RT6997:18-6998:6; 7000:3-7002:25.

iv. Dose response

Dr. Yessaian considered the issue of "dose response." She explained that a "dose response is kind of like the linear increase in a

result with the increased exposure of what risk factors you're using." 25RT6997:9-17. She found evidence of a dose response in the Wu, Cramer 1982, Cramer 1999, and Terry 2013 studies, showing that the risk increases with use. *Id.*; 25RT7056:9-7057:7; 25RT6997:9-17.

The longer the duration and the greater the frequency of use, the greater the risk for developing ovarian cancer. *Id.*

c. The totality of the evidence led to Dr. Yessaian's conclusion that Defendants' products caused Ms. Echeverria's cancer

Dr. Yessaian relied upon the totality of the evidence in determining that Ms. Echeverria's use of Defendants' talcum powder was the most probable cause of her ovarian cancer.

> Q So after doing your differential diagnosis … and based on your differential diagnosis, what are your opinions on whether or not talc caused … Ms. Echeverria's ovarian cancer?
>
> A I looked at the risk factors, the protective factors, ruling in and ruling out those, then evaluated her own exposure to talc, the fact that talc was found in the ovarian cancer tissue of hers, of our patient, the biologically plausible mechanism of migration and … a biologically plausible general mechanism of migration, inflammation, and how talc can migrate, how it can cause inflammation, and how inflammation can cause cancerous transformation through very well-established pathways from that – oxidatives, the cytokines.

24RT7057:8-27.

All these items led to Dr. Yessaian's conclusion "that talc was more probable than not the causing agent in Ms. Echeverria's developing high-grade serous ovarian cancer." 25RT7057:28-7058:3.

> Q Do you have an opinion as to – that it's more probable than not that, but for Ms. Echeverria's use of talc, that she would not have developed her serous epithelial ovarian cancer?
>
> A Correct.
>
> Q Your answer is she would not have developed it?
>
> A Correct.

25RT7057:8-7058:10.

Dr. Yessaian clarified that her "more probable than not" conclusion rested on more than the four epidemiological studies.

> Q Now, counsel asked you about the epi, but, you know, are you only relying on the epidemiology here for your opinion on your differential diagnosis?
>
> A I'm not relying only on those four studies with the 2.0 and beyond. I'm not only relying on the epidemiology. **I'm looking at all those elements and the totality of all of those elements**, including her history, the mechanism, migration, risk, protective, all of the factors that I included. Epi is nothing but a facet of those –

26RT7391:10-19, emphasis added.

> Q What is your medical doctor opinion as to the cause of her ovarian cancer?
>
> A [A]s I stated in my report, after evaluating all of that with the fact that I am a medical doctor, that **talc stood out as the more probable than not**

cause for her developing serous epithelial high grade ovarian cancer.

26RT7395:8-14, emphasis added.

2. Dr. John Godleski found talc in Ms. Echeverria's ovarian tissue, and concluded with reasonable medical certainty that the presence of talc can help show a causal link to ovarian cancer

Pathologist John Godleski is both a medical doctor and a research scientist who taught at Harvard Medical School and the Harvard School of Public Health. He spent 37 years at Brigham Women's Hospital, the teaching hospital for Harvard Medical School, where his experience included examining ovarian cancer tissue. 21RT5761:1-5762:6, 21RT5763:20-5764:27, 21RT5766:12-15. Dr. Godleski focused on inflammation and cancer as primary disease processes, and he authored or co-authored 20 or 30 articles about tissue response to foreign particles. 21RT5768:3-5769:13.

In 2007 Dr. Godleski co-authored a study, "Presence of Talc in Pelvic Lymph Nodes of a Woman with Ovarian Cancer and Long-Term Genital Exposure to Cosmetic Talc." 33AA14951; 21RT5769:14-5771:11. Scanning electron microscopy and x-ray analysis of the pelvic lymph nodes of the woman who was diagnosed with ovarian cancer after using talc for over 30 years revealed a very large amount of talc particles. 21RT5771:9-5772:9.

Dr. Godleski examined the tissue samples from Ms. Echeverria's 2007 surgery to determine whether there was talc in her tissue. 21RT5782:3-20. He identified both cancerous tumors and talc

particles in the left ovary, in the omentum in the upper abdomen, and in the peritoneal cavity, a total of eleven particles and fibers of talc – eight in the ovary and three in the pelvic peritoneum and omentum. 21RT5762:7-5763:19. That these eleven particles were found within a small fraction of a portion of Ms. Echeverria's cancerous tissue indicates there was a substantial burden (hundreds of particles) of talc in the totality of Ms. Echeverria's tissue. 21RT5812:20-5814:12. Dr. Godleski is convinced the talc particles he identified were present as a result of perineal usage of talc. 21RT5825:22-5828:6. Defense pathologist, Dr. Felix, did not dispute that Dr. Godleski found talc in Ms. Echeverria's ovarian tissue. 29RT8189:22-26.

Exhibit EE40B, an image from the pelvic peritoneum, shows a fiber that electron microscopy and x-ray analysis revealed to be a fibrous form of talc. There was a cellular reaction, a macrophage, with it. 21RT5809:27-5811:13; 35AA15600. Exhibit EE155, an image of Ms. Echeverria's tissue close to the ovary, shows ten or twelve inflammatory cells (macrophages) and several individual fibers characteristic of a fibrous form of talc. 21RT5808:5-5809:17; 34AA15587. All those macrophages in proximity to the fibers is evidence of a chronic inflammatory process. 21RT5809:18-26. Dr. Felix agreed that some of the macrophages that Dr. Godleski identified were indeed macrophages. 29RT8155:5-12.

Dr. Godleski also analyzed Johnson's Baby Powder under a scanning electron microscope. 21RT5796:22-24. Talc is magnesium silicate and has certain recognizable structural or morphologic

features and a specific atomic weight percentage. 21RT5796:22-5798:4. The size of the particles Dr. Godleski saw when he looked at Johnson's Baby Powder were consistent with the particle size he saw in Ms. Echeverria's pathology. 22RT6077:15-6078:1.

Dr. Godleski's ultimate opinion was that, to a reasonable degree of medical certainty, the presence of talc in ovarian tissue contributes to showing a causal link in the development of ovarian cancer. 22RT6123:21-26.

3. Dr. Jack Siemiatycki concluded it is more likely than not that genital exposure to talc can cause ovarian cancer

Dr. Jack Siemiatycki is an epidemiologist with degrees in mathematics and statistics, a Ph.D. in epidemiology from McGill University in Montreal, and a two-year postdoctoral fellowship at IARC. 22RT6150:16-6151:25; 23RT6338:28-6341:7. A full professor with 40-plus years of experience in researching the causes of diseases, Dr. Siemiatycki has been involved in ovarian cancer publications and an international evaluation of the relationship between ovarian cancer and talcum powder use. 22RT6152:15-6153:15. 22RT6164:27-6165:9.

Dr. Siemiatycki testified that studies, including Terry 2013 and Wu 2015, show a very strong statistical association, and a dose-response relationship, between the use of talc and ovarian cancer. 23R6361:23-6365:19; 6429:8-6430; 6411:7-6412:5. Dr. Siemiatycki derived a highly statistically significant point estimate of 1.28 relative risk from a meta-analysis of case-control and cohort studies

from the 1980's through 2017. 23RT6422:14-6423:17. He explained that if a study shows a 1.3 relative risk for all women, that average covers women with low, medium and high exposure. Women with high exposure would have a relative risk greater than 1.3. 23RT6326:18-6327:22.

In formulating his opinions Dr. Siemiatycki also considered the Bradford Hill criteria that are well accepted in the medical field for making causal judgments. 23RT6424:10-6425:18; *Wendell v. GlaxoSmithKline LLC* (9th Cir. 2017) 858 F.3d 1227, 1235, n.4. These include:

- **Temporal relationship:** Ms. Echeverria's exposure occurred before the ovarian cancer. 23RT6424:17-28
- **Strength of association**: The relative risk is 1.28 with a very highly statistically significant confidence interval, making it almost impossible that the association was the result of chance or random fluctuation. 23RT6425:1-13.
- **Dose response relationship**: The studies show the more applications, the greater the risk, clearly indicating dose response. 23RT6361:23-6365:19, 6425:14-6430:17; 6436:2-6437:13.
- **Replication**: Almost every study shows a point estimate greater than one – "like flipping a coin 28 times and coming up with heads 27 times." 23RT6437:28-6438:14.
- **Biological plausibility**: Consultation with experts in biological mechanisms of cancer provided a plausible explanation through talc migration to the ovaries and

inflammation resulting from presence of talc particles. 23RT6442:4-6443:3.

Dr. Siemiatycki testified that causality can be proven with a relative risk of less than 2.0. A classification of carcinogenicity has been made using a relative risk of less than two, in many cases with relative risks of 1.3 or even 1.1 (air pollution), for as many as half of all substances classified for which there is epidemiologic data. 24RT6795:11-28.

Dr. Siemiatycki opined that talc usage in the genital area is a modifiable risk factor that influences the probability of disease. 23RT6306:14-6307:10. His review of the epidemiology, application of the Bradford Hill criteria, and emphasis on the propriety of classifying a substance as carcinogenic based on a relative risk similar to the risk ratio identified for talc, led Dr. Siemiatycki to conclude that it is more likely than not that exposure to talc in the genital area can cause ovarian cancer. 22RT6148:23-6149:5; 23RT6441:19-25.

4. Dr. Laura Plunkett concluded that decades of genital use of talc is dangerous and causes ovarian cancer

Dr. Laura Plunkett is a Ph.D. pharmacologist and toxicologist. After two years of research with the National Institutes of Mental Health she taught toxicology and pharmacology at the University of Arkansas Medical School. 17RT4646:23-4649:26. Since 1989 she has consulted in human health risk assessment, and she works with companies attempting to get product approval or encountering

problems in dealing with regulatory agencies such as the FDA and EPA. 17RT4649:27-4654:19. Her experience includes cosmetics, medical devices, dietary supplements, drugs and pesticides, typically looking at safety and risks. 17RT4654:5-19; 4660:5-25.

In arriving at her opinion that talc causes ovarian cancer, (17RT4735:5-7), Dr. Plunkett also applied the Bradford Hill methodology. 17RT4735:8-4736:26; 18RT4832:16-4833:19. She concluded that all nine tenets have been met and that there is enough evidence to state that genital exposure to talc causes ovarian cancer. 18RT4864:3-25.

Dr. Plunkett explained that talc can migrate from the vagina to the upper genital tract to the ovaries, as demonstrated by many peer-reviewed and published scientific studies beginning in the early 1960s, and it can "retrogradely migrate" from the genitals into the upper parts of the female reproductive tract, reaching the ovaries and peritoneal cavity. 17RT4714:17-4724:11.

Dr. Plunkett described a 2007 case report by Godleski and Cramer showing "actual evidence" of talc particles in the pelvic lymph nodes of a woman who had been diagnosed with ovarian cancer and reported long-term genital use of talc. 17RT4725:10-4726:22. She also noted the Heller study, which found that women who reported genital use of talc had more talc in their ovaries following oophorectomy (surgical removal of ovaries) than in the unexposed group. 17RT4727:10-4729:25. The authors stated that the talc in the unexposed group could be attributable to exposure during diapering. 17RT4732:23-4733:17.

Also, Dr. Plunkett explained that talc can cause inflammation in human tissues, and chronic inflammation can cause ovarian cancer. 17RT4671:14-19. The weight of evidence indicates that micron-size particles of talc in baby powder can lead to cancer. 18RT4810:19-4812:6. Chronic inflammation is a biologically plausible mechanism whereby talc can cause cancer, and specifically ovarian cancer. 17RT4678:13-4679:8; 4710:22-4713:23; 18RT4831:14-4832:12. Ms. Echeverria's genital talc use over 40 years was chronic exposure. 31RT4682:8-23.

Dr. Plunkett relied in part on animal studies that show that talc can cause inflammation that is shown in cellular pathology. The Hamilton 1984 study demonstrated that rats, whose ovaries were injected with a single dose of talc, underwent papillary changes in tissues. The ovaries became abnormal and developed cysts and precancerous lesions. 17RT4687:8-4693:7; 34AA15490. An NTP study in 1992 showed that rats inhaling talc had a chronic inflammatory response, as well as precancerous lesions and tumors. 17RT4694:14-4697:6; 4736:28-4737:6.

Dr. Plunkett also looked at studies that have examined the toxicity of talc in human cells. Buz'Zard 2007 showed talc produces neoplastic transformation in epithelial ovarian cells (cells that line the surface tissue of the ovary), causing them to take on precancerous characteristics that can become a cancerous tumor. 17RT4704:2-4706:14; 33AA14803. When talc interacts with the tissue it can stimulate reactive oxygen species (ROS), chemical mediators, to react to tissue and cause tissue damage. A chemical's

ability to increase the levels of ROS is an important component of the inflammatory process that underlies cancer. 17RT4706:16-4709:9.

The Shukla 2009 study regarding the reaction of human cells to talc looked at peritoneal mesothelial and ovarian cells. Shukla was looking for changes in the way DNA forms proteins and other chemicals within a cell, which can cause the cell to change from normal, to precancerous, and then to a cancerous cell. 17RT4709:10-4712:22. Both the Buz'Zard and Shukla studies provide evidence that links talc as a mechanism that initiates an inflammatory response that leads to cancer. Chronic exposure induces insult to the tissues, changes the genes that are expressed, and generates reactive oxygen species within the tissues that lead to cancer. 17RT4712:23-4713:23.

Other evidence of how talc causes inflammation is pleurodesis, a medical procedure used for treating very sick patients with fluid accumulating in their lungs. Pleurodesis uses the inherent properties of talc to produce an acute inflammatory process of scarring to allow a patient to live a little longer and more comfortably. 18RT4807:23-4810:18. The animal studies and the human cell studies "are pieces of the puzzle" in "understanding mechanism and understanding whether or not it makes sense…that talc can cause cancer." 17RT4712:23-4713:23. Dr. Plunkett shares the Canadian government's opinion that talc is "very toxic." 20RT 5416:14-5420:21.

Dr. Plunkett also looked at human epidemiological data. She testified that there are somewhere between 20 and 30 different

epidemiological studies about talc and ovarian cancer spanning over 40 years, and **only one did not show an increased risk**. 18RT4846:21-4849:20. Every meta-analysis and every pooled study on talc has shown a statistically significant increased risk of ovarian cancer. 18RT4820:5-4830:28. Thus, Dr. Plunkett opined, the scientific evidence shows that talc causes ovarian cancer. 18RT4864:3-25.

C. Ms. Echeverria suffered for ten excruciating years

In 2007, Dr. Yessaian performed an exploratory laparotomy on Ms. Echeverria, removing her uterus, both her ovaries and Fallopian tubes, the omentum (the fatty apron in the abdomen), and "a sliver, partial part of the stomach as well." 25RT6955:9-6956:16. The pathology showed high-grade serous papillary ovarian cancer, stage IIIC. 25RT6954:20-6959:1. The largest tumor measured thirteen centimeters, the size of a large cantaloupe. 25RT6956:17-23.

Following surgery, Dr. Yessaian started Ms. Echeverria on chemotherapy, "the gold standard of care of treatment for advanced metastatic stage IIIC ovarian cancer." Dr. Yessaian explained that even if every visible tumor is removed "it is naïve to assume that there's no microscopic ovarian cancer cells hiding." 25RT6961:11-6962:20. Dr. Yessaian treated Ms. Echeverria with 114 cycles of chemotherapy from 2007 to 2017:

Eva Echeverria: Chemotherapy Treatment

	Dates of Chemotherapy	Chemotherapy Medications	Approximate Number of Cycles
1	5/2007 to 10/2007	Carboplatin & Taxol	6 cycles
2	8/2008 to 10/2008	Carboplatin & Paclitaxel	4 cycles
3	10/2008 to 6/2009	Gemzar & Cisplatin	11 cycles
4	6/2009 to 10/2009	Doxil	4 cycles
5	10/2009 to 1/2010	Acastin	3 cycles
6	1/2010 to 4/2010	Topotecan	3 cycles
7	5/2010 to 7/2010	Alimta	3 cycles
8	2/2011 to 4/2011	Gemzar & Cisplatin	2 cycles
9	4/2011 to 7/2011	Carboplatin and Taxotere	3 cycles
10	7/2011 to 10/2011	Paclitaxel	4 cycles
11	10/2011 to 5/2014	Abraxane & Xeloda	31 cycles
12	6/2014 to 8/2014	Carboplatin	3 cycles
13	8/14/2014 to 11/2014	Paclitaxel	5 cycles
14	2/2015 to 7/2015	Phase 1 Clinical Trial (TROP2ADC)	8 cycles
15	9/2015 to 10/2015	Oxaliplatin & Avastin	3 cycles
16	11/2015 to 10/2016	Bayer's 17350 (Bay 1217389) protocol	11 cycles
17	1/4/2012 to 2/22/2017	FPA 008 003 protocol and Opdivo	4 cycles
18	3/9/2017 to 3/28/2017	FPA 008 003 protocol and Opdivo	4 cycles
19	5/27/17 to Present	Niraparib	2 cycles

Total cycles of chemotherapy: 114

Exhibit EE-639; 40AA017745.

Chemotherapy kills rapidly dividing cells, both cancerous cells and normal ones. 25RT6966:23-6967:12. One chemotherapy regime caused Ms. Echeverria such severe skin toxicity and nerve pain that she was unable to walk. Other chemotherapies resulted in fatigue, nausea, vomiting (a lot of nausea and vomiting), anemia, susceptibility to infection, neuropathy, nephrotoxicity, ototoxicity and hearing loss, chemo brain, hair loss and pain. 25RT6968:25-6970:17. Sometimes the chemotherapy temporarily succeeded, but then the agents would fail and the disease would again progress. Dr. Yessaian deemed reduction in disease as success, "because when you're desperate you are not aiming for a cure. You're aiming for

stable disease," and a "miserable status quo is success because [she] cannot do better. 25RT6962:27-75:6; 40AA17745 (Exhibit EE639).

Despite the chemotherapy, new tumors appeared after the 2007 surgery. A 2017 PET scan showed a large tumor in Ms. Echeverria's pelvis, a ten-centimeter tumor pressing on her bladder and bowel, a thirteen centimeter mass next to her stomach, and masses on top of her left kidney, in the middle of her chest, in her right rib, plus a few lesions on the liver and one in the bone area of her sternum. Dr. Yessaian concluded Ms. Echeverria was "terminal." She provided Ms. Echeverria palliative care, controlling her pain. The tumor on the rib was "hugely painful." 25RT6977:5-6983:2.

Ms. Echeverria was too ill to testify at trial, but her videotaped deposition described what she went through.

1. Pain and mental suffering

> The pain is so bad. It's – I can't sleep at night because I can't move on my right side because of the liver and the kidneys.... I have the kidney pain, I have the leg pain, pelvic pain, abdominal pain. And when the tumor feels like moving, it will move and cause, like, my leg to have pain. That's the pelvic mass. That's the big, big mass. And it's just – you know, I can't sleep. I can't sleep because of pain. I can't get comfortable left. I can't go right. I can't lay on my stomach. I'm just in pain.

27RT7556:1-17.

2. Loss of quality and enjoyment of life, physical impairment, and inconvenience

I'm extremely fatigued. I have nausea; I have vomiting. I have headaches. ... I'm not balanced well and I can't taste. I can't smell. My hearing is going too. And then, you know, the pain.

Oh, I have neuropathy. It's so bad that my feet feel like I'm walking on broken glass. And I've fallen several times because I can't feel – can't feel myself walking.

27RT7556:18-7557:3.

3. Disfigurement and embarrassment

Q [Y]ou have lost your hair; right?

A Yes, I have.

Q So, I mean, you look fine. You look great. I'm just saying, but you don't – that's a wig; right?

A Yes. It is a wig, and this is makeup.

Q Okay. You are bald?

A I'm bald. I've been bald.

27RT7555:18-28.

4. Fright, nervousness, apprehension, terror, shock and mortification

Q Do you have any fear that you might die here?

A Yes.

Q How often is it with you?

A I thought I was going to die for Christmas because I was so sick. I have a grandson. He is five years old and he loves me so much. I love him so much. And I don't know what I would do without

him. And I know he loves me so much. He tells me he loves me every day, and he hugs me and kisses me. It makes me sad because I don't know how long I'm going to be able to tell him that I love him.

27RT7557:4-19.

5. Grief, anxiety, depression, indignity and emotional distress

Q Is your daughter special to you?

A Her as well. She has been so good.

Q She takes care of you?

A Yes. I was diagnosed when she was 16 years old, and she didn't graduate until she was 21 because she was taking care of me. I feel that she was cheated out of her teen years because she had to stop and take care of me. And I was usually very active with her.

27RT7557:20-7558:4.

D. Defense Contentions and Witnesses

Defendants asserted that epidemiology studies do not show a strong association between genital talc use and ovarian cancer, noting that the epidemiology studies reveal average risk ratios of 1.24-1.3. 19RT5214:23-5218:8, 24RT6753:5-6755:13, 30RT8437:10-8438:8. This relatively weak association could be the result of chance. 33AA14832 (Exhibit L-1769); 19RT5259:12-5260:21; 24RT6626:25-6639:18; 6724:12-28; 6750:16-6752:4; 6742:14-6783:13; 27RT7724:217726:20; 28RT7957:21-7966:19; 30RT8437:10-8442:4.

Also, Defendants presented evidence that study results are inconsistent (33AA14909 at 14911 (Exhibit P-104); 33AA14832

(Exhibit L-1769); 19RT5242:2-15; 5246:5-5249:5; 30RT8451:2-8453:28; 19RT5249:25-5254:5; 30RT8442:98444:19; 27RT7722:14-7724:7; 28RT7957:2-20; 30RT8458:10-8460:5; 29RT8274:12-8278:13) and that studies fail to establish a dose-response relationship. 41AA17838 (L-1811); 30RT8460:19-8461:1; 34RT6641:21-6688:1; 6677:10-6683:5; 26RT7286:3-7287:9; 27RT7728:14-7729:25; 30RT8460:8-8473:2. Echeverria's expert, Dr. Siemiatycki, testified that although a study by Terry (2013) showed "compatibility" with dose response, it was equally compatible with no dose-response. 24RT6677:10-6683:5.

Defendants addressed animal studies, offering evidence that none has shown that talc causes ovarian cancer. 34AA15490 (Hamilton 1974); 46AA19654 (P-47); (1995 Boorman); 27RT7732:11-7741:20; 18RT4957:23-27; 4971:26-4973:2; 27RT7732:11-7741:20; 18RT4988:19-4994:28.

Defendants offered evidence to support their theory that the proposed biological mechanism for talc causing ovarian cancer is speculative. 33AA14882 (Exhibit L-811); 46AA19654 at 19656-58 (Exhibit P-47); 29RT8147:13-8150:23; 8163:20-26; 8135:9-8136:23; 8139:23-8151:23; 8163:20-26; 8207:4-13; 8238:12-8239:6; 8272:12-8273:1; 19RT5175:3-10; 5179:12-19; 5199:3-9; 24RT6777:11-6780:28; 19RT5170:23-5173:9. The defense evidence claimed that the consensus view in the regulatory, scientific, and medical community is that the science does not support a causal relationship. 46AA19654 (Exhibit P-47); 18RT4914:7-23; 4916:8-4920:2; 23RT6351:18-6352:10; 6471:5-6472:28; 6474:23-26; 6480:15-23;

20RT5539:6-5540:8. Talc is not recognized as an ovarian cancer risk by the Centers for Disease Control or medical associations such as the American Congress of Obstetrics and Gynecologists or Society of Gynecological Oncology. 25RT7096:2-7103:9; 29RT8251:9-8261:5. No published peer-reviewed articles declare talc to cause ovarian cancer. 23RT6465:21-6466:19; 6469:2-10; 30RT8432:19-8433:7; 8486:12-8487:1. The Clyde 2017 study, which was comprehensive, did not include talc as a risk factor even though it was considered as part of its analysis. 19RT5264:26-5265:9.

1. Dr. Alan Andersen

Dr. Alan Andersen, a Ph.D. biophysicist who worked at the FDA and Cosmetic Ingredient Review (CIR), testified about CIR policies and procedures and practices. 27RT7659:16-7674:22. Dr. Andersen's degree is in biophysics; he has no formal training in toxicology. 27RT7660:11-7661:9; 28RT7865:28-7866:11, 7867:4-7

Dr. Andersen testified that CIR reviewed the safety of talc and classified it as safe. 27RT7690:22-24, 7716:1-4. He and the CIR panel did not believe that talc could move from the outside of the body in the perineal area to inside the body, and end up in the ovaries. 27RT7720:12-7722:13. Dr. Andersen also testified that he and the CIR believed a lack of consistent statistically significant positive associations was part of what contributed to the view that that the associations are not valid. 27RT7723:20-7724:7. He stated that the association could be explained by chance, confounding factors, and bias. 27RT7724:12-7726:20. Dr. Andersen opined that talc is safe in

the present practices of use and concentration, including the perineal use of talc. 28RT7851:24-7852:2.

Dr. Andersen explained that the Cosmetic Ingredient Review was an independent organization in the same breath that he testified he was installed as the director of the CIR "from day one" by the president of the industry trade association (the CTFA) that has been "securing the industry's future since 1894" 27RT7661:5-9, 7668:4-16, 7670:2-5, 28RT7865:28-7866:11; 31AA14306 (P-57). Dr. Andersen also testified that CIR panel members certified that they did not do any work for the cosmetics industry, but admitted that CIR panel members who evaluated talc were receiving payments from J&J while they were reviewing talc. 27RT7680:1-18, 28RT7911:25-28; 7915:3-15, 7916:5-12, 7917:6-18, 7919:27-7920:10.

Dr. Andersen believed that talc could not migrate from the perineal area to the ovaries even though he was aware that the FDA said it was "indisputable." 27RT7717:12-7718:2, 7722:3-13, 28RT7941:16-23.

2. Dr. Douglas Weed

Physician and epidemiologist Dr. Douglas Weed opined that "it has not been established that general [sic] use of talc causes ovarian cancer. That causal relationship at this present time with the evidence that we have does not exist." 30RT8418:21-8419:12, 8488:2-10. Dr. Weed stated that the relative risk measured in the epidemiology studies has to be at least 2 to show a more than 50 percent likelihood that an exposure caused a disease. He said, "I

need to have general causation, exposure to disease, exclude the alternatives and whatever the relative risk is that applies to that individual has to be greater than 2 in order to get to that more likely than not." 30RT8488:13-8496:10.

Defendants have paid Dr. Weed $800,000 to testify in talc trials. While Defendants called him to support their claim that only "strong" associations can be causal, before starting his consulting business Dr. Weed had published an article declaring the opposite. 30RT8515:8-11, 8519:7-8522:19.

3. Dr. Juan Felix

Dr. Juan Felix, a pathologist at the Medical College of Wisconsin (28RT8001:17-8002:4), testified that he has never observed chronic inflammation in any of his patients' ovarian cancer tissue and that he did not observe any signs of chronic inflammation in Ms. Echeverria's pathology slides. 29RT8135:9-8136:23, 8146:17-8153:18, 8163:20-22, 8207:4-13. He said that unknown causes are the leading cause of ovarian cancer. 29RT8128:13-8129:5. Dr. Felix did not identify any inflammation in Ms. Echeverria's tissue slides and no inflammation associated with the talc particles that Dr. Godleski identified. 29RT8165:21-8166:11. Dr. Felix also testified that the talc particles identified by Dr. Godleski were the result of contamination in the hospital. 29RT8169:22-8170:1.

Dr. Felix has previously testified three times on behalf of Philip Morris in lung cancer trials that cigarette smoke did not cause the plaintiff's cancer. 29RT8167:1-6, 8131:19-8132:11. He has

testified in eight talc trials that the talc found in the plaintiffs' tissue was a contaminant from the eight different hospitals where the samples were collected. 29RT8168:20-8170:22.

4. Dr. Cheryl Saenz

Dr. Cheryl Saenz, an obstetrician/gynecologist and gynecologic oncologist, testified that she has never observed chronic inflammation in any of her patients' ovarian cancer tissue and that chronic inflammation does not cause ovarian cancer. 29RT8228:25-8231:27, 8238:12-8239:6. She opined that use of talc in the perineal region does not contribute to the development of ovarian cancer. 29RT8236:26-8238:11, 8279:12-21. Dr. Saenz also opined that Ms. Echeverria's family history, obesity, having a child after age 30, and early age at menarche increased her risk of ovarian cancer. 29RT8248:13-8250:18. Dr. Saenz testified that "it's more likely than not that talc had nothing to do with Ms. Echeverria developing ovarian cancer." 29RT8272:13-8274:11.

Dr. Saenz admitted that she does not believe anyone can ever identify what caused a patient's cancer, and even if an ovarian cancer patient had the BRCA gene, a known risk factor for ovarian cancer, she would not say it caused the patient's ovarian cancer. 29RT8309:16-24. Dr. Saenz further admitted that she had never read the Sjosten study, the Henderson 1991 study, the Ness 1999 study, the Shukla 2009 study, the Genofre 2007 study, or even the Buz'Zard 2007 study. 29RT8317:11-8320:8, 8321:2-7, 8321:20-8322:5. She had never seen any of Defendants' internal documents. 29RT8325:22-28. While Dr. Saenz said that she had never seen

inflammation in an ovarian cancer patient's tissue, she admitted inflammation is not something she would be able to visualize with her eye. 29RT8322:6-25.

E. Procedural history

Ms. Echeverria filed this action in 2016 (52AA23470), and filed a first amended complaint in January, 2017. 1AA749. An expedited trial was ordered in light of Ms. Echeverria's medical condition, and trial commenced in 2017 against J&J and JJCI. 52AA23470. This was the first trial in a coordinated proceeding involving plaintiffs who developed ovarian cancer as a result of using Defendants' talcum powder products in their perineal area. 52AA23470.

1. The court rejected each of Defendants' pre-verdict challenges to Dr. Yessaian's conclusion that talc exposure caused Ms. Echeverria's cancer

Before and during trial, Defendants challenged the admissibility of Dr. Yessaian's opinion three times; each time, the court ruled against Defendants.

a. 402/*Sargon* hearing

Defendants moved to exclude the case-specific opinions of Plaintiff's experts. 1AA1250, 1AA1300, 1304, 2AA1510, 1791; Plaintiff opposed in writing. 15AA6970. The court held four days of evidentiary hearing under Evidence Code section 402 and *Sargon Enterprises, Inc. v. University of Southern Cal.* (2012) 55 Cal.4th

747. Its tentative decision rejected as "misplaced" Defendants' objection that Dr. Yessaian failed to establish that some unknown risk factor was not the cause of the cancer. 23AA 10766, 10789. Citing *Cooper v. Takeda Pharmaceuticals America, Inc.*, *supra*, 239 Cal.App.4th at 578, the court elaborated:

> 'Under the applicable substantial factor test, it is not necessary for a plaintiff to establish the negligence of the defendant as the proximate cause of injury with absolute certainty *so as to exclude every other possible cause of a plaintiff's illness,* even if the expert's opinion was reached by performance of a differential diagnosis.' [Citation.] No such etiology would ever be permitted if Defendants' standard – requiring that all *unknown* factors be eliminated – were adopted.

Id., italics by the court.

The court then allowed Defendants to depose Dr. Yessaian again. After more argument, the court issued an eleven-page final order permitting Dr. Yessaian to testify. 24AA11855-11865. It concluded that "**the methodology employed, and the studies relied upon, are sufficient to put the issue to a jury.** It is not the Court's function, under *Sargon*, to weigh the scientific evidence nor is it to determine which scientist is 'right.'" AA24:11865.

b. Nonsuit motion

After Plaintiff's case in chief, Defendants moved for nonsuit. They argued that Plaintiff had not proved specific causation in that Dr. Yessaian's testimony based on the epidemiology studies and differential etiology is "not reliable," and that Dr. Yessaian had "no

reliable basis for 'ruling in' talc." AA41:17945-17951. The trial court denied the motion. 29RT8101:15-8126:24.

c. Directed verdict motion

Defendants moved for a directed verdict on duty to warn and causation, and on punitive damages as to J&J in particular, arguing that there was no evidence showing that a managing agent, officer, or director acting on behalf of J&J engaged in conduct constituting malice. 31RT8742:15-27. The trial court denied this motion as well. 31RT8743:9.

2. The jury found for Plaintiff

The jury awarded $417,000,000 against J&J and JJCI: compensatory damages of $68,000,000 and punitive damages of $340,000,000 against J&J, plus compensatory damages of $2,000,000 and punitive damages of $7,000,000 against JJCI. 52AA2355-023552.

3. The trial court granted Defendants' motions for JNOV and for new trial

Defendants filed a combined motion for new trial along with separate motions for JNOV. 49AA21046, 49AA21066; 50AA21097.

The court granted JNOV, concluding that:

- Plaintiff did not establish that J&J was liable for JJCI's acts;

- Plaintiff did not show that before 1967 J&J knew or should have known that talc was associated with ovarian cancer;
- J&J did not have an ongoing duty to warn after 1967;
- Plaintiff did not produce clear and convincing evidence of malice on the part of a J&J director or managing agent, or on the part of JJCI; and
- Plaintiff did not establish specific causation because Dr. Yessaian did not "rule in" talc as a cause of Ms. Echeverria's cancer, and speculated to rule out other causes.

52AA23479:1-23503:7.

The court granted new trial on the same grounds and elaborated that the evidence was insufficient "as to causation as to both defendants." It also held that new trial was necessary because of error in law, jury misconduct, excessive compensatory damages as to Johnson & Johnson and excessive punitive damages as to both defendants. 52AA23475:19-23476:2, 23503:9-23518:17.

DISCUSSION

Despite decades of mounting evidence showing a significantly increased risk of ovarian cancer to users of Johnson's Baby Powder and Shower to Shower, J&J's and JJCI's managers and directors intentionally chose not to give women an opportunity to make an informed decision whether to take that risk. Instead of warning women, as others have done, Defendants deliberately embarked on a

campaign to vigorously defend J&J's hallmark product at all costs. Defendants worked "on several fronts" to discredit the "'real' statistically significant association" between the product and the disease, even though that association had been "undeniably established independently by several investigators" and would "be readily attested to by a number of reputable scientists/clinicians." 40AA17750, 51 (P-20), 25RT6921:12-6924:5. They pursued a decades-long strategy of "denying the obvious in the face of all evidence to the contrary" to protect talcum powder sales. *Id*.

Defendants' products caused Ms. Echeverria's ovarian cancer and the ten years of misery she endured before succumbing to the disease. Although Dr. Yessaian concluded that talc was more probably than not the cause of Ms. Echeverria's ovarian cancer, and it is more probable than not that but for her use of talc Ms. Echeverria would not have developed the cancer (25RT7057:8-7058:19; 26RT7392:21-7393:1), the trial court erroneously ruled that Dr. Yessaian's opinion "is insufficient as a matter of law to support the verdict" because Dr. Yessaian did not have a basis to "rule in" talc and she did not rule out other causes of cancer. 52AA23579:10-23583:20.

No reasonable judge who viewed the evidence and the law correctly could have concluded that either new trial or JNOV is appropriate.

III. Appealability

The trial court entered judgment November 17, 2017.

53AA23831. Plaintiff timely filed her notice of appeal December 18, 2017. 53AA023918. The judgment is appealable under Code of Civil Procedure section 904.1(a)(1). The backup order granting a new trial is also appealable. § 904.1(a)(4).

IV. Standard of Review

A. Order granting new trial

Appellate courts review orders granting new trial for abuse of discretion. *Mercer v. Perez* (1968) 68 Cal.2d 104, 112. However, "exercises of discretion must be guided by applicable legal principles." *David v. Hernandez* (2014) 226 Cal.App.4th 578, 592. To the extent the trial court's exercise of discretion rests on its resolution of legal questions, the appellate court reviews that resolution de novo. *Id.* at 590 "If the court's decision is influenced by an erroneous understanding of applicable law ..., the court has not properly exercised its discretion" and the decision must be reversed. *Williams v. Superior Court* (2017) 3 Cal.5th 531, 540 ("An order that implicitly or explicitly rests on an erroneous reading of the law necessarily is an abuse of discretion.")

On a motion for new trial based on insufficiency of the evidence, the court may draw inferences from facts contrary to those drawn by the jury (*Horsford v. Board of Trustees of California State University* (2005) 132 Cal.App.4th 359, 379), and the appellate court will defer to the trial court's resolution of conflicts in the evidence. (*Oakland Raiders v. National Football League* (2007) 41 Cal.4th 624, 636.) Nevertheless, deference is proper only when the trial

court correctly states the evidence it is relying upon. *Robbins v. Alibrandi* (2005) 127 Cal.App.4th 438, 452 ("We do not defer to the trial court's ruling when there is no evidence to support it"); *People v. Cluff* (2001) 87 Cal.App.4th 991, 998 ("A trial court abuses its discretion when the factual findings critical to its decision find no support in the evidence.") In other words, the trial court must exercise its discretion in light of the **actual** evidence before it, not a set of facts that is contrary to the record.

Before granting new trial on the basis of erroneous evidentiary rulings, jury instruction errors, or misconduct, the court must find prejudice as well as error. Cal. Const., Art. VI, § 13. The court has no discretion to grant new trial for harmless error. (*Sherman v. Kinetic Concepts, Inc.* (1998) 67 Cal.App.4th 1152, 1161.)

A trial judge is not permitted to substitute her judgment for that of the jury on the amount of damages unless the award is excessive. *Bigboy v. County of San Diego* (1984) 154 CA3d 397, 406. A verdict is excessive where it is "so grossly disproportionate as to raise a presumption that it is the result of passion or prejudice" (*Neal v. Farmers Ins. Exchange* (1978) 21 Cal.3d 910, 928), or "so large that, at first blush, it shocks the conscience and suggests passion, prejudice or corruption on the part of the jury." *Major v. Western Home Ins. Co.* (2009) 169 Cal.App.4th 1197, 1213. When the evidence is sufficient to sustain some but not all alleged damages, the court of appeal will reduce the judgment to the amount supported by the evidence. *Behr v. Redmond* (2011) 193 Cal.App.4th 517, 533.

B. Judgment notwithstanding the verdict

This Court reviews an order granting JNOV de novo, under the same standard that applies to the trial court, i.e. in the light most favorable to the party who won the verdict. *Oakland Raiders v. Oakland-Alameda County Coliseum, Inc.* (2006) 144 Cal.App.4th 1175, 1194. The trial court may grant JNOV only if there is no substantial evidence and no reasonable inferences available to support the verdict. *Webb v. Special Electric Co., Inc.* (2016) 63 Cal.4th 167, 192; *Hauter v. Zogarts* (1975) 14 Cal.3d 104, 110.

In ruling on a motion for JNOV, a court may not change a prior ruling as to the admissibility of evidence. "[W]e must take the record as we find it. We cannot strike or disregard any evidence favorable to the prevailing party merely because it was erroneously received." *Waller v. Southern California Gas Co.* (1959) 170 Cal.App.2d 747, 757; *Estate of Callahan* (1967) 67 Cal.2d 609, 617. "In assessing whether judgment notwithstanding the verdict was properly granted, we consider the trial that was actually conducted, not the one that might have been conducted." *Garretson v. Harold. Miller* (2002) 99 Cal.App.4th 563, 575,

Neither the trial court nor this Court may invade the province of the jury, reweigh the evidence or determine the credibility of witnesses. *Quintal v. Laurel Grove Hospital* (1964) 62 Cal.2d 154, 159*; Knight v. Contracting Engineers Co.* (1961) 194 Cal.App.2d 435. Conflicts in the evidence are resolved **against** the moving defendant and in favor of the plaintiff; all reasonable inferences are drawn against the moving defendant and in favor of the plaintiff.

Cooper v. Takeda Pharm. Am., Inc., *supra*, 239 Cal.App.4th at 572-573. The order granting JNOV must be reversed if any substantial evidence supports the jury's conclusion, regardless whether there was also conflicting evidence. *Gillotti v. Stewart* (2017) 11 Cal.App.5th 875, 898.

V. Both the Order Granting New Trial and the Judgment Notwithstanding the Verdict Must Be Set Aside Because the Trial Court Misinterpreted the Law and Misstated the Testimony in Concluding There Was Insufficient Evidence to Support the Verdict

The court adopted the same reasoning for granting new trial as it used to grant JNOV. (52AA23508:12-14.) Both the new trial and JNOV rulings reflected abuses of discretion and legal error, because the court both misunderstood the law and misstated the evidence. *Williams v. Superior Court*, *supra*, 3 Cal.5th at 540; *Robbins v. Alibrandi*, *supra*, 127 Cal.App.4th at 452.

A. The court misinterpreted the law of causation and misstated Dr. Yessaian's causation opinion

The new trial order states that Dr. Yessaian did not have a basis to "rule in" talc as a cause of Ms. Echeverria's ovarian cancer (52AA23495) and that she did not "rule out" other causes of cancer. 52AA23498. Also, the court stated that Dr. Yessaian supposedly "did not consider all available epidemiology and apply it to the facts relative to Echeverria except when it favored Echeverria." 52AA23508:15-17. The court erred.

1. A plaintiff need not rule out all other possible causes to show that the defendant's product was a substantial factor in causing harm

Acknowledging that Dr. Yessaian was able to rule out genetics; history of family members with cancer at an early age or breast or ovarian cancer; polycystic ovarian syndrome; endometriosis; tobacco and alcohol use and use of hormone replacement therapy, the court took issue with the fact that Dr. Yessaian was unable to completely rule out other possible causes- age, number of ovulatory cycles and obesity, and only "discounted" them because of their lower statistical probability. 52AA023498-23499.

This critique of Dr. Yessaian's differential diagnosis directly conflicts with the explicit holding in *Cooper, supra*. ("Dr. Smith was not required to rule out all other possible causes of bladder cancer before his testimony could be deemed admissible. The trial court's ruling to the contrary contravened California law." 239 Cal.App.4th at 581; "To be admissible, an expert physician's testimony, even in the context of the physician's performance of a differential diagnosis, need not *rule out* the applicability of all other possible causes of disease where there is no substantial evidence that other known risk factors for bladder cancer acted on Jack Cooper and provided an alternative explanation for his disease." *Id*. at 586, italics in original.)

To prove causation in a toxic tort action it is only necessary to show that the toxin in question is a substantial factor in causing the disease. This is true even where other factors have *admittedly* played a role in the development of the disease in question. *Cooper,* 239 Cal.App.4th at 587 (although physician acknowledged alternative

causes also played an important role in the development of the plaintiff's bladder cancer, jury was free to give weight to physician's testimony that prescription drug was "the most substantial factor.")

According to the *Cooper* court, the trial court's rationale that the plaintiff's expert in that case "did not adequately consider and definitively rule out potential causes" of cancer other than the defendant's drug "misapprehended the substantial factor test of causation." *Id.* at 577. A plaintiff does not have to rule out all other possibilities to express an opinion that the defendants' conduct caused the plaintiff's harm, "even if the expert's opinion was reached by performance of a differential diagnosis." 239 Cal.App.4th at 578.

"Bare conceivability of another possible cause does not defeat a claim; the relevant question is whether there is 'substantial evidence' of an alternative explanation for the disease." 239 Cal.App.4th at 586.

2. In concluding that Dr. Yessaian did not "rule in" talc as a cause of ovarian cancer, the trial court misstated Dr. Yessaian's testimony that talc was more likely than not the cause of Ms. Echeverria's cancer

The trial court mistakenly concluded that "[i]n conducting a differential etiology Yessaian was required **first** to establish talc **is a probable cause** of ovarian cancer. Without establishing that fact, she could not "rule in" talc as a probable cause of Echeverria's disease." 52AA23496, emphasis added. This is not only inconsistent with the court's repeated pre-verdict rulings, but is a clear error of

law and demonstrates a fundamental misunderstanding of a differential diagnosis.

The authorities cited by the court (*Glastetter v. Novartis Pharms. Corp.* (8th Cir. 2001) 252 F.3d 986, 989 and *Cooper, supra*, 239 Cal. App. 4th at 593-594) do not make such a statement. There is no such requirement. While a plaintiff must show that a substance **can cause** cancer, and that it was more likely than not **a cause** of the plaintiff's injury, a plaintiff is not required to show that the substance "is a probable cause of cancer" in any member of the general population in order to conduct a differential diagnosis. *See* 31RT8755:27-8757:7 ("To establish this claim, Plaintiff Eva Echeverria must prove all of the following: … 7. That the Johnson & Johnson Defendants' failure to warn was a substantial factor in causing Plaintiff Eva Echeverria's harm. A substantial factor in causing harm is a factor that a reasonable person would have considered to have contributed to the harm… It doesn't have to be the only cause of the harm.").

The term "probable cause" is not found anywhere in the *Glastetter* decision. As the court there correctly pointed out, the differential diagnosis considers ***plausible*** causes: "In performing a differential diagnosis, a physician begins by "ruling in" all **scientifically plausible** causes of the plaintiff's injury. The physician then "rules out" the least **plausible** causes of injury until the most likely cause remains." 252 F.3d at 989, emphasis added. This is exactly what Dr. Yessaian did here.

The one time the term "probable cause" is mentioned in *Cooper* is in a completely different context – the cause of the plaintiff's disease. The *Cooper* court pointed to studies showing a relative risk greater than 2.0, stating: "Thus, having considered and ruled out other background causes of bladder cancer based on his medical records, Dr. Smith could rely upon those studies to make his differential diagnosis ruling in Actos® – as well as smoking –and concluding was the most **probable cause** of Jack Cooper's disease." *Cooper, supra,* 239 Cal.App.4th at 594, emphasis added. Again, this is what Dr. Yessaian did here. She relied on four epidemiology studies that had relative risks above 2.0 in forming her opinion that talc more likely than not caused Ms. Echeverria's ovarian cancer, as well as the fact that other epidemiological studies all reported relative risks in the 1.2 to 1.3 range, consistently indicating a trend of 30 percent increased risk for the general population. 26RT7283:1-7284:2.

Further, in concluding that Dr. Yessaian did not have a basis to "rule in" talc, the court mischaracterized Dr. Yessaian's reliance on the four studies she testified about.

> The only basis upon which Yessaian opined that talc is a scientifically plausible cause of ovarian cancer was epidemiology and general reference to inflammation. But, none of the four studies on which she was permitted to rely (Cramer 1982; Rosenblatt 1992; Cramer 1999; and Wu 2009) showed odds ratios in excess of 2.0 that a woman using talc would develop serous ovarian cancer (i.e. that she had 50% or greater chance of developing cancer than women who did not use talc). Two did not break out serous ovarian cancer, although Yessaian admitted that it

> was important to focus on histological type. [Record refs.] The two that did (Cramer 1999 and Wu 2009) showed a relative risk ratio of 1.70."

52AA23496-23497, citing (Tr. 2896:1-4; 2834:27-2835:12 [26RT7359:1-4. 7297:27-7298:12].).

The conclusion misinterprets California law, misapprehends principles of epidemiology, misstates the evidence in the record, and fails to acknowledge critical testimony to the contrary. In permitting Dr. Yessaian to testify and allowing the case to go to the jury, the trial court had specifically rejected these arguments, including the contention that the studies did not stratify their data for the Plaintiff's specific **subtype** of ovarian cancer. 24AA11865.

The court ignored Dr. Yessaian's testimony about why she chose 2.08 relative risk when it stated that the relative risk reported by Wu 2009 most applicable to Ms. Echeverria was 1.70 (between ever use talc and serous ovarian cancer), and therefore tended to disprove causation. 52AA24396-24397. Dr. Yessaian testified that it was reasonable for her to choose the 2.08, which was a conservative estimate of the risk: It is important to look at frequency and duration of exposure (25RT6994:12-6995:4), as there is evidence of a dose response – a linear increase in risk with increased exposure 25RT6997:9-17. Wu assessed use for greater than 20 years of use more than 30 times per month; Ms. Echeverria had used the product for 40 years, more than 60 times a month. 25RT7054:21-7055:9; 26RT7369:3-7370:18, 7372:24-7375:26. As Dr. Yessaian explained: "that's a conservative estimate. She used it more than 40 years and more than 60 times per month. **So, if anything, she should fall**

on the higher end of that confidence interval, that 3.23." 26RT7374:25-7375:7, emphasis added.

The trial court could not substitute its opinion for the opinion of Dr. Yessaian about the import of the studies. (*Cooper, supra*, 239 Cal.App.4th at 587.)

a. There is no requirement of a 2.0 or greater risk assessment

Before trial, and before the verdict, the court recognized that California law does not require a showing of a "plaintiff specific" relative risk in excess of 2.0: "I did not agree with the defense that you've got to put in a 2.0 risk assessment. I don't think the case law requires that." 11RT2808:13-15. It correctly rejected Defendants' claim that *Cooper v. Takeda, supra*, requires that a "plaintiff specific" odds ratio in excess of 2.0. 24AA11858. Thus the court correctly concluded that Dr. Yessaian could properly opine on specific causation through a differential diagnosis, relying not only on studies showing 2.0 and above, but on other studies showing an increased risk of less than 2.0. 11RT2821:28-2823:24. It explained how using this information and ruling out other factors, Dr. Yessaian could opine that talc was the cause of the Plaintiff's cancer. 10RT2424:20-2426:24. The court's later statement that Dr. Yessaian's "specific causation" opinion was supported by only four studies contradicts the court's own premise.

No California court, including *Cooper,* has ever held that when performing a differential diagnosis, an expert may rely only on studies that show greater than a 2.0 relative risk for the general

population to conclude that an exposure is more likely than not a potential cause of a specific plaintiff's disease. *Cooper* said the studies were admissible because they showed a relative risk greater than 2.0, but did not say if they were less than 2.0 they would be inadmissible, or that such studies could not be used to establish that a substance can cause disease. 239 Cal.App.4th at 593.

Cooper relied on *Daubert v. Merrell Dow Pharmaceuticals, Inc.* (9th Cir. 1995) 43 F.3d 1311 ("*Daubert II*"). *Daubert II* likewise did not require that studies show more than a 2.0 relative risk. On the contrary, the Ninth Circuit explained that studies showing less than a 2.0 relative risk for the general population are relevant and admissible to show causation for a particular plaintiff, where, as here, the expert is relying upon not just epidemiology, but information and factors specific to the plaintiff. 43 F.3d at 1321, fn. 16. See also *Pick v. Am. Med. Sys., Inc.*, 958 F.Supp. 1151, 1160 (E.D. La. 1997) (stating that a relative risk of 2.0 implies a 50% probability of specific causation, but acknowledging that a study with a lower relative risk is admissible, if not sufficient, to support a verdict on causation); *Pafford v. Sec'y, Dept. of Health & Human Servs.*, 64 Fed. Cl. 19 (2005) (acknowledging that epidemiological studies finding a relative risk of less than 2.0 can provide supporting evidence of causation), aff'd, 451 F.3d 1352 (Fed. Cir. 2006); *Stevens v. Sec'y of HHS*, 2001 WL 387418, at *12-13 (Fed. Cl. 2001); *Grassis v. Johns-Manville Corp.*, 591 A.2d 671, 675 (N.J. Super. Ct. App. Div. 1991) ("The physician or other qualified expert may view the epidemiological studies and factor out other known risk factors such

as family history, diet, alcohol consumption, smoking ... or other factors which might enhance the remaining risks, even though the risk in the study fell short of the 2.0 correlation.); see also Restatement (Third) of Torts: Liability for Physical and Emotional Harm, § 28 cmt. c.(4) ("[A]ny judicial requirement that plaintiffs must show a threshold increase in risk or a doubling in incidence in a group study in order to satisfy the burden of proof of specific causation is usually inappropriate.")

b. Epidemiological studies showing less than a 2.0 relative risk do not disprove causation

The trial court's post-verdict analysis also relied upon the mistaken assumption that epidemiological studies showing less than 2.0 relative risk "tend to disprove causation." 52:AA23496-23497. To the contrary, this presents a jury question. As the court had earlier correctly noted: "[F]rom a scientific perspective, whether an odds ratio of 1.3 represents an association that, when supplemented with other factors, could be sufficient for purposes of general causation is a jury question. While it may be appropriate for Defendants to argue that a 1.3 ratio is not a 'strong' association, that is an issue a jury must weigh." 23AA10793 at 96.

The only time a study showing a statistically significant increased risk less than 2.0 would tend to disprove causation for an individual would be the "rare situation" where there is no evidence specific to the injured party, and therefore nothing to differentiate the probability of causation from the general population. Otherwise,

"a relative risk of less than two could be combined with other information to show that it is more likely than not that the alleged cause is responsible for the plaintiff's injury." *See* Ref. Guide on Epidemiology, Ann. Ref. Manual on Sci. Evid. 333 (2d ed.) 2004 WL 48155, 52; *Landrigan v. Celotex Corp.* (N.J. 1992) 605 A.2d 1079, 1087). Such data could come from a differential diagnosis, clinical data, or animal studies. *Caterinicchio v. Pittsburgh Corning Corp.* (N.M. 1992) 605 A.2d 1092; *Daubert II*, *supra*, 43 F.3d at 1321, fn. 16.

c. Dr. Yessaian's differential diagnosis-based conclusion relied on more than epidemiology and inflammation

The trial court's statement that "[t]he only basis upon which Yessaian opined that talc is a scientifically plausible cause of ovarian cancer was epidemiology and general reference to inflammation" (52AA23496) misstates the record. To determine potential mechanism and biological plausibility, Dr. Yessaian considered studies in both humans and animals showing that talc applied externally can migrate to the peritoneal cavity. 25RT6994:25-6996:1; 25RT7036:15-7038:20; 25RT6950:20-6951:11. She relied upon other non-epidemiological evidence, including cell studies, when she considered the mechanism reported in the literature as to how talc causes inflammation, which leads to malignant transformation of normal cells to cancerous cells. 25RT6997:18-6998:6; 7000:3-7002:25.

Further, unlike the expert in *Daubert II* (43 F.3d at 1319), a significant amount of Dr. Yessaian's testimony was devoted to evidence that did not involve epidemiology. As Ms. Echeverria's treating doctor for over ten years, Dr. Yessaian conducted a differential diagnosis, and relied upon multiple examinations of the Plaintiff as well as her records and the results of testing of her blood and cancerous tissue. (Section II. B. 1.) Dr. Yessaian also relied upon the presence of talc in Ms. Echeverria's cancer tissue. 25RT:7038:21-7039:11; 21RT5761:8-5762:27; 25RT6911:17-20.

This is all consistent with the court's opinion during trial that using a differential etiology was "an acceptable methodology" and that it was "not unreasonable" for Dr. Yessaian to rely on literature showing a RR of 1.3, and "if you look at it as a whole, it's not an improper way to use a differential diagnosis." 26RT7412:17-7414:24. The court also noted that **statistics are "only one piece of this whole testimony.** But I'm not going to strike the testimony." 26RT7416:13-28, emphasis added.

d. The court misstated Dr. Yessaian's testimony

The court twice emphasized that Dr. Yessaian believed the cause of the cancer was unknown, stating that Dr. Yessaian conceded "that it was *probable* Echeverria's cancer was caused by some risk factor science does not yet know about" and testified it was "'probable' the cause of the cancer was unknown." 52AA023499, italics by the court. The actual record contradicts these statements.

Dr. Yessaian testified that there was less than a 50% chance that Ms. Echeverria's cancer was idiopathic. 26RT7351:16-26; 7353:24-7354:1; 7357:13-18. Even though at the beginning of a lengthy answer to one question (26RT7350:20) Dr. Yessaian used the word "probable," the remaining 80 words of her 83-word response make it apparent she emphatically believes that an unknown risk factor is less than probable, and only a possibility. 26RT7350:17-7351:26. Dr. Yessaian repeatedly emphasized that an unknown risk factor was only a possibility; she concluded by saying "Less probable than not, it's a possibility. But less than 50 percent. Yes, it is a possibility, but, again, less than 50 percent." 26RT7353:18-23. The trial court also faulted Dr. Yessaian because she "could not put a 'percentage' on how less likely that was." 52AA023499. This conflicts with the law as well as the court's earlier statements that Dr. Yessaian could rule in talc without putting a specific number on the risk. 26RT7412:17- 7414:24. If she could rule in talc without a specific risk number, it would make no sense to require her to use specific percentages to rule out unknown causes. Anyway, there is no requirement that an expert must rule out unknown causes in performing a differential diagnosis, let alone establish percentages to do so. *Cooper, supra,* 239 Cal.App.4th at 585–86. ("Bare conceivability of another possible cause does not defeat a claim; the relevant question is whether there is 'substantial evidence' of an alternative explanation for the disease.")

Even ignoring the holding of *Cooper*, Dr. Yessaian's testimony ruling out other possible causes shows that her conclusions cannot

be written off as "speculation." Her extensive analysis is well-supported by scientific evidence, and her differential diagnosis methodology was appropriate and properly utilized. She ruled in all scientifically plausible causes of Ms. Echeverria's disease and ruled out the least plausible causes until the most likely cause remained.

B. The trial court misinterpreted the law and ignored the evidence establishing J&J's direct liability for failure to warn

In granting new trial and JNOV as to J&J the court found:

- Plaintiff did not establish that J&J was liable for JJCI's acts;
- Plaintiff did not show that before 1967 J&J knew or should have known that talc was associated with ovarian cancer; and
- J&J did not have an ongoing duty to warn after 1967.

52AA023469 at 23503 to 519. These rationales overlook the law and the facts.

Decades of documents demonstrated that J&J knew of the ovarian cancer risk posed by genital use of talcum powder, and remained intimately involved in suppressing information relating to the link between talc and ovarian cancer, and trying to stifle negative recommendations of health professionals. That the jury understood the substantial evidence of J&J's involvement from 1967 through 2017 is demonstrated by the amounts awarded as against each of the Defendants.

Manufacturers have a duty to warn consumers about the known and reasonably knowable hazards inherent in their products (*Taylor v. Elliott Turbomachinery Co. Inc.* (2009) 171 Cal.App.4th 564, 577), but no duty to warn of risks that are "merely speculative or conjectural, or so remote and insignificant as to be negligible." *Carlin v. Superior Court* (1996) 13 Cal.4th 1104, 1112. "The supplier of a product must use reasonable care to give users of the product the information the supplier possesses which is necessary to make its use safe." *Buckner v. Milwaukee Electric Tool Corporation* (2013) 222 Cal.App.4th 522, 535, internal citations omitted.

The trial court commented that Plaintiff did not ask for a jury instruction on a manufacturer's duty to cause a subsequent manufacturer to place a warning on a product or to recall the product. (52AA23488:4-15.) This is irrelevant. See *Cleveland v. Johnson* (2012) 209 Cal.App.4th 1315, 1334 (jury verdict upheld though plaintiff "did not expressly proceed on this theory at trial, and the jury was not instructed on this principle of successor liability").

1. The duty to warn applies to possible risks

The trial court misunderstood the law when it found that J&J had no duty to warn as of 1967 because it did not "kn[ow] or should have known prior to 1967 that talc more probably than not caused ovarian cancer…" 52AA023480. This was error. Plaintiff was **not** required to prove that required to prove that J&J knew that "talc more probably than not caused ovarian cancer." As CACI 1222 makes clear, Plaintiff was required to prove that J&J "knew or

reasonably should have known that the [*product*] **was dangerous or was likely to be dangerous when used or misused in a reasonably foreseeable manner."** The fact that there is clear evidence in the form of an admission that J&J was aware the product was **not safe** is sufficient by itself to establish this element. The fact there is a debate or triable issue of fact as to whether or not a product poses a danger to consumers does not mean that as a matter of law manufacturers have no obligation to warn consumers of the potential for injury. California law specifies no threshold level or degree of risk that must be achieved in order to impose a duty to warn, but instead asks what a reasonably prudent manufacturer would have done. *Anderson v. Owens-Corning Fiberglas Corp.* (1991) 53 Cal.3d 987, 1002; *Chavez v. Glock, Inc.* (2012) 207 Cal.App.4th 1283, 1305.

The fact that there is only a possibility of injury as to any given consumer does not immunize a manufacturer from liability. When the lives of thousands of consumers are endangered, the fact a risk may harm only a small fraction of product users does not preclude a finding of malice. Not every Ford Bronco will roll over and injure the occupants. *Romo v. Ford Motor Co.* (2003) 113 Cal.App.4th 738 (affirming punitive damage award). Not everyone who smokes will suffer from lung cancer. *Bullock v. Philip Morris USA, Inc.* (2011) 198 Cal.App.4th 543 (same). Not everyone who is exposed to asbestos products contracts mesothelioma. *Pfeifer v. John Crane, Inc.* (2013) 220 Cal.App.4th 1270 (same). Not everyone who drives a Pinto will be involved in post-collision fire. *Grimshaw v. Ford Motor*

Co. (1981) 119 Cal.App.3d 757 (same) Not everyone who uses Actos will get bladder cancer. *Cooper v. Takeda Pharmaceuticals America, Inc.*, *supra*, 239 Cal.App.4th 555 (same); see also, *Wooderson v. Ortho Pharmaceutical Corp.* (1984) 235 Kan. 387, 408 (manufacturer had duty to warn of "possible association" between use of product and serious medical risks).

Consumers deserve the opportunity to make informed choices, even though manufacturers like J&J are willing to gamble with their lives. "[T]o simply conclude that it is unreasonable to impose liability where the known danger threatens only a statistically small percentage of the drug's users is to beg the very question of negligence. The size of the class of endangered persons is one-albeit only one of the factors to be considered in deciding whether the manufacturer's warnings were, in fact, reasonable." *McEwen v. Ortho Pharmaceutical Corp.* (1974) 270 Or. 375, 389. "[N]either approval of its labelling by the Federal Drug Administration nor the fact that the danger threatens a statistically small percentage of users will, as a matter of law, relieve a drug manufacturer of its duty to warn of dangers it knows or has reason to know." *Stanback v. Parke, Davis & Co.* (W.D. Va. 1980) 502 F.Supp. 767, 770 fn.8.

2. By 1967, J&J knew or should have known that their talcum powder was unsafe but nevertheless failed to warn consumers

J&J manufactured Johnson's Baby Powder until 1967. 52AA023480. Plaintiff used Johnson's Baby Powder for at least two years while J&J was the manufacturer (27RT7521:8-15, 7526:6-11,

7527:21-7528:3), and that fact alone supports a finding of direct liability on the part of J&J.

The court nevertheless concluded that J&J had no duty to warn because "[t]here was no showing that as of 1967 there was any suggestion by the scientific or medical community that talc was associated with ovarian cancer. And, no internal documents from the company prior to that date suggest that conclusion." 52AA3480. This is incorrect. The fact that there is clear evidence in the form of an admission that J&J was aware the product was **not safe** is sufficient by itself to establish a duty to warn.

In early 1964 (prior to the incorporation of JJCI), a "manager or director of J&J," Ashton, established the largest commercial uses of Dry Flo [cornstarch product] are … as a condom lubricant where it replaced talc because it was found to be **absorbed safely** in the vagina whereas, of course, **talc was not**." 31AA14294 at 14296, emphasis added. In other words, by 1964, J&J knew that talc could not be safely absorbed in the vagina, "of course," but did not warn women not to apply its talcum powder to their vagina. Whether or not J&J knew or should have known at that time that talc caused ovarian cancer, under California law they had a duty to warn women that their product was not safe, i.e. dangerous. *Buckner v. Milwaukee Electric Tool Corporation* (2013) 222 Cal.App.4th 522, 535 ("The supplier of a product must use reasonable care to give users of the product the **information the supplier possesses which is necessary to make its use safe**. ([*Gall v. Union Ice Co.* (1951) 108 Cal.App.2d 303, 309]; Rest.2d Torts, § 388, com. g, pp.

1043–1044.) The supplier may be required to warn of the risks of the product, or to instruct the user how to use the product safely. (*Finn v. G.D. Searle & Co.* (1984) 35 Cal.3d 691, 699]," emphasis added; see also 8755:27-8757:16 ("Plaintiff Eva Echeverria must prove all of the following:… 2. That the Johnson & Johnson Defendants knew, or reasonably should have known, prior to April 2007 that the Johnson's Baby Powder… products where dangerous or likely to be dangerous when used or misused in a reasonably foreseeable manner… 5. That a reasonable manufacture or seller under the same or similar circumstances would have warned of the danger.")

Even if J&J considered the product unsafe for only a fraction of users, that would not negate its duty to warn. See e.g. *McEwen v. Ortho Pharmaceutical Corp.* (1974) 270 Or. 375, 389 (substantial evidence existed to support finding that if adequate warnings had been timely given plaintiff's use of oral contraceptives would have been discontinued before her eye injuries became irreversible) "[T]o simply conclude that it is unreasonable to impose liability where the known danger threatens only a statistically small percentage of the drug's users is to beg the very question of negligence. The size of the class of endangered persons is one-albeit only one-of the factors to be considered in deciding whether the manufacturer's warnings were, in fact, reasonable."; *Stanback v. Parke, Davis & Co.* (W.D. Va. 1980) 502 F.Supp. 767, 770 fn.8 ("[N]either approval of its labelling by the Federal Drug Administration nor the fact that the danger threatens a statistically small percentage of users will, as a matter of law, relieve a drug manufacturer of its duty to warn of dangers it

knows or has reason to know"); *Wooderson v. Ortho Pharmaceutical Corp.* (1984) 235 Kan. 387, 408 (manufacturer had duty to warn of "possible association" between use of product and hemolytic uremic syndrome, malignant hypertension, or acute renal failure).

Moreover, the reasonable inference from the evidence presented is that when Ashton established that talc could not be safely absorbed in the vagina in 1964, he was referring to the risk of ovarian cancer. While no evidence was introduced showing that Ashton was referring to another risk that made talc not safely absorbed in the vagina, Plaintiff presented evidence that J&J knew or should have known in 1964 that talc caused ovarian cancer. A study published by Henderson in 1971 in the open literature reported the "concern… about the perineal exposure to talc and the occurrence of ovarian cancer in woman" as well as the presence of talc particles in ovarian tissue. 17RT4577:13-4578:1; 18RT4989:25-4990:24. By 1975, J&J was concerned that a small donation it had made to a cancer researcher would give the researcher an "opening to put [them] on notice re the talc/ovary problem." 31AA14305. Clearly, in 1975, the "talc/ovary" problem was the talc/ovarian cancer problem. The reasonable inference is that the 1964 comment about talc "of course" not being safely absorbed in the vagina referred to the risk of ovarian cancer. The jury could have, and did, reasonably infer that by 1967 J&J knew that talc could not be safely absorbed in the vagina and knew or reasonably should have known

that it could not be safely absorbed in the vagina because of the risk of ovarian cancer.

3. The duty to warn persists after the manufacturer stops making the product

California law does not condition a manufacturer's duty to warn on continuing to market the product. To the contrary, a manufacturer's duty to warn arises when it learns of a product's dangerous propensities, even after the product has been on the market for a while. *Lunghi v. Clark Equipment Co.,* (1984) 153 Cal.App.3d 485, 494.

The duty to warn persists as to products even after the manufacturer stops producing the product and when the product is sold by a third party. E.g, *T.H. v. Novartis Pharmaceuticals Corporation* (2017) 4 Cal.5th 145, 201-202 (rejecting manufacturer's claim that it had no duty to warn users of drug it no longer manufactured that was sold several years later by another company to which it had transferred manufacturing rights); see also, *Hernandez v. Badger Construction Equipment Co.* (1994) 28 Cal. App.4th 1791, 1827 (post-sale duties owed to prior product purchasers); *Balido v. Improved Machinery, Inc.* (1972) 29 Cal.App.3d 633, 649. The modified CACI 1222 given here did not place a time limit on how long the duty continued. In fact, with the trial court's modifications, the instruction indicated to jurors that the duty extended to 2007. 31RT8755:24-8757:23.

Turning over manufacturing to JJCI in 1967 did not terminate J&J's duties to consumers of Johnson's Baby Powder. (Not only is

the product called "Johnson's Baby Powder," but the front of the label itself prominently states "Johnson & Johnson." See 35AA15615 (P-49).)

4. J&J remained directly involved in hiding the risk of ovarian cancer associated with talcum powder products from 1967 to when Ms. Echeverria's cancer surfaced

Even if the duty to warn would not ordinarily persist, the undisputed record shows that the trial court erred in placing a temporal boundary on J&J's continuing duty to warn, because J&J played an active role, at least until Ms. Echeverria's cancer symptoms began, in ongoing efforts to denigrate or even conceal the scientific evidence of the link between their product and ovarian cancer:

- A study published by Henderson in 1971 reported the "concern… about the perineal exposure to talc and the occurrence of ovarian cancer in woman" as well as the presence of talc particles in ovarian tissue. 17RT4577:13-4578:1; 18RT4989:25-4990:24.
- By 1975, J&J was concerned that a small donation it had made to a cancer researcher would give the researcher an "opening to put [them] on notice re the talc/ovary problem." 31AA14305. Clearly, in 1975, the "talc/ovary" problem was the talc/ovarian cancer problem. 31AA014305 (P-55); 17RT4545:1-4548:12.
- A 1986 "Technological Forecast" document from Mr. Ashton's files repeatedly referred to J&J, not to JJCI or any

other entity. The document notes that "[s]afety of cosmetic powders has been a concern, especially among health professionals." It also states, "[r]etrospective studies have implicated talc use in the vaginal area with the incidence of ovarian cancer. While a CTFA sponsored animal study has shown that talc does not migrate, this concern does affect use of powders by adult women." 31AA14340 (P-9); 17RT4548:13-4555:9.

- A 1992 J&J document titled "Johnson's Baby Powder" listed "negative publicity from the health community on talc (inhalation, dust, negative doctor endorsements, cancer linkage) continues as a "major obstacle." 31AA14263 (P-10); 4555:10-4557:21.
- A 1994 "Talc Question and Answers" document also repeatedly referenced J&J without mentioning JJCI. The document noted that studies had "linked the use of talcum powder to ovarian cancer" and that scientists had reported that "there may be a link between the use of talc and increased risk of ovarian cancer." 31AA14326 (P-764); 17RT4563:11-4571:2.
- The entity bound to the 1994 agreement to support the CTFA's efforts to "secur[e] the industry's future" is J&J, not JJCI. 31AA14306 (P-57); 17RT4584:23-4586:25.
- In 2002, Bill Ashton, the J&J manager or director who established that talc could not be safely absorbed in the vagina in 1964, was still working to hide the link between perineal talc use and ovarian cancer. Mr. Ashton

communicated with Imerys about how they had "been successful thus far in fending off the NTP classification of talc as being a potential human carcinogen." 40AA017752 (P-27); 16RT4375:4-4380:1.

- In 2004, Mr. Ashton communicated with Imerys about a study that offered "some compelling evidence in support of the 'migration' hypothesis" and a "formula for NTP classifying talc as a causative agent in ovarian cancer." 30AA14091 (P-396); 16RT4380:2-4384:5. The parties stipulated that J&J, not JJCI, received this fax in 2004. 44AA19052; 27RT7654:16-7655:1.
- In 2005, Mr. Mann of JJCI expressed frustration to other executives at JJCI and J&J, including Susan Nettesheim, a J&J Vice President, and John Hopkins, "a director at Johnson & Johnson in research and development," about how "it [wa]s VERY difficult to have any impact on IARC." 31AA14286 (P-264); 17RT4611:17-20, 4612:14-18.
- Also in 2005, Gerd Ries, a J&J regulatory employee, wrote to his colleagues at JJCI, including Mr. Mann, to inquire "[t]he critical question that determines how we need to handle this case [the NTP review of talc] internally is what the chances are that we can prevent this [NTP] classification. Can you offer a percentage of success?" 31AA014280; 17RT4607:13-20.

All of these show J&J's direct involvement with the product and its warnings over a period of decades. Up through at least 2005,

J&J's managing agents and employees played a continuing, key role in public relations and regulatory efforts to discredit the results of medical and scientific demonstrations connecting talc use to ovarian cancer. High level J&J employees actively engaged in a strategy of "denying the obvious in the face of all evidence to the contrary," and countering negative recommendations of health professionals. See section II.A., *supra*; see also 27RT7657:7-7658:10; 17RT4541:15-4544:25; 17RT4544:26-4545:10; 17RT4555:13-4556:11; 40AA17750; 52AA23490; 31AA14283 (P-262).

5. J&J directed the actions of JJCI

Aside from the undisputed evidence of J&J's direct involvement, the jury could have easily and reasonably drawn the inference that J&J was directing the actions of high level JJCI employees. Most of the evidence presented at trial referred to "Johnson & Johnson," not "Johnson & Johnson Consumer, Inc." Lorena Telofski was designated to testify on behalf of both J&J and JJCI. 16RT4397:11-18. Where her testimony was specific to "Johnson & Johnson Consumer, Inc." alone, she drew a distinction and limited her testimony to only JJCI – but she did so in only three instances. 16RT4398:23-4399:4, 4401:7-19, 4410:10-23. Neither Ms. Telofski nor any other witness contradicted the documents showing J&J's involvement with Johnson's Baby Powder after the formation of JJCI in 1967. Further, employees, managers, directors and officers shifted back and forth between the two entities such that it was often unclear which persons worked for which entity. *See e.g.* 17RT4592:10-4593:2. Internally generated correspondence likewise

failed to distinguish. In an August 30, 1993 letter to John Hopkins, Donald Jones identified him as "Johnson & Johnson Limited, England." 31AA14279. The letter, signed by Donald Jones, is on JJCI letterhead. Yet the corporate representative for J&J stated that Don Jones "was in the research and development group in research and planning" and confirmed that this was a J&J document. 17RT4558:10-15.

6. JJCI knew about the risk of ovarian cancer from talc but continued to ignore the danger and promote the product as safe

JJCI was not only aware of the risk of ovarian cancer from perineal talc use, but worked with Imerys and J&J to hide the risk from the public and prevent agencies like the NTP and IARC from classifying talc as a human carcinogen. Further, the reasonable inference from the documents showing how J&J worked with JJCI to prevent the classification of talc as a human carcinogen is that the subsidiary could not have warned of this risk without the parent company's approval. For example:

- In 1993, Donald Jones and John Hopkins of J&J were working together to get Mr. Hopkins on the ISRTP symposium on the safety of talc because of his "leverage with the ISRTP," which was considered important "as part of a strategy to keep J&J at the forefront of cosmetic talc…" 31AA14279 (P-238).
- In 1994, Defendants' consultant, Dr. Wehner, wrote to Mr. Chudkowski, a manager at JJCI, recommending that JJCI not object to studies that were being considered, even though he

told JJCI the studies "would be like continuing to fish for small fish with a wide-mesh net." 31AA14265 (P-16).

- A 1995 memo on JJCI letterhead recommended that the company "[t]ake a pro-active stance in educating opinion leaders that cosmetic talc is safe when used properly." 31AA14307 (P-59).
- In 1997, Dr. Wehner wrote to JJCI and warned that "[s]everal investigators have independently reported talc particles in ovarian tissue" and noted that "[a]t that time there had been about 9 studies (more by now) published in the open literature that did show a statistically significant association between hygienic talc use and ovarian cancer." Dr. Wehner further warned that "[a]nybody who denies this risks that the talc industry will be perceived by the public like it perceives the cigarette industry: denying the obvious in the face of all evidence to the contrary." 40AA17750 (P-20).
- In 2003, Mr. Mann, the JJCI Director of Toxicology, wrote to Imerys to inform the supplier that "J&J management" was willing to fund a study on talc and ovarian cancer by Drs. Huncharek and Muscat, but first wanted to know how strong the case defending talc was likely to be. Mr. Mann also asked Imerys "any news on NTP backing away as you expected you might hear by the end of January?" 31AA14283 (P-262).
- In a 2005 string of emails between J&J and JJCI employees, Mr. Mann informed his colleagues that he had been "working on several fronts to assure a good outcome [for the company regarding the NTP review of talc], including both working with

the CTFA Talc Interested Party Task Force, and independently with our major supplier Luzenac and their Washington, DC legal team." 31AA014284 (P-263).

7. J&J and JJCI directors and managing agents acted with malice

The trial court had previously heard and denied nonsuit and directed verdict motions addressing the sufficiency of the evidence to support a claim for punitive damages as to both Defendants. 41AA17927;17959-17969; 29RT8101:15-8126:24; 31RT8742:15-8743:10. However, the court reweighed the evidence after the verdict and granted JNOV as to punitive damages for both Defendants. 52AA23491.

Malice may be proved either expressly through direct evidence or by implication through indirect evidence from which the jury draws inferences. *Angie M. v. Superior Court* (1995) 37 Cal.App.4th 1217, 1228.

Substantial evidence supported the jury's award of punitive damages, based upon malice and despicable conduct showing a conscious disregard for the safety of the public. See section II.A., *supra*. The evidence showed that the Defendants were aware of the probable dangerous consequences of their conduct, and that they were exposing thousands of women to ovarian cancer, yet they deliberately failed to warn in order to protect their flagship product. Despite decades of mounting evidence showing a significantly increased risk of this fatal disease, Defendants, through their managers and directors, intentionally chose not to warn women

and/or give them an opportunity to make an informed decision whether to take the risk of contracting ovarian cancer.

Instead of issuing warnings regarding ovarian cancer, as others have done, including other manufacturers of talcum powder products and J&J's own supplier, the Defendants instead deliberately embarked on a campaign to vigorously defend the company's "hallmark product" (16RT4324:17-20) at all costs. 20RT5594:11-5595:18; 21RT5716:20-5721:12, 5740:10-22; 35AA15619(P-920); 35AA15622 (p-921); 35AA15625 (P-922); 40AA17755. The Defendants worked "on several fronts" to discredit what their own consultant referred to as "a 'real' statistically significant association [which] has been undeniably established independently by several investigators, which without doubt will be readily attested to by a number of reputable scientists/clinicians," and engaged in a decades long strategy of "denying the obvious in the face of all evidence to the contrary," and countering negative recommendations of health professionals. All of this evidence is undoubtedly why the trial court denied motions for nonsuit and directed verdict addressed to this same issue.

Nevertheless, after the verdict was in, the court found that *as a* **matter of law**, knowledge that talc was only "'possibly' carcinogenic," as opposed to "a 'probable' cause of cancer" was insufficient to support an award of punitive damages. 52AA23453. This is a clear misstatement of the law. The legal authorities cited by the trial court are patently distinguishable and do not support its conclusion. *Satcher v. Honda Motor Co.* (5th Cir. 1995) 52 F.3d 1311,

1316 (injured motorcycle rider contended under Mississippi law that all motorcycles are defective for failing to include guards to protect the riders' legs from collisions); *Kendall Yacht Corp. v. United California Bank* (1975) 50 Cal. App. 3d 949, 959 (action to recover damages as a result of a bank's breach of agreements to loan money to a corporation).

The Defendants marketed a product that numerous peer-reviewed epidemiological studies for several decades have consistently and repeatedly shown creates at least a 30% increase in the number of cases of ovarian cancer among the general public. While not every woman who uses the product is a "probable" victim of ovarian cancer, it is a virtual certainty that among the many women nationwide using the Defendants' product, thousands of them will contract ovarian cancer who otherwise would not have. The Defendants knew of the danger and had a duty to warn, and their deliberate failure to do so constitutes malice. *Karlsson v. Ford Motor Co.* (2006) 140 Cal.App.4th 1202, 1230 (affirming punitive damages award in failure to warn action) ("Marketing a product that is known to be defective and dangerous to consumers supports an inference of malice for purposes of punitive damages.")

VI. The Trial Court Abused Its Discretion in Granting New Trial on Other Grounds

A. The court properly admitted the condom article, and Plaintiff's counsel properly discussed it

The trial court granted new trial for error in law under Code of Civil Procedure section 657(7) on the theory that exhibit P-19 (46AA19649) should not have been admitted. 52AA23511-23513. This exhibit is an article asserting that medical concern about talc as an ovarian carcinogen goes back 50 years and that condom makers removed talc from condoms in the 1990s for that reason. 52AA23511. The court agreed that the article was admissible for purposes of notice, and gave a limiting instruction that it was not admissible for its truth, but concluded the limiting instruction was undermined because "repeated references to it were clearly prejudicial ..." 52AA23512-23513.

The document is highly relevant to the issue of notice, and there is nothing unduly prejudicial about it. J&J's defense heavily relied upon the hearsay statements of third parties, including industry, medical and government organizations, and their alleged opinions, or lack thereof, regarding whether or not talc causes ovarian cancer. Plaintiff attempted to preclude the Defendants' use of opinions of non-testifying third parties via a motion *in limine*. In denying the motion the trial court opined that it would be proper for the Defendants to use these hearsay statements to prove their knowledge and intent. 20AA9650. This ruling became the foundation for admission of third party hearsay evidence proffered

by Defendants, and repeated arguments by defense counsel that talc is not dangerous, and that Defendants believed it to be safe.

For the same reasons the trial court permitted Defendants to use this type of evidence, Plaintiff's use of this document was entirely proper. It was offered to show that concerns were expressed – true or not – and that those concerns were known to the Defendants. Certainly, if the Defendants were permitted to offer out-of-court statements and opinions (as well as the absence of opinions) of third parties to the effect that talc was safe in order to attempt to show the absence of notice or knowledge of a danger, there is nothing prejudicial about Plaintiff offering evidence of notice and knowledge that showed just the opposite.

Moreover, there was no prejudice to Defendants whatsoever, as there was evidence in the record demonstrating that those statements were in fact true. The fact that talc was removed from condoms by the 1990s was admitted for its truth in a different exhibit. 31AA14294 (P-343), 17RT4541:15-4544:25.

B. Plaintiff's lawyers did not violate limiting instructions

The court found that Plaintiff's counsel disregarded limitations on use of lobbying evidence and improperly argued that Defendants improperly "fended off" the NTP, and "that what defendants did to 'prevent regulation' was reprehensible conduct supporting an award of punitive damages." 52AA23513-514. The court concluded that although the jury was instructed that lobbying

activity was permissible, the totality of this argument disregarded the court's limiting instruction and must be viewed as prejudicial and grounds for a new trial as an error in law under section 657(7).

Defendants waived any right to complain by failing to make a timely objection. *Saret-Cook v. Gilbert, Kelly, Crowley & Jennett* (1999) 74 Cal.App.4th 1211, 1230; *Soto v. BorgWarner Morse TEC Inc.* (2015) 239 Cal.App.4th 165, 200. There was no objection to argument about lobbying or anything relating to lobbying. The few objections that were actually made did not address the issue upon which the court's limiting instruction was based.

In arguing for a mistrial (which was actually based upon counsel's statements about causation [16RT4286:27-4287:12]), counsel for Defendants conceded this particular argument did not amount to misconduct (16RT4288:20-4289:7), and requested a "lobbying instruction." 16RT4310:8-4314:20. The instruction the court gave in response told jurors that companies, like individuals, have a right to petition the government and engage in free speech and association, including to present views on scientific issues, and that they may not base any findings of liability on any petitioning or lobbying effort or on any statements made by any federal, state, or local legislative, executive, or regulatory body. It also instructed the jury that they could consider evidence of lobbying activities to show Defendants' knowledge of the dangerous nature of its product or a failure to exercise ordinary care. 31RT8758:25-28.; See *Hernandez, supra,* 215 Cal.App.4th at 680.

In light of J&J's repeated reliance on the fact that the NTP had not opined that talc causes ovarian cancer, Plaintiff's counsels' arguments cannot possibly be considered prejudicial, let alone improper. *Bigler-Engler v. Breg, Inc.* (2017) 7 Cal.App.5th 276, 296–297. They were not only an appropriate response, but necessary to counter the defense arguments that the NTP's inaction is evidence talc does not cause cancer. From "mini-openings," to opening statement, to closing argument, defense counsel repeated that various organizations, including the NTP, have never concluded that talc causes ovarian cancer. 13RT3346:13-3347:8; 16RT4364:15-4365:9; 31RT8903:10-22. They also argued that "all of the internal documents" "show a desire on the part of Defendants to get the science in front of the organizations that were reviewing it, like the National Cancer Institute, like the NTP – National Toxicology Program …" 16RT4337:16-22.

Far from encouraging the jury to consider the lobbying evidence for an improper purpose, counsel for Plaintiff made it clear he was asking just the opposite. Mr. Smith even drew the limiting instruction to their attention and read from it, explaining that companies are permitted to petition the government, and that he was asking them to consider evidence of lobbying activities to show Defendants' knowledge of the dangerous nature of its product or a failure to exercise ordinary care. 31RT8825:21-8826:3. Likewise, counsel for Defendants' also reminded jurors of the instruction, essentially paraphrasing the same portion which Mr. Smith quoted. 31RT8891:2-8.

Thus the arguments by Plaintiff's counsel did not violate any order or instruction of the court, and were entirely proper.

C. The record does not establish prejudicial jury misconduct

The trial court's finding of juror misconduct (52AA23514-16), based upon the declarations of two jurors (50AA21136 and 50AA21141), was an abuse of discretion, as it was based upon legal error and factual findings unsupported by the record. A jury verdict cannot be impeached by evidence of the jurors' mental processes and reasoning. Evid.Code, § 1150; *Bandana Trading Co., Inc. v. Quality Infusion Care, Inc.* (2008) 164 Cal.App.4th 1440, 1446. See *Maxwell v. Powers* (1994) 22 Cal.App.4th 1596, 1604 (juror affidavits reciting reasoning process jury employed to arrive at damages figures inadmissible as they reflected jurors' subjective mental processes); *Mesecher v. County of San Diego* (1992) 9 Cal.App.4th 1677, 1683 (declarations about jury's subjective collective mental process purporting to show how the verdict was reached were inadmissible). The declarations here patently violated this rule, as they attempted to show the jury's subjective mental processes in reaching the verdict.

Additionally, neither declaration establishes an "agreement." One says only "other jurors expressed an agreement" – and another juror's presumed "agreement" would be speculation about that juror's mental processes. The other declaration says "other jurors agreed to raise the amount." There are absolutely no specifics regarding the alleged agreements, and no specific statements

attributed to any particular juror. There are no details provided as to who agreed with whom or what was agreed upon – and particularly not how much jurors may or may not have agreed to raise the verdict. It is pure speculation to somehow draw an inference from these conclusory statements that there was an agreement at all, let alone an inference as to what was agreed upon. See *Sarti v. Salt Creek Ltd.* (2008) 167 Cal.App.4th 1187, 1213–14 ("The absence of any supporting detail about the jurors having supposedly 'agreed' to do something contrary to an instruction supports the reasonable inference that the affidavits were mere conclusions about the jurors' mental processes.")

More importantly, the declarations fail to meet even minimal requirements for admission. All declarations or "affidavits relied upon as probative must state evidentiary facts." *Greshko v. County of Los Angeles* (1987) 194 Cal.App.3d 822, 834. "Affidavits or declarations setting forth only conclusions, opinions or ultimate facts are to be held insufficient." *Id.* Deference to an order granting a new trial is inappropriate when it is based on inadmissible juror affidavits. *Bell v. Bayerische Motoren Werke Aktiengesellschaft* (2010) 181 Cal.App.4th 1108, 1126.

There is nothing which even logically connects the alleged vague "agreement" to the amount ultimately awarded. Neither declaration states that the amount was raised "as a result" of the discussion. Neither declaration states that the jurors agreed to raise the amount of the award specifically for the purpose of covering fees or costs. Neither declaration states that a lower amount would have

been awarded but for the alleged discussion of fees and costs. In fact, the only attempt at connecting the discussion of fees and costs with the amount of the award is the relative point in time– that one allegedly preceded the other. This is the classic logical fallacy *post hoc ergo propter hoc*.

The only authority cited by the court for the proposition that the conduct alleged here is serious misconduct warranting a new trial is another off-point and extreme example. *Weathers v. Kaiser Foundation Hospitals* (1971) 5 Cal.3d 98, 106–108 (instances of misconduct too numerous to mention, including juror telephoning physician for opinion, movement to impeach foreman, racially charged statements about a black plaintiff, etc.) The declarations here do not show prejudicial misconduct requiring a new trial. And even if they had, as discussed below at Section VI. E. 4. remittitur would have been the appropriate remedy.

The trial court's ruling in this regard is an abuse of discretion for several reasons. As shown above, there was no misconduct by the jury. Additionally, the trial court's reference to "other reasons why a new trial is required" are not clear, but as shown above, the other grounds specified by the court were all founded upon errors of law, improper criteria, incorrect legal assumptions and factual findings not supported by the evidence.

D. The trial court's finding of violations of *in limine* orders is unsupported by the record

The trial court's statement that Plaintiff's counsel violated *in limine* orders finds no support in the record. The court's order, comprising some 51 pages, does not refer to a single *in limine* motion or ruling, let alone a violation of one. 52AA23469-23519. It appears that in its eagerness to overturn the verdict, the court simply assumed that a ruling must have been violated by someone somewhere.

E. The court abused discretion in finding the damages excessive

An order granting new trial on the basis of excessive damages shall be reversed if there is no substantial basis in the record for any of the reasons the court provided for granting new trial. Code Civ. Proc., § 657.

The court found that the $2 million dollar compensatory damages award against JJCI was not excessive and that '[t]he number is well in line with other verdicts in comparable cases." However, the court found that as to J&J, "the jury should have reached a different verdict" and that the $68 million compensatory verdict was "plainly excessive." 52AA23516-517.

1. The court did not offer a meaningful basis for finding compensatory damages excessive

The trial court never explained why it believed that $68 million is too much money for the horrible pain Ms. Echeverria endured. Its only reason for setting aside the compensatory

damages as to J&J was its incorrect belief that J&J is not liable for all the harm caused by Ms. Echeverria's use of Johnson's Baby Powder because it stopped manufacturing the product in 1967. (52AA23517.) But this proposition is legally erroneous, and therefore the court abused its discretion in relying on it. *Rickey v. County of Los Angeles* (2004) 114 Cal.App.4th 1002, 1008-1009.

2. The court abused its discretion in setting aside the punitive damages without analyzing Defendants' conduct

The only rationale the trial court cited for finding the punitive damages award excessive was that "the evidence was insufficient to uphold a punitive damage award of any kind. Analysis of what constitutes a 'proper' amount of punitive damages is thus unnecessary. The punitive damages were excessive based on the evidence." 52AA23518.

Defendants' failure to warn, despite their knowledge of the danger of their product, and their active efforts to keep that information from consumers, as set forth in section II. A., were despicable conduct. The post-verdict ruling that the evidence was insufficient to support any award of punitive damages was based upon the erroneous finding that **as a matter of law**, knowledge that talc was only "'possibly' carcinogenic," as opposed to "a 'probable' cause of cancer," was insufficient to support an award of punitive damages. 52AA23453. As set forth *supra* at V. A., this is a clear misstatement of the law, and the order relying on that misstatement is an abuse of discretion.

3. New trial for excessive damages must be reversed because the trial court did not provide a specification of reasons

Code of Civil Procedure section 657 requires that when a court grants new trial, its order "shall specify the ground or grounds upon which it is granted and the court's reason or reasons for granting the new trial upon each ground stated." The specification may be in the order granting new trial or in a separate document filed within ten days after the new trial order. The court must personally prepare and sign the order and specification. (*Ibid*.)

These procedural steps are "mandatory and must be strictly followed." *Smith v. Moffatt* (1977) 73 Cal.App.3d 86, 91. An order granting new trial on the ground of excessive damages "shall not be affirmed" on appeal without a specification of reasons (§ 657.) The court did not provide a separate specification, and the statements in the order granting new trial are inadequate to meet this requirement.

Both Dr. Yessaian and Ms. Echeveria's testimony provided evidence of how much Ms. Echeverria suffered over ten years. The jury was able to observe Ms. Echeverria during voir dire, but by the time the trial commenced she was too ill to appear, and previous deposition testimony had to be played in her absence.

The court did not cite any part of this testimony. It merely offered a sanitized version of Ms. Echeverria's statement about her fight against cancer and concluded that the $2 million in

compensatory damages against JJCI is not excessive because it is "well in line with other verdicts in comparable cases."

As to J&J, however, the court determined that the $68 million compensatory damages award is "plainly excessive" if liability were established." 52AA23517. The only reasons the court provided for finding excessiveness were that "[t]here is no evidence Johnson & Johnson manufactured baby powder after 1967" and there is no evidence J&J manufactured Shower to Shower. *Id.* The court never compared the injuries Ms. Echeverria suffered to damages awarded in other supposedly "comparable" cases; it did not even identify what cases it was thinking about. Nor did the court cite any evidence suggesting that Ms. Echeverria exaggerated her suffering, nor any other evidence supporting a lower award.

As to punitive damages, the order was even more cryptic. It referred to the factors the Defendants contend shape review of punitive damage awards, then faulted Ms. Echeverria for not identifying a case upholding a "very significant punitive damages award layered on top of a substantial compensatory award." However, the court made no analysis; it merely wrote that "[it] is sufficient to state for these purposes that the evidence was insufficient to uphold a punitive damage award of any kind," so the court deemed it "unnecessary" to analyze what would be a proper award. 52AA23517-18.

This too is legal error. Section 657 requires a court to analyze the facts concerning damages before setting aside a punitive damages award as excessive. *Smith v. Moffatt, supra,* 73 Cal.App.3d

at 91. Where the only ground for granting the new trial motion was excessive damages, it "shall not be affirmed . . . unless such ground is stated in the order granting the motion and . . . it shall be conclusively presumed that said order as to such ground was made *only* for the reasons specified. . . ." Code Civ. Proc., § 657, italics added.

4. If the Court considers the damages excessive, it should reduce the judgment rather than granting new trial

When the evidence is sufficient to sustain some, but not all, of a compensatory damages award, an appellate court may (subject to plaintiff's consent) reduce the judgment to the amount supported by the evidence and affirm as modified. Eisenberg, Horvitz & Wiener, Cal. Prac. Guide: Civil Appeals & Writs (The Rutter Group 2018) ¶ 11:56.1, citing *Behr v. Redmond* (2011) 193 Cal.App.4th 517, 533-535 and *Bermudez v. Ciolek* (2015) 237 Cal.App.4th 1311, 1338. Appellate courts may likewise modify an excessive punitive damages judgment by reducing the amount and affirming the judgment as modified instead of setting aside the judgment. Eisenberg, et al., at ¶ 11:58a, citing *Boeken v. Philip Morris, Inc.* (2005) 127 Cal.App.4th 1640, 1704. Nevertheless, the trial court concluded that remittitur was not appropriate in light of, inter alia, "the misconduct of the jury in considering matters that were not to be included." 52AA023517. This was an abuse of discretion. Even assuming that the juror declarations had been admissible and sufficient to make a finding of misconduct (which they were not), remittitur would have been the appropriate remedy. See *Moore v. Preventive Medicine Medical*

Group, Inc. (1986) 178 Cal.App.3d 728, 743 (holding that even though jury had improperly fashioned a damage formula, resulting in excessive damages, reversal was not required); *Thompson v. Friendly Hills Regional Medical Center* (1999) 71 Cal.App.4th 544, 548-49 ("Jury misconduct may result in excessive damages and support a remittitur. That was the situation in *Tramell v. McDonnell Douglas Corp.* (1984) 163 Cal.App.3d 157, 171, where the trial judge concluded damages were excessive based on juror declarations stating that plaintiff's counsel 'would receive 33% of what we awarded to Mrs. Tramell and her children…'"); *Kotla v. Regents of University of California* (2004) 115 Cal.App.4th 283, 289.

The trial court did not need to know whether the jurors improperly added something to the award, or how much they may (or may not) have added. A trial judge has broad discretion in reducing a jury award she believes is excessive, even where the award includes general damages for items such as pain and suffering and emotional distress that, are not readily susceptible to precise calculation. See e.g. *Izell v. Union Carbide Corporation* (2014) 231 Cal.App.4th 962, 978-981. Even defense counsel pointed out that the verdict provided the court with "benchmark[s]" for a remittitur for both compensatory and punitive damages. 32RT9163:21-9164:10.

VII. CONCLUSION

This Court should reverse the order granting the motion for new trial and also reverse both of the judgments notwithstanding the verdict. It should remand the matter to the trial court to enter

judgment on the verdict. If, however, the Court believes the jury awarded too much, the Court should remit the judgment to an amount it deems appropriate in light of the evidence.

Dated: July 18, 2018 **Respectfully submitted,**

By ***/s/ Mark P. Robinson, Jr.***

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CERTIFICATE OF WORD COUNT

(Rule 8.204, California Rules of Court)

The text of this brief consists of 21,653 words as counted by the Microsoft Word word-processing program used to generate this brief.

Dated: July 18, 2018 **/s/ Mark P. Robinson, Jr.**
Mark P. Robinson, Jr.

CERTIFICATE OF SERVICE

COURT: Court of Appeal, Second Appellate Dist., Div. 4
Case No.: B286283
Los Angeles Superior Court Case No. BC628228/JCCP 4872

Elisha Echeverria, Acting Trustee of the 2017 Eva Elaine Echeverria Living Trust v. Johnson & Johnson, et al.

1. I declare at the time of service I was a citizen of the United States, employed in the County of Orange, State of California. My business address is 19 Corporate Plaza Drive, Newport Beach, California 92660.

2. I further declare that on July 18, 2018, I served

APPELLANT'S OPENING BRIEF

on the parties for the entities indicated below, electronically via the TrueFiling Electronic Servicing Notification System.

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3. I further declare that on July 18, 2018, I served:

APPELLANT'S OPENING BRIEF

By United States Mail: Following the ordinary business practices, I sealed true and correct copies of the above documents in addressed envelope(s) and placed them at my workplace for

collection and mailing with the United States Postal Service. I am readily familiar with the practices of this office for collecting and processing mail. In the ordinary course of business, the sealed envelope(s) that I placed for collection would be deposited, postage prepaid, with the United States Postal Service that same day.

To: CLERK OF THE COURT
Spring Street Courthouse
Hon. Maren E. Nelson Superior Court of the State of California
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I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed on the July 18, 2018 at Newport Beach, California.

/s/ *Donna Hosea*
Donna Hosea