

Case No. _____

**IN THE SUPREME COURT OF THE
STATE OF CALIFORNIA**

Elisha Echeverria, Acting Trustee of the
2017 Eva Elaine Echeverria Living Trust,
Plaintiff and Appellant

v.

Johnson & Johnson *et al.*,
Defendants and Appellants

Petition for Review of a Decision of the Court of Appeal,
Second Appellate District, Division Three, No. B286283

Superior Court, County of Los Angeles
Civil Case No. BC628228, JCCP No. 4872
Honorable Maren E. Nelson

PETITION FOR REVIEW

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**TO THE HONORABLE CHIEF JUSTICE OF CALIFORNIA
AND ASSOCIATE JUSTICES OF THE CALIFORNIA
SUPREME COURT:**

Plaintiff-Appellant Elisha Echeverria respectfully petitions for review of the July 9, 2019 decision of the Court of Appeal, Second District, Division Three, published at 37 Cal.App.5th 292 (hereinafter “Opinion”). Review is necessary to settle important questions of law and secure uniformity of decision.

ISSUES PRESENTED

1. Does *T.H. v. Novartis Pharmaceuticals Corp.* (2017) 4 Cal.5th 145, which held that the original manufacturer of a product may be liable for failing to warn of a risk in connection with use of the same product made by a successor manufacturer, apply only to circumstances involving the “distinctive legal framework governing labeling for brand-name and generic pharmaceuticals” and conduct before the original manufacturer ceases production, or is the duty of a manufacturer outside the pharmaceutical industry defined by analysis under the factors set forth in *Rowland v. Christian* (1968) 69 Cal.2d 108, 113?

2. On appellate review of an order granting JNOV after a jury awards punitive damages, is the reviewing court simply required to find substantial evidence to support the jury's finding of malice, or must it find substantial evidence from which the jury could have made that finding by clear and convincing evidence?
3. Does the abuse of discretion standard of review compel an appellate court to uphold a trial court's determination that is based upon objectively verifiable errors of law and unsubstantiated factual assumptions?

WHY REVIEW SHOULD BE GRANTED

Review of the Court of Appeal's published Opinion is necessary to decide important legal questions and secure uniformity in case law. The issues presented for review affect not only hundreds of personal injury and wrongful death cases presently pending in a Judicial Council Coordinated Proceeding (JCCP), but also cases nationwide.

First, this Court should grant review in order to define the scope of *T.H. v. Novartis Pharmaceuticals Corp.*, *supra*, (hereinafter "Novartis") which held that the original manufacturer of a product may be liable for failing to warn of a risk in a successor

manufacturer's product where the original manufacturer influences or controls the content of the warnings used by the successor. The Opinion limits the application of *Novartis* to circumstances involving prescription drugs and the predecessor manufacturer's conduct before it discontinued manufacture. However, this Court specifically rejected the contention that an original manufacturer is categorically relieved of any failure-to-warn liability relating to another manufacturer's products, and distinguished the ordinary situation where a manufacturer has no "control or influence" over warnings the other manufacturer might place on the product. The Court also rejected the notion that liability should turn on the defendant's role in the manufacturing process or actual production of the product. This Court instead held that the question of duty must be based upon a much broader analysis balancing the factors outlined in the seminal case of *Rowland v. Christian* (1968) 69 Cal.2d 108, 113. (*Novartis, supra*, 4 Cal.5th at 163-165)

The Opinion is therefore inconsistent with *Novartis*, which is neither confined to pre-sale conduct, nor to prescription pharmaceuticals. Here, the original manufacturer continued for decades to exercise much more influence and control over the label and the absence of a warning than the defendant in *Novartis*.

The Court of Appeal’s decision has significant consequences for many products liability actions, including mass torts involving pharmaceuticals and household products. This is because, in the ordinary course of business, many products originally manufactured by one entity are later manufactured by subsidiaries, licensees and other successor entities.¹

Second, this Court should grant review to resolve the conflict of decision among courts of appeal about the proper standard of review of a jury’s award of punitive damages. The Opinion holds that a reviewing court “must inquire whether the record contains ‘substantial evidence to support a determination by clear and convincing evidence ...’” (Opinion 57.) It concluded that Defendants’ conduct “continued to fall short of establishing clear and convincing evidence of malice”, and that the evidence was “not clear and convincing evidence of ‘despicable conduct.’” (Opinion 59, 60.) Conversely, other courts of appeal hold that on appeal from a judgment required to be based upon clear and convincing evidence, the clear and convincing test “disappears,” and the usual rule of

¹ These successor or subsidiary manufacturers often have nowhere near the assets of the original manufacturer, limiting the availability of compensation to victims of mass torts. (E.g. At the end of 2014, J&J’s net worth was \$68.2 billion, whereas JJCI’s was \$1.5 billion. [30RT8604:24-8605:5].)

conflicting evidence is applied, giving full effect to the respondent's evidence, however slight, and disregarding the appellant's evidence, however strong. Various courts of appeal disagree not only as to the standard of review in such cases but as to how it is applied. (E.g., *Morgan v. Davidson* (2018) 29 Cal.App.5th 540, 549, declining to adopt the standard in *Pulte Home Corp. v. American Safety Indemnity Co.* (2017) 14 Cal.App.5th 1086.)

This Court recently granted review in a case involving this same issue, and conflict of decisions, in the context of conservatorship proceedings. (*In re O.B.*, no. S254938 [“On appellate review in a conservatorship proceeding of a trial court order that must be based on clear and convincing evidence, is the reviewing court simply required to find substantial evidence to support the trial court's order or must it find substantial evidence from which the trial court could have made the necessary findings based on clear and convincing evidence?”]) This case provides the Court an opportunity to settle the standard of review question for civil actions involving findings based upon clear and convincing evidence.

Finally, the Court should grant review because the Opinion raises an important legal question as to the limits of a trial court's discretion in ruling on a motion for a new trial, and the extent to

which the trial court may overturn a jury's verdict based upon its own view of the law and evidence. Here the trial court denied motions for nonsuit and directed verdict on the issues of duty and causation. But following a jury verdict for Plaintiff, the trial court held that the same evidence it had previously found sufficient was instead legally insufficient to support the jury's findings, and granted JNOV and a new trial.

The Court of Appeal partially reversed the JNOV but affirmed the new trial, despite the fact the trial court erred in holding Plaintiff's treating doctor and cancer surgeon's causation opinion should have been stricken. The Opinion deferred to the trial court's discretion as a "thirteenth juror" to weigh conflicting evidence and make credibility determinations. Yet the Opinion shows that the trial court's key rulings on the motion for new trial were based upon erroneous legal standards, misapplication of law and findings which were unsubstantiated by the record. This raises the question whether the deference afforded a trial court is so indulgent as to require a reviewing court to affirm even when the ruling is based upon errors of law and unsubstantiated or mistaken assumptions of fact. This necessarily has constitutional implications because it impacts the right to a jury trial.

INTRODUCTION

Following the verdict, the trial court granted the Defendants' motions for JNOV and new trial, and Plaintiff appealed. This was the first trial in a coordinated proceeding involving hundreds of cases brought by 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"), the original manufacturer, and its subsidiary Johnson & Johnson Consumer Inc. ("JJCI"), which manufactured the products after 1967. Eva Echeverria, who used these products for over 40 years, was diagnosed with high grade serous epithelial ovarian cancer in 2007. She sought punitive damages based on Defendants' despicable conduct in intentionally failing to warn consumers about the known risk of ovarian cancer from perineal use of talcum powder.

Before trial the court held a lengthy 402/*Sargon* hearing to address Defendants' challenges to Plaintiff's experts' opinions, and held the evidence admissible. During trial the court denied Defendants' motions for nonsuit and directed verdict challenging the sufficiency of the evidence to support Plaintiff's claims on the issues of duty, causation and punitive damages. However, the trial

court granted JNOV and new trial, finding, inter alia, that the evidence as to both duty and causation was insufficient to support the verdict, and that the causation opinion of Dr. Annie Yessaian, Plaintiff's treating doctor and cancer surgeon, should have been stricken.

The Court of Appeal reversed the JNOV as to the subsidiary, JJCI, finding:

1. **“[T]he evidence as it applied to JJCI was sufficient to allow the jury to conclude the known risks of genital talc use were concrete enough that it was unreasonable for JJCI to fail to warn consumers of them.”** (Opinion 38-39.)²
2. **“Substantial evidence supported the jury's finding that talcum powder was a substantial factor in causing Echeverria's cancer.”** (Opinion 56.)

The Court of Appeal affirmed JNOV as to J&J, however, holding there was no substantial evidence it breached a duty to warn, as it had ceased manufacturing the product in 1967 when it created JJCI, despite evidence showing that J&J continued to exercise

² Bold emphasis throughout this brief is added.

influence and control over the content of the label used by its subsidiary for decades after it last made the product. In doing so, this published Opinion adopts a narrow, restrictive and incorrect view of *Novartis*, which held that the original manufacturer of a product may be liable for failing to warn of a risk in connection with the use of the same product made by a successor manufacturer. The Court of Appeal distinguished *Novartis* as limited to circumstances involving the “distinctive legal framework governing labeling for brand-name and generic pharmaceuticals,” and conduct prior to discontinuance of the sale of the product.

The Court of Appeal affirmed JNOV on punitive damages against both Defendants, finding that there was no substantial evidence to support a finding by “clear and convincing evidence” of despicable conduct. However, there is presently a disagreement among appellate courts as to whether the “clear and convincing” standard “disappears” on appellate review, and this Court recently granted review of the same question in the context of conservatorship proceedings.

The Court of Appeal also affirmed the new trial, based upon the trial court’s discretion to assess the credibility of witnesses, weigh the evidence, and draw inferences from the evidence different from the jury. Yet the trial court in fact abused its discretion in both

weighing the evidence and in assessing the credibility of experts. The Opinion shows that the trial court conducted its analysis while operating under mistaken interpretations of law, based upon unsubstantiated factual findings plainly contradicted by the record. The Opinion therefore goes too far and grants unbridled deference to trial courts to overturn verdicts, even when they are wrong on the law and wrong on the facts.

STATEMENT OF FACTS

Three times before the verdict, the trial court ruled there was sufficient evidence of causation: 1. following a lengthy 402/*Sargon* hearing; 2. denying Defendants' motion for nonsuit after Plaintiff rested; and 3. denying Defendants' motion for directed verdict as to duty, causation and punitive damages after all the evidence had been heard. (23AA10766; 24AA11865; 29RT8101:15-8126:24; 31RT8742:15-8743:10.) The trial court made those rulings having just heard the testimony and reviewed the evidence.

The jury awarded \$417,000,000: compensatory damages of \$68,000,000 and punitive damages of \$340,000,000 against J&J; compensatory damages of \$2,000,000 and punitive damages of \$7,000,000 against JJCI. Sixty days after the verdict, the trial court changed its mind and granted a new trial and JNOV to both

Defendants, based upon, inter alia, insufficiency of the evidence, (the only ground addressed by the Court of Appeal here). The trial court found that specific causation was not shown (52AA23499), and that the testimony of Dr. Yessaian, Plaintiff's treating oncologist and cancer surgeon, was insufficient as a matter of law to support the verdict. (52AA23495.)

Plaintiff appealed, asking the Court to reinstate the judgment on the jury's verdict, or in the alternative, if the Court believed the amount of damages to be excessive, to remit the judgment to the amount it deemed appropriate in light of the evidence.³ The Court of Appeal disagreed with the trial court on the major issues of duty and causation, concluding that "[s]ubstantial evidence supported the jury's finding that talcum powder was a substantial factor in causing Echeverria's cancer" (Opinion 56) and that "Substantial Evidence Supported the Jury's Finding That JJCI Breached Its Duty to Warn" (Opinion 38.)

The Court of Appeal partially reversed the JNOV in favor of JJCI. However, it affirmed as to J&J, holding that there was no substantial evidence J&J breached a duty to warn, as it had ceased

³ Eva Echeverria passed away one month after the verdict. Her daughter, Elisha Echeverria was substituted as the plaintiff.

manufacturing the product in 1967, when it created the subsidiary JJCI. (Opinion 29.)

At trial, Ms. Echeverria had relied on internal documents to show J&J continued to control and influence the content of the label and the absence of a warning on the products long after it turned over manufacturing to its subsidiary. The following unambiguous characterizations were made by J&J's own managing agents and consultants.

As the Court will see from the documents below, William Ashton remained involved with talc as a managing agent or director from 1964 to 2004:

- William Ashton, a “manager or director” of J&J, (17RT4592:10-4593:2) wrote that “because it [cornstarch] was found to be **absorbed safely in the vagina whereas, of course, talc was not.**” (31AA14294 (P-343) [1964, J&J document].) Ashton was involved in the failure to warn about the ovarian cancer risk associated with J&J talcum powder through 2004. (See P-396, *infra*, dated September 30, 2004.)
- Eight years after JJCI was formed, a letter on J&J letterhead referred to “the talc/ovary problem” in connection with cancer research (31AA14305), seeking information about current research “**concerning talc and ovarian cells.**” (31AA14305, [P-55], emphasis added; 17RT4545:4-4546:20), that created an “opening to **put us**” – that is, J&J – “**on notice re the talc/ovary problem.**” (31AA14305, [P-55], emphasis added; 17RT4546:21-4548:12.)

- “**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.” (31AA14353 (P-9) [1986, J&J document].)

J&J’s corporate representative Telofski (16RT4397:11-18) testified:

Question: Can you tell us what exhibit P9 is?

Answer: This is a technological forecast.

Question: And is this a Johnson & Johnson document?

Answer: Yes, it is.

Question: Do you recognize this document?

Answer: Yes, I do.

Question: This document was kept in your files; true?

Answer: It is coming from J&J files.

...

Question: Do you have any reason to disagree with that, that the metadata indicates that this document indicates that it was in Bill Ashton’s files and later in your files?

Answer: No.

(17RT4548:19-4549:24.)

- “[**S**]tudies have **implicated** talc use in the vaginal area with the **incidence of ovarian cancer.**” (31AA14353 (P-9) [1986, J&J document].)
- “technologies which **control** or prevent **potential safety hazards must be pursued to stifle** the **negative recommendations of health professionals.**” (31AA14353 (P-9) [1986, J&J document].)

- “it is inevitable that a **last straw safety concern** will lead to abandonment of powder use” (31AA14353 (P-9) [1986, J&J document].)
- “**nearly one hundred years** of talc based powder experience has kept **us the market leader**” (31AA14353 (P-9) [1986, J&J document].) (The “us” referred to in this document is clearly J&J, not JJCI, **as JJCI did not exist until 1967.**)
- “negative publicity from the health community on talc (inhalation, dust, **negative doctor endorsements, cancer linkage**) continues” was listed as a “**major obstacle**” for Johnson Baby Powder. (31AA14263 (P-10) [8/5/1992, J&J document].)

J&J’s corporate representative Lorena Telofski testified:

Question: Do you recognize exhibit P10 as being a Johnson & Johnson company document?

Answer: From the stamp, yes.

Question: You understand this document was in Johnson & Johnson’s company files?

Answer: Yes.

(17RT4555:13-4555:20.)

- J&J and JJCI worked together “**to keep J&J at the forefront of cosmetic talc...**” (31AA14279 (P-238) [1993].)
- “Harlow paper resurfacing the **ovarian cancer connection** to cosmetic talc use first proposed by Cramer.” (17RT4559:13-19; 31AA14279 (P-238) [1993].)
- J&J supported the CTFA’s efforts to “secur[e] the industry’s future.” (31AA14306 (P-57) [1994, J&J document].)

- J&J’s consultant, Dr. Wehner, told JJCI to support additional epidemiology studies on talc, even though he told the company that the additional studies “would be like continuing to fish for small fish with a wide-mesh net.” (31AA14265 (P-16) [1994].)
- “there **may be a link** between the use of talc and increased **risk of ovarian cancer.**” (31AA14326-7 (P-764) [1994, J&J Document].)
- J&J executives recommended taking “a pro-active stance in educating opinion leaders that cosmetic talc is safe when used properly” to “handle adverse press and media issues around talc.” (31AA014307 (P-59) [1995].)
- J&J’s consultant Dr. Alfred Wehner warned JJCI that:

At the time there had been **about nine studies**, more by now, published in the open literature **that did show a statistically significant association between hygienic talc use and ovarian cancer.** Anybody who denies this risk, 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....** 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. (40AA17750 (P-20); 25RT6923:17-6923:27.

Telofski testified:

Question: Do you know who Al Wehner is?

Answer: Al Wehner was an outside -- he had an outside company who did consulting and testing.

Question: For Johnson & Johnson?

Answer: And others.

Question: Including Johnson & Johnson?

Answer: Yes.

(17RT4561:2-4561:11.)

- J&J communicated with its talc supplier how they had **“been successful thus far in fending off the NTP classification of talc as being a potential human carcinogen.”** (40AA017752 (P-27) [2002, J&J document].)
- JJCI asked its talc supplier, “any news on NTP backing away as you expected you might hear by the end of January?” (31AA14283 (P-262) [2003].)
- “offers some **compelling evidence** in support of the ‘migration’ hypothesis.” (30AA14091 (P-396); 16RT4380:2-4382:14, 44AA19052 [2004, J&J Document].)
- “you have a potential formula for NTP classifying talc as **a causative agent in ovarian cancer.**” (30AA14091 (P-396); 16RT4382:22-4384:5. [2004, J&J Document].)
- Gerd Ries, a J&J regulatory employee, wrote to his colleagues at JJCI, including Mr. Mann, to inquire “what the chances are that we can prevent this [NTP] classification.” (31AA014280 (P-261) [2005, J&J document]; 17RT4607:13-20.)
- J&J and JJCI employees discussed how they 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) [2005, J&J document].)

- JJCI directors expressed frustration to J&J directors about how “it [wa]s VERY difficult to have any impact on IARC.” (31AA014286 (P-264) [2005, J&J document]; 17RT4607:13-20.)
- JJCI directors were initially happy when they thought “one of the epidemiologists that worked with us in 2000 has been asked to participate [in the IARC evaluation of talc]. Dr. Muscat is currently working with Dr. Mike Huncharek, Luzenac and J&J on a couple of projects related to the NTP talc review. I am very pleased that Dr. Muscat will be involved in the IARC process as he has been very helpful to us.” (31AA014291 (P-267) [2005].)
- JJCI complained that “IARC has become very sensitive about any industry connections” when their consultants did not get selected to the IARC review committee. (31AA014289 (P-266) [2005].)
- JJCI discussed with its talc supplier sending a “letter of ‘objection’ to IARC as how the talc review was handled” before IARC even released its evaluation of talc. (31AA014273 (P-204) [2006].)
- J&J’s talc supplier sent the company 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) [2009, Imerys to J&J document]; 16RT4388:14-4391:17.)

The Court of Appeal found that this evidence was insufficient to establish a duty on the part of J&J, distinguishing *Novartis* in that the circumstances there involved the “distinctive legal framework

governing labeling for brand-name and generic pharmaceuticals,” and conduct prior to the time the original manufacturer discontinued selling the product. (Opinion 33-34.) The documents above clearly show that the original manufacturer, J&J, along with JJCI, remained jointly involved in failing to warn that talc use may cause ovarian cancer, even though as the Court of Appeal found, there was substantial evidence a reasonable manufacturer would conclude talc use was likely to be dangerous or “probably” dangerous. (Opinion 41.)

The Appellate Court also affirmed JNOV as to punitive damages, finding the evidence failed to support the jury’s finding of malice. The evidence showed, and the Court of Appeal held, that “the evidence as it applied to JJCI was sufficient to allow the jury to conclude the known risks of genital talc use were concrete enough that it was unreasonable for JJCI to fail to warn consumers of them,” based on “several epidemiological studies” between 1967 and 2007 “finding a statistically significant association between genital talc use and ovarian cancer, as well as studies concluding talc can migrate to the ovaries” and that “[i]nternal documents reflected JJCI’s knowledge of the studies and of the evidence of increased risk of ovarian cancer associated with perineal talc use.” (Opinion 38-39.)

Additionally, the Appellate Court held that “there was substantial evidence that, if credited, allowed the jury to find that by 2007, a reasonable manufacturer would conclude there were facts showing genital talc use was likely to be dangerous, or “probably” dangerous. As noted above, there was evidence of repeated studies showing a statistical association between perineal talc use and ovarian cancer...” (Opinion 41.) The evidence also showed that other manufacturers of similar talc products warn of the ovarian cancer risk, including some in three different languages. (35AA15619-21, P-920, 35AA15622-24, P-921; 35AA15625-627, P-922.) So does J&J’s talc supplier. (40AA17755 at 757.)

The Appellate Court reviewed this evidence and the jury’s finding as to malice under the heightened standard of “clear and convincing evidence.” (“Further, the post-injury conduct continued to fall short of establishing clear and convincing evidence of malice.” [Opinion 59.] “But it is not clear and convincing evidence of “despicable conduct,” ... [Opinion 61].)”)

The Appellate Court affirmed the new trial as to both Defendants. The trial court had based its rulings on both the JNOV and new trial motions primarily on two alleged deficiencies in Dr. Yessaian’s testimony: 1. Dr. “Yessaian did not have a basis to ‘rule in’ talc”, because “epidemiology was the *only* basis that Yessaian could

and did ‘rule in’ talc as a disease agent.” (52AA23498, italics in original), and 2. “Dr. Yessaian did not ‘rule out’ other causes of cancer,” including age and ovulatory cycles and idiopathic causes. (52AA23498-99; see also Opinion 42.) Upon these findings the trial court concluded that Yessaian’s testimony was insufficient to establish specific causation and should have therefore been stricken. (52AA23510.) The trial court also found general causation evidence was lacking. (52AA23508.)

Not only did the Appellate Court find that there was in fact substantial evidence to support that finding that talc use caused Ms. Echeverria’s cancer, but it disagreed with the trial court on these alleged deficiencies, as well as several critical points in the trial court’s application of the law and its factual findings. The Opinion concluded that “Yessaian’s Reliance on Epidemiological Studies Supported Her Opinion,” and that “Yessaian’s reliance on epidemiological studies was a valid basis for her ultimate opinion.” (Opinion 44 and fn. 12.)

The Opinion flatly contradicts the trial court’s key finding that epidemiology was the *only* basis that Yessaian could “rule in” talc: “Yessaian did not only rely on epidemiological studies. She considered the migration studies and evidence regarding the general processes of inflammation and resulting carcinogenesis, in

combination with the evidence of talc particles in Echeverria's ovarian tissues and other areas where the cancer was found. Her differential diagnosis evaluated and ruled out other known causes and risk factors. It was therefore permissible for Yessaian to also rely in part on epidemiological studies with risk ratios less than 2.0.” (Opinion 48-49.)

The Appellate Court identified a fatal legal error in the trial court’s reasoning: “Yessaian’s Opinion Was Not Invalid for Failure to Rule Out Other Known Causes or the Possibility of an Unknown Cause.” (Opinion 49.) The Court held that under *Cooper v. Takeda Pharmaceuticals America, Inc.* (2015) 239 Cal.App.4th 555, “Yessaian was not required to conclusively exclude other potential causes for her testimony to be sufficiently reliable to support her opinion.” (Opinion 51.)

In spite of the trial court’s mistaken understanding as to the law and as to the facts on these critical issues and others, the Appellate Court affirmed the new trial, holding that the trial court was permitted to assess the credibility of witnesses, weigh the evidence, and draw inferences from the evidence different from the jury. (Opinion 63.)

LEGAL DISCUSSION

- 1. THIS COURT SHOULD GRANT REVIEW TO DEFINE THE SCOPE OF A PRODUCT MANUFACTURER'S DUTY TO WARN, AS THE PUBLISHED OPINION OF THE COURT OF APPEAL IS AT ODDS WITH THIS COURT'S OPINION IN *T.H. v. NOVARTIS*.**

This Court has repeatedly reminded that courts should create exceptions to the duty of care “only where clearly supported by public policy.” (E.g., *Kesner v. Superior Court* (2016) 1 Cal.5th 1132, 1143; *Cabral v. Ralphs Grocery Co.* (2011) 51 Cal.4th 764, 771; *Rowland v. Christian, supra*, 69 Cal.2d at 112.) But the Appellate Court here created an exception that conflicts with public policy when it narrowed the holding of *T.H. v. Novartis, supra*, by confining its application to conduct occurring before the original manufacturer discontinues selling the product. ([Opinion 33] “*Novartis* concerned continuing liability for a negligent failure to warn in labeling that occurred prior to a manufacturer divesting itself of the rights to the drug”; [Opinion 33-34] “This holding is of no assistance to Echeverria because there was no substantial evidence that Johnson & Johnson negligently failed to warn prior to 1967, when it was manufacturing Johnson's Baby Powder.”) The Appellate Court concluded that no duty existed because it incorrectly believed that “the *Novartis* court’s reasoning and analysis are inextricably tied to the ‘distinctive legal framework governing

labeling for brand-name and generic pharmaceuticals.” (Opinion 33.)

Public policy calls for imposing liability on a parent company that allows its name to remain on its subsidiary’s product label, attempts to influence government research agencies and industry associations, and tries to shape public perceptions of the subsidiary’s product, all without alerting customers of the product’s dangers. This Court should reject the Appellate Court’s pinched analysis of *Novartis*.

A. The Duty Analysis Under *Novartis* Is Not Limited to Prescription Pharmaceuticals, Nor to Conduct Prior to Discontinuation of Production.

This Court held in *Novartis* that although a manufacturer ordinarily has no duty to warn consumers of a risk from an identical product sold by a successor manufacturer, the original manufacturer may be liable where its failure to warn causes foreseeable harm. (4 Cal.5th at 182-183.) A manufacturer’s liability under *Novartis* does not depend upon a defendant’s continued manufacture or sale of the product. (*Id.* at 180-182.) In holding that a brand-name drug manufacturer has a duty under state law to warn regardless of whether the consumer is prescribed the brand-name drug or its generic bioequivalent produced by another manufacturer, this Court pointed out that “it is not clear why

liability should turn on Novartis’s role in the manufacturing process. What warning label liability stems from is Novartis’s failure to warn about a drug’s risks, not its production of a defective drug.” (*Id.* at 182.)

Nowhere did this Court purport to limit a manufacturer’s duty to warn to actions involving prescription drugs. Nor did it restrict its reasoning to negligent acts by a manufacturer prior to discontinuing or transferring production to another entity. Instead, this Court considered the question of duty by analyzing the familiar *Rowland* factors: “the foreseeability of harm to the plaintiff, the degree of certainty that the plaintiff suffered injury, the closeness of the connection between the defendant’s conduct and the injury suffered, the moral blame attached to the defendant’s conduct, the policy of preventing future harm, the extent of the burden to the defendant and consequences to the community of imposing a duty to exercise care with resulting liability for breach, and the availability, cost, and prevalence of insurance for the risk involved.” (*Rowland*, 69 Cal.2d at 113; *Novartis* 4 Cal.5th at 164.)

B. Under *Novartis* and *Rowland*, Influence or Control Over Product Warnings Will Impose a Duty to Warn.

By engaging in the *Rowland* analysis, this Court expressly rejected the notion that California law relieves a manufacturer of any

failure-to-warn liability for another manufacturer's products, and said it would be no easier to justify than an exception relieving prescription drug manufacturers from liability for generic drugs. (4 Cal.5th at 180.) Notably, this Court distinguished its decision in *O'Neil v. Crane Co.* (2012) 53 Cal.4th 335, where it found no duty on the part of a predecessor manufacturer, by pointing to a key factor not found there, but which is present in both *Novartis* and in this case: continuing influence and control over the content of the label. (4 Cal.5th at 174.) In *Novartis*, that influence and control took the form of preparing a label the successor was required to use.

It is precisely this influence or control of the label that distinguishes *Novartis* and this case from the ordinary situation. (4 Cal.5th at 180 [“A product manufacturer ordinarily will have no control over the design or safety of another manufacturer's product, the other manufacturer's use of dangerous materials, or any warnings the other manufacturer might place on the product”].) Because such control or influence is ordinarily absent, the manufacturer's influence and control over the content of the label figured prominently in this Court's *Rowland* analysis. (See *Novartis*, *supra*, 4 Cal.5th at 190 [explaining that significant moral blame attaches to the failure to warn, and the fact the manufacturer has exited the market does not alter the calculus, because “the actionable

conduct occurred while the manufacturer still had control over the warning label”]; *Id.* at 186 [discussing considerations of public policy, and noting that “Novartis *did* have control over the label and could have modified it”] [italics in original.]

Here, J&J’s control over the label and its influence over the warnings continued for decades beyond the creation of JJCI. (*Supra*, pp. 18-23.) For over forty years, Ms. Echeverria continued using the identical product designed, developed and marketed by J&J, and sold under the name Johnson & Johnson. (35AA15615, [P-49].) If J&J no longer controlled the baby powder manufacture and labeling, why was it involved in a project to “defend” talc? (See 31AA14284 at 85 [P-263]; 17RT4598:16-4601:9.)

Any doubt about J&J’s ongoing involvement in selling talc-based baby powder is erased by the 1986 Technological Forecast’s suggestion that “. . . Effort should probably be directed at cornstarch technologies since the limits of market penetration and potential benefit have not been approached.” (31AA14353, [P-9]; 17RT4532:17-4533:3, 4534:19-4535:12, 4548:13-4555:9.) If J&J were not making and selling Johnson’s Baby Powder, why did it need to comment on where effort should be directed? The Forecast also said, **“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.) J&J would not have needed to “stifle” anything but for its ongoing involvement in the production, labelling and sale of talc.

A 1992 Johnson’s Baby Powder document discussed “major obstacles, including “[n]egative publicity from the health community on talc (inhalation, dust, negative doctor endorsements, cancer linkage)” (17RT4555:13-20; 31AA14263, 64 [P-10].) If J&J were not involved in the manufacture of the product after 1967, why was the company concerned about negative health publicity?

In 2005, J&J personnel discussed Defendants’ “ongoing project to defend talc.” (31AA14284, at 85, [P-263]; 17RT4598:16-4601:9.) Why did J&J need to prevent classification of talc as a carcinogen if it did not manufacture or control the baby powder product? At trial J&J never attempted to explain why the documents discuss J&J 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 AOB, 19-30; see also 27RT7657:7-7658:10; 17RT4541:15-4544:25; 17RT4544:26-4548:12; 17RT4555:13-4557:21; 40AA17750; 31AA14283, [P-262].)

In short, J&J exerted control and influence over the label long after it created JJCI, and made ongoing efforts to ensure that consumers would not be warned. Under *Novartis*, J&J owed a duty to warn.

Under the Opinion's narrow reading of *Novartis*, a predecessor manufacturer of any product that is not a prescription drug has no duty to consumers of identical products once it ceases manufacturing. It may continue indefinitely to influence and control the label and the absence of a warning, regardless of its continuing investigation of the risk, and regardless of the information that comes to its attention demonstrating that consumers are in danger. Such a result is inconsistent with the principles and policies outlined in *Novartis* and *Rowland*. The Opinion's conclusion that no duty exists as a matter of law erroneously and unreasonably restricts the holding in *Novartis*, and is contrary to California law.

2. THIS COURT SHOULD GRANT REVIEW TO SETTLE THE DISAGREEMENT AMONG THE COURTS OF APPEAL AS TO THE APPROPRIATE STANDARD OF REVIEW OF PUNITIVE DAMAGES VERDICTS.

It is up to the jury to decide not only which evidence is the most credible, but just how convincing that evidence is. Allowing the Appellate Court to decide if the evidence was substantial enough to

be “clear and convincing” takes the determination of the weight of the evidence out of the jury’s hands.

Crail v. Blakely (1973) 8 Cal.3d 744, 750 held that the “clear and convincing” standard was adopted for the edification and guidance of the trier of fact, and was not intended as a standard for appellate review. The Court affirmed the rule that the sufficiency of evidence to establish a given fact, where the law requires proof of the fact to be clear and convincing, is primarily a question for the trier of fact, and if there is substantial evidence to support its conclusion, the determination is not open to review on appeal.

A. Under the Substantial Evidence Standard of Review, the “Clear and Convincing” Test “Disappears,” and the Usual Rule of Conflicting Evidence is Applied.

Although at trial a plaintiff must prove malice by “clear and convincing evidence” (Civ. Code, § 3294, subd. (a)), the standard of review from an order granting JNOV is de novo, using the same standard as the trial court, i.e. viewing the evidence 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.) Neither the trial court nor the appellate court may reweigh the evidence. (*Quintal v. Laurel Grove Hospital* (1964) 62 Cal.2d 154, 159.)

Therefore, numerous cases have held that “on appeal from a judgment required to be based upon clear and convincing evidence, ‘the clear and convincing test disappears [and] the usual rule of conflicting evidence is applied, giving full effect to the respondent’s evidence, however slight, and disregarding the appellant’s evidence, however strong.’” (*Morgan v. Davidson* (2018) 29 Cal.App.5th 540, 548-549; *Parisi v. Mazzaferro* (2016) 5 Cal.App.5th 1219, 1227, fn. 11; *Sheila S. v. Superior Court* (2000) 84 Cal.App.4th 872, 881.) “The practical effect of this rule is that the quantum, or weight, of the evidence before the jury is not a factor for appellate review.” (*Mazik v. Geico General Ins. Co.* (2019) 35 Cal.App.5th 455, 462-463.)

But not all courts of appeal agree as to the standard of appellate review for a finding of malice. (See, e.g., *Morgan v. Davidson, supra*, 29 Cal.App.5th at 549 [declining to adopt the standard in *Pulte Home Corp. v. American Safety Indemnity Co.* (2017) 14 Cal.App.5th 1086, 1125, which held that “we must inquire whether the record contains ‘substantial evidence to support a determination by clear and convincing evidence.’”].)

Review is necessary to settle this important question of law and secure uniformity in the context of jury determinations. *Crail, supra*, and the cases it relies upon, all arose from determinations by a trial judge, not a jury, in contexts such as probate and family law

where there never was a right to a jury. The contrary view that the Appellate Court adhered to in this case invaded Ms. Echeverria's right to have a jury determine if the evidence of malice was clear and convincing.

This issue is presently before the Court in the context of conservatorship proceedings in *In re. O.B., supra*. The Court should make explicit that the principle applies to jury trials as well as to court trials.

B. The Appellate Court Erroneously Reviewed the JNOV as to Punitive Damages Under a “Clear and Convincing Evidence” Standard.

The trial court here heard and denied nonsuit and directed verdict motions challenging the sufficiency of the evidence to support a claim for punitive damages. (41AA17927;17959-17969; 29RT8101:15-8126:24; 31RT8742:15-8743:10.) It thus necessarily found the evidence was sufficient to support a claim for punitive damages against both Defendants. The jury then found by clear and convincing evidence that both J&J and JJCI had acted with malice.

The evidence was more than sufficient to support that jury finding. Conscious disregard for the safety of another is present where the defendant “is aware of the probable dangerous consequences of his or her conduct and he or she willfully fails to avoid such consequences. [Citation.] Malice may be proved either

expressly through direct evidence or by implication through indirect evidence from which the jury draws inferences.” (*Pfeifer v. John Crane, Inc.* (2013) 220 Cal.App.4th 1270, 1299 [manufacturer’s failure to warn of known cancer risk supported finding of malice]; *Karlsson v. Ford Motor Co.* (2006) 140 Cal.App.4th 1202, 1230.)

Defendants were aware of the probable dangerous consequences of their conduct, but they exposed thousands of women to ovarian cancer, deliberately failing to warn to protect their flagship product. Despite decades of mounting evidence showing a significantly increased risk of this fatal disease, Defendants chose to deny women an opportunity to make an informed decision whether to risk contracting ovarian cancer. Instead of issuing warnings about ovarian cancer, as others have done, including other manufacturers of talcum powder products and J&J’s own supplier, Defendants deliberately embarked on a campaign to vigorously defend the company’s “hallmark product” at all costs. (16RT4324:17-20; 20RT5594:11-5595:18; 21RT5716:20-5721:12, 5740:10-22; 35AA15619, [P-920]; 35AA15622, [P-921]; 35AA15625, [P-922]; 40AA17755.)

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.” (40AA17750, [P-20].)

The Appellate Court affirmed the JNOV as to punitive damages, under the mistaken assumption that appellate review should be under the “clear and convincing” standard. (Opinion 57, 59 [“Further, the post-injury conduct continued to fall short of establishing clear and convincing evidence of malice”], 60 [“The jury could reasonably conclude this was unreasonable and negligent. But it is not clear and convincing evidence of ‘despicable conduct,’ that is, conduct”] “[having] the character of outrage frequently associated with crime.”].) That amounts to appellate reweighing of the evidence that the trial court twice found adequate to present to the jury.

3. THIS COURT SHOULD GRANT REVIEW TO DETERMINE WHETHER A COURT OF APPEAL MUST DEFER TO A NEW TRIAL ORDER, BASED UPON ERRORS OF LAW AND UNSUBSTANTIATED FINDINGS OF FACT.

The Opinion recognizes that the trial court misconstrued the law and misperceived the facts, but it nevertheless upholds the grant of new trial as an exercise of discretionary “thirteenth juror” power. (Opinion 63.) This Court should grant review to explain that the

power to grant new trial is not a license to overturn any jury verdict the trial court disagrees with.

As it stands, the Opinion permits trial courts to disregard the fundamental right to a trial by jury in a civil action guaranteed by Article 1 Section 16 of the California Constitution. It essentially renders every jury verdict merely an advisory ruling, and every jury a mock jury. This cannot be the law.

A. A Trial Court Abuses its Discretion When It Misinterprets the Law or Makes Factual Findings Not Supported by the Evidence.

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.) But “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.”])

A trial court abuses its discretion when it applies the wrong legal standard (*Warren v. Kia Motors America, Inc.* (2018) 30 Cal.App.5th 24, 39 [judge’s comments at attorney fees hearing and in its written ruling indicated it was “clearly wrong” about standard for attorney fee award]), when its factual findings are not supported by substantial evidence (*Edwards Wildman Palmer v. Superior Court* (2014) 231 Cal.App.4th 1214, 1224; *Sukumar v. City of San Diego* (2017) 14 Cal.App.5th 451, 464), and “when it relies on a factor that is not relevant” (*S.Y. v. Superior Court* (2018) 29 Cal.App.5th 324, 229; see also, *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”].)

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. NFL* (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.”] 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. A trial court sitting as a thirteenth juror cannot objectively and impartially weigh the credibility of an expert whose testimony it has erroneously stricken based upon misapplication of the law and objectively verifiable errors of fact.

Likewise, “evidentiary 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.)

Just as a reviewing court would not uphold a verdict where a juror brought in their own jury instruction or introduced a fact that was not in evidence, an appellate court should not uphold a trial court’s determination resting on faulty legal and factual premises. The abuse of discretion standard does not permit an appellate court to look the other way when a trial court grants new trial based on mistakes of law and fact.

B. The Opinion Defers to Trial Court Determinations of Law That the Appellate Court Held Erroneous and to Factual Assumptions That the Appellate Court Found Were Unsubstantiated.

The Opinion demonstrates that the trial court’s rulings on both the new trial and the JNOV, particularly with respect to Dr. Yessaian’s testimony, rested on errors of law and objectively verifiable misstatements of the record.

First, the trial court found that Dr. “Yesssain did not have a basis to ‘rule in’ talc,” because “epidemiology was the *only* basis that Yessaian could and did ‘rule in’ talc as a disease agent.” (52AA23498, italics in original.) The Appellate Court held exactly the opposite, finding that “Yessaian’s Reliance on Epidemiological Studies Supported Her Opinion,” and concluding that “Yessaian’s reliance on epidemiological studies was a valid basis for her ultimate opinion.” (Opinion 44.) The trial court’s key factual finding – that epidemiology was the *only* basis on which Yessaian ruled in talc, was unsubstantiated by the record. The Appellate Court pointed to what the record actually showed: “Yessaian did not only rely on epidemiological studies. She considered the migration studies and evidence regarding the general processes of inflammation and resulting carcinogenesis, in combination with the evidence of talc

particles in Echeverria's ovarian tissues and other areas where the cancer was found. Her differential diagnosis evaluated and ruled out other known causes and risk factors. It was therefore permissible for Yessaian to also rely in part on epidemiological studies with risk ratios less than 2.0. (Opinion 48-49.) Moreover, Yessaian relied on four studies with odd ratios or relative risk estimates in excess of 2.0. (Opinion 20-21.)

The second key error in the trial court's ruling was its belief that Dr. Yessaian's testimony was insufficient because she "did not 'rule out' other causes of cancer," including age and ovulatory cycles and idiopathic causes. (52AA23498-99.) The Opinion refutes this based on *Cooper v. Takeda Pharmaceuticals America, Inc., supra*, stating that "Yessaian's Opinion Was Not Invalid for Failure to Rule Out Other Known Causes or the Possibility of an Unknown Cause." (Opinion 49-53.)

In *Cooper* the appellate court reversed JNOV and new trial rulings, based upon the same fatal error of law the trial court made here: "The reviewing court held the trial court erred when it ruled the expert's testimony was inadmissible because he failed to 'adequately consider and definitively rule out' potential causes of the cancer other than the defendant's drug." (Opinion 49, citing *Cooper, supra*, at 577.) Under *Cooper* and established California causation

law regarding causation, this was error. (239 Cal.App.4th at 576.) The trial court here, as in *Cooper*, erred by holding Plaintiff's expert "to a more rigid standard than is required to prove causation in civil cases." (*Id.* at 578.) This was a mistake of law – a "misapprehension" of the law of causation and a "Misapplication of the Substantial Factor Test." (*Id.* at 577.) As evidenced by the trial court's three previous rulings on the subject, it is substantially likely the court would not have granted new trial.

The foregoing were not the trial court's only demonstrable errors affecting weighing the evidence and determining credibility. It operated under the mistaken assumption that Dr. Yessaian had testified that the most probable cause of the cancer was unknown (52AA023499), yet the record completely contradicts these statements. Dr. Yessaian repeatedly emphasized that there was less than a 50% chance that Ms. Echeverria's cancer was idiopathic. (26RT7350:17-7351:26, 26RT7353:18-23; see also Opinion 24-25, referring to "Yessaian's testimony that it is **less than 50 percent likely** that the cause of Echeverria's cancer is unknown." [emphasis added.]

The trial court's errors of law and unsubstantiated findings of fact also tainted its credibility assessments and its weighing of the evidence for Plaintiff's general causation experts as well. Dr. Laura

Plunkett, a toxicologist, testified how scientific evidence, including epidemiology, demonstrates that genital exposure to talc causes ovarian cancer. (Opinion 11-13.) Dr. Jack Siemiatycki, an epidemiologist, testified based upon dozens of epidemiological studies that it is more likely than not genital talc use can cause ovarian cancer. (Opinion 13-16.) But in concluding that evidence of general causation was lacking (52AA23058), the trial court erroneously assumed that epidemiological studies greater than 2.0 are necessary to prove general causation. (52AA23497.) No legal authority exists for such a requirement in California or elsewhere. The trial court was confusing general causation — whether a substance is generally capable of causing disease, with specific causation — whether it caused the plaintiff’s disease. (Opinion 44 and fn.12.)

The trial court made the same error in concluding that such studies are necessary to prove specific causation, rejecting Dr. Yessian’s reliance on two studies that reported a 1.7 odds ratio for the serous histologic subtype. (Opinion 46.) However, the Court of Appeal’s analysis contradicted this reasoning, concluding that “[s]ubstantial evidence supported the jury’s finding that talcum powder was a substantial factor in causing Echeverria's cancer,” and pointing to the numerous legal and scientific authorities which have

rejected a 2.0 threshold requirement for proof of specific causation, let alone for proof of general causation. (Opinion 46-48.)

Despite these critical errors of law and unsubstantiated findings, the Appellate Court deferred to the trial court's ability to assess the credibility of witnesses and weigh the evidence. (Opinion 63.) But the trial court's mistaken assumptions of law and fact as to pivotal questions were an unfair thumb on the scale it used to weigh the evidence and assess credibility. The trial court's errors were not on minor points; they were the fundamental factual and legal underpinnings of its ruling.

CONCLUSION

For all the foregoing reasons, review should be granted.

Dated: August 9, 2019

Respectfully submitted,

ROBINSON CALCAGNIE, INC.

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Document received by the CA Supreme Court.

CERTIFICATE OF WORD COUNT
(Cal. Rules of Court, rule 8.504(d)(1).)

The text of this petition consists of 8,261 words as counted by the Microsoft® Word for Office 365 MSO (16.0.11328.20362) 64-bit word processing program version used to generate the petition.

Dated: August 9, 2019

Mark P. Robinson, Jr.

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CERTIFIED FOR PUBLICATION

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

SECOND APPELLATE DISTRICT

DIVISION THREE

**JOHNSON & JOHNSON
TALCUM POWDER CASES.**

B286283

JCCP No. 4872

**ELISHA ECHEVERRIA,
as Trustee, etc.,**

**(Los Angeles Super. Ct.
No. BC628228)**

Plaintiff and Appellant,

COURT OF APPEAL - SECOND DIST.

FILED

v.

JUL - 9 2019

JOHNSON & JOHNSON et al.,

DANIEL P. POTTER Clerk

Defendants and Appellants.

Deputy Clerk

**APPEALS from a judgment of the Superior Court of
Los Angeles County, Maren E. Nelson, Judge. Affirmed in part,
reversed in part, and remanded.**

**Robinson Calcagnie, Mark P. Robinson, Kevin F. Calcagnie;
Ferguson Case Orr Paterson, Wendy C. Lascher; Esner, Chang &
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Appellant.**

Document received by the CA Supreme Court.

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Cole Pedroza, Curtis A. Cole, Cassidy C. Davenport and
Scott M. Klausner for California Medical Association, California
Dental Association, and California Hospital Association as Amici
Curiae on behalf of Defendants and Appellants.

INTRODUCTION

This case is one of several coordinated suits in which the plaintiffs allege talcum powder products manufactured by Johnson & Johnson and Johnson & Johnson Consumer Inc. (JJCI; collectively, defendants) caused them to develop ovarian cancer. In July and August 2017, bellwether plaintiff Eva Echeverria's case was tried to a jury on a single claim of negligent failure to warn. The jury returned a verdict in Echeverria's favor against both defendants, awarding compensatory damages of \$68 million against Johnson & Johnson and \$2 million against JJCI. The jury awarded punitive damages of \$340 million against Johnson & Johnson and \$7 million against JJCI.¹ Defendants filed motions for judgment notwithstanding the verdict (JNOV) as to liability and punitive damages, as well as a joint motion for a new trial. The trial court granted the motions. Both sides have appealed.

¹ Echeverria died in September 2017. Her daughter, Elisha Echeverria, acting as trustee for the 2017 Eva Elaine Echeverria Living Trust, was substituted as plaintiff in October 2017.

We affirm the JNOV in favor of Johnson & Johnson, but partially reverse as to JJCI. To establish her negligence claim, Echeverria was required to prove each defendant had a legal duty to warn consumers about hazards inherent in their talc-based products; they breached that duty; and the breach caused Echeverria's injury. The causation element required evidence that talc-based products not only cause ovarian cancer in general (general causation), but also that defendants' products caused Echeverria's ovarian cancer in particular (specific causation). We conclude there was no substantial evidence to support a finding of liability as to Johnson & Johnson, a parent company that stopped manufacturing Johnson's Baby Powder in 1967, several years before there were any investigations or studies about a link between genital talc use and ovarian cancer. The evidence also failed to support a finding of malice as required for a punitive damages award, and we affirm the JNOV in favor of JJCI on that ground. We conclude there was substantial evidence to support the jury's other findings as to JJCI. However, we must apply a different standard of review when evaluating the trial court order granting JJCI's motion for a new trial. We determine the causation evidence was in significant conflict and would have supported a defense verdict. We therefore reverse the JNOV in favor of JJCI as to liability, but affirm the trial court order granting JJCI's motion for a new trial.

FACTUAL AND PROCEDURAL BACKGROUND

General Background

Plaintiff Eva Echeverria began using Johnson's Baby Powder as a feminine hygiene product in 1965, when she was 11 years old. She continued using the product two to three times each day, applying it to her genital area, underwear, and sanitary napkins, until 2016. She also briefly used the product "Shower to Shower."

In 2007, Echeverria was diagnosed with invasive, serous, high-grade ovarian cancer.

Johnson & Johnson manufactured Johnson's Baby Powder from 1893 until 1967. In 1967, JJCI began manufacturing the product. JJCI is a wholly owned subsidiary of Johnson & Johnson.

Investigations of a Link Between Talc and Ovarian Cancer in the Scientific, Medical, and Regulatory Communities

According to Echeverria's evidence at trial, the first epidemiological study to investigate a link between talc and ovarian cancer was published in 1982. In the decades that followed, researchers published over 30 additional epidemiological studies exploring whether there is an association between talc use and ovarian cancer. The parties' experts offered competing trial testimony about the validity, significance, and proper interpretation of these studies.²

Other scientific studies have hypothesized that talc causes ovarian cancer by creating inflammation in the ovaries. Studies have concluded talc can migrate from the vagina into the peritoneal cavity, where the ovaries are located. Experts for both sides testified talc causes inflammation. Studies have found chronic inflammation plays a role in the development of some types of cancer. Studies referenced at trial have also indicated increased inflammation may be linked to ovarian cancer. However, no

² The parties' appellate briefing includes citations to documents that were identified at trial, but not admitted, such as complete copies of scientific publications. "It is axiomatic that in reviewing the liability aspect of a judgment based on a jury verdict, we may not review exhibits identified, but not admitted at trial." (*Frank v. County of Los Angeles* (2007) 149 Cal.App.4th 805, 815.)

published studies, regulatory agencies, or scientific organizations have concluded *talc-based* inflammation *causes* ovarian cancer.

The World Health Organization International Agency for Research on Cancer (IARC) evaluates the carcinogenicity of different agents. In 2006, the IARC evaluated talc. The agency characterized perineal use of talc as possibly carcinogenic to humans, giving it a “2B” rating. This rating reflected a determination that there was “limited evidence” of carcinogenicity in humans and in experimental animals. The limited evidence determination meant: “A possible association has been observed between exposure to talc and ovarian cancer for which a causal interpretation is considered by the working group to be credible, but chance, bias, and confounding could not be ruled out with reasonable confidence.”

Some medical and scientific organizations have publicly identified genital talc use to be a risk factor for ovarian cancer, while others have not. In 2014 and 2015, the National Cancer Institute identified perineal talc use as a risk factor for ovarian cancer; in 2017, it indicated the weight of the evidence does not support an association between perineal talc exposure and an increased risk of ovarian cancer.

Defendants’ Response to Ongoing Questions Regarding a Link Between Talc and Ovarian Cancer

The evidence at trial included a series of documents from defendants’ files regarding talc and Johnson’s Baby Powder. Several of the documents lacked identified authors or other information to distinguish whether they were generated by Johnson & Johnson or JJCI. Other documents reflected communications between or among employees of both companies.

In 1964, W.H. Ashton, a Johnson & Johnson scientist, penned a memo to the file regarding plans for a test of a baby powder product composed of cornstarch, rather than talc. The goal was to “determine a preference rating” of Johnson’s Baby Powder compared to another product. The memo suggested “Dry Flo,” “a low substituted A1 salt of mildly treated cornstarch,” could be used as a potential additive. Although other potential additives were identified, Ashton wrote Dry Flo “has a very appealing tone because it would open the door to a merchandising advantage which could refer to an all starch product” The memo reported: “Since the meeting, Ashton established the largest commercial uses of Dry Flo are in Vitamin A manufacture . . . and 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.”

A 1975 letter on “Johnson & Johnson” letterhead bore the subject line “Talc in the Ovaries.” A handwritten note on the document suggested a Johnson & Johnson scientist’s contact with a cancer research institute may have provided “the opening to put us on notice re: the talc/ovary problem.”

Documents from 1986 and 1992 acknowledged genital talc use had been “implicated” or “linked” to ovarian cancer. The 1986 document expressed a continuing belief that talcum powder products were safe. It referenced a Cosmetics, Toiletries, and Fragrance Association (CTFA) sponsored animal study concluding talc does not migrate, and also cited the company’s “extensive experience in use.” Still, the documents recognized that cancer concerns, risks from inhalation, and a move among health professionals to discourage use of talc-based powders on babies, all posed a potential obstacle to sales.

Documents from 1993 to 1995 reflected defendants’ awareness of epidemiological studies about talc use and ovarian

cancer, their creation of a "Worldwide Talc Steering Committee," their monitoring of scientific studies and regulatory action on talc, and their strategies to respond to adverse press or media inquiries about talc safety issues. For example, a 1994 document prepared by a JJCI employee proposed answers to questions about a causal link between talc and cancer, and about two specific epidemiological studies. The proposed answers stated one study did not show a causal relationship between talc and ovarian cancer, while the other study found a higher incidence of ovarian cancer in women who routinely used talc, yet ultimately concluded talc was unlikely to be the cause of the majority of epithelial ovarian cancers. In response to the question of whether cosmetic talc use could lead to ovarian cancer, the document offered the answer: "Studies in animals have shown that talc does not migrate from the vagina to the ovaries. In conventional animal dosing studies, there is no evidence of ovarian cancer. Based on the available scientific data, no cause and effect relationship has been established showing that the use of talc can cause ovarian cancer."

A 1995 memo on "Johnson & Johnson Consumer Products Worldwide" letterhead, authored by "John Hopkins of Johnson & Johnson," addressed methods for responding to "adverse press and media issues around talc." The memo laid out three potential strategies, ranging from "do nothing," to a more "pro-active" strategy. Hopkins reported they had been taking the first approach: "We do not cause waves and we give no further publicity to adverse comments." Hopkins recommended a middle approach that would entail "responding to articles in the press, possibly including medical journals where we believe we can influence future behaviors and comment." A note from a vice president of research and development suggested "it might be worthwhile to have some effort" in the "proactive" strategy as well.

In 1997, an outside consultant wrote to a JJCI employee, offering criticisms of CTFA responses to claims of a link between talc and ovarian cancer. The consultant noted “several investigators have independently reported talc particles in ovarian tissue” and it was inaccurate to state that studies had failed to demonstrate “any real association” between hygienic talc and ovarian cancer. The letter pointed out that at least nine studies published in the open literature had shown a statistically significant association between the two. The consultant cautioned that denying the association “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. This would be a particularly tragic misperception in view of the fact that the industry does have powerful, valid arguments to support its position.” He suggested the better arguments were that the study results were “ambiguous, inconsistent, contradictory and therefore inconclusive” He concluded the letter: “I realize that CTFA is not J&J. However, I believe that a defeat or embarrassment of CTFA also negatively affects J&J to some extent.”

In 2002, a director of product safety at Luzenac, defendants’ talc supplier in the United States, sent a document to Ashton reporting: “We’ve been successful thus far in fending off the [National Toxicology Program (NTP)] classification of talc as being a potential human carcinogen. But we must also keep an eye out for IARC. If they decide to re-review the status of talc because of all the ovarian epidemiology studies that have been published since 1986, IARC can surprise us all and decide to list ‘talc’ as a potential human carcinogen. . . . Their threshold for required medical evidence is predictably quite minimal. You might want to counsel your management on this potential (and not to be too complacent about the status of talc).”

In 2004, the same Luzenac employee forwarded Ashton a study published earlier that year. He indicated the study “offers some compelling evidence in support of the ‘migration’ hypothesis. Combine this ‘evidence’ 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.” In 2006, Luzenac began including the IARC 2B classification in its talc material data safety sheets (MSDS).

Internal documents and e-mails from 2005 and 2006 reflected discussions among several individuals, including JJCI employees in the United States and Johnson & Johnson “regulatory” and “research” employees in Europe, about NTP and IARC evaluations of talc as a potential carcinogen. The e-mails referenced a project to “defend talc” and efforts to prevent a classification of talc as a carcinogen. They revealed the correspondents’ desire for certain “helpful” scientists to participate in the evaluations. The e-mails also discussed efforts to promote or develop studies or documents “that scientifically support the lack of a relationship of talc and ovarian cancer.”

In 2016, the Food and Drug Administration (FDA) issued a request to JJCI for information on talc. The JJCI response noted that in 2014, the FDA reviewed the safety of talc and denied citizen petitions filed in 1994 and 2008. The “‘FDA did not find that the data submitted presented conclusive evidence of a causal association between talc use in the perineal area and ovarian cancer.’” According to the response, the FDA also reviewed “the toxicity literature from 1980 to 2008 and did not find enough additional support at that time for the types of warning labels proposed” in the citizen petitions.

The JJCI response summarized the company's position: "At Johnson & Johnson Consumer Inc., our confidence in using talc is based on more than 100 years of safe use and more than 30 years of research by independent researchers, scientific review boards and global regulatory authorities. Various agencies and governmental bodies have examined whether talc is a carcinogen, and none have concluded that it is. The scientific literature, post-market experience, and expert opinion do not support the association of talc and ovarian cancer."

The Expert Testimony at Trial

Echeverria offered the testimony of four experts: pharmacologist and toxicologist Dr. Laura Plunkett; epidemiologist Dr. Jack Siemiatycki; pathologist Dr. John Godleski; and Echeverria's treating gynecologic oncologist, Dr. Annie Yessaian.

There was extensive pretrial litigation on the admissibility of plaintiff's proposed expert testimony, including a hearing pursuant to *Sargon Enterprises, Inc. v. University of Southern California* (2012) 55 Cal.4th 747. The trial court ruled only Dr. Yessaian would be allowed to testify as to "specific causation," i.e., offering an opinion that talc caused Echeverria's ovarian cancer. The other experts whose testimony was not completely excluded were allowed to testify only about general causation, i.e., offering an opinion that talc in general may cause ovarian cancer. Dr. Godleski was also allowed to provide opinions based on his personal examination of Echeverria's tissues.

Defendants offered the testimony of Dr. Alan Andersen, a biophysicist and former high-level employee at the FDA and the Cosmetic Ingredient Review (CIR); Dr. Douglas Weed, an epidemiologist and medical doctor; Dr. Juan Felix, a gynecologic pathologist; and Dr. Cheryl Saenz, a gynecologic oncologist.

General Causation: Plaintiff's Expert Testimony

Dr. Laura Plunkett

Dr. Plunkett is a former assistant professor of pharmacology and toxicology at the University of Arkansas. She is currently a consultant in the areas of toxicology, pharmacology, and human health risk assessment. Dr. Plunkett opined talc is toxic, it can migrate from the vagina to the ovaries, it can cause inflammation in human tissues, and chronic inflammation can cause ovarian cancer. Plunkett's opinion that talc is toxic was based on animal studies and human and animal cell studies. Plunkett testified she cited hundreds of studies in her expert report, a few of which she highlighted in her testimony.

For example, Plunkett described a 1984 study in which the injection of a talc solution near rat ovaries caused precancerous lesions in the rat's tissues. Plunkett also relied on a 1993 NTP study showing rats exposed to airborne talc for two years—a lifetime—developed precancerous lesions and, in some cases, tumors. She noted “dozens” of earlier studies established “talc can cause inflammation at the site.”

Plunkett also discussed two human cell studies. According to Plunkett, a 2007 study found talc produced neoplastic transformation in human ovarian cells.³ A 2009 study showed talc had effects in human cells, “as far as the type of genes it turns on and off,” that are similar to the effects observed with compounds known to cause cancer. Plunkett testified these studies supported her opinion that talc initiates an inflammatory response that leads

³ Plunkett described “neoplastic” or “neoplasm”: “That means tumor. So transformation is a process where it takes a cell and where the cell is changing from a preneoplastic cell—or a normal cell to a preneoplastic cell, taking on the characteristics of a cell that could become a cancer cell and could form a tumor.”

to cancer. Her opinion that talc can migrate from the vagina to the upper genital tract and to the ovaries was based on five studies dating from the early 1960's to the early 2000's, each of which she described for the jury.

Defendants tested and challenged Plunkett's interpretation of these scientific studies on cross-examination. She acknowledged weaknesses and limitations in the studies, but still felt they provided useful information. She also admitted there were several studies that came to different conclusions about the role of chronic inflammation in the development of ovarian cancer and the effect of talc on the female genital system.

Plunkett additionally based her opinion on her review of the epidemiological literature, including six meta-analyses showing a statistically significant increased risk between exposure to talc in the genital area and ovarian cancer. Plunkett explained that no single study could conclude talc causes cancer. Instead, she described each study as a piece of the causation puzzle.

Having reviewed the scientific data, Plunkett opined that regular genital use of talc sets up a chronic inflammatory condition in the cells that causes them to change to precancerous cells. The precancerous cells eventually lead to tumor growth, metastasizing tumors, and "full-blown advanced stage ovarian cancer." Plunkett also evaluated the Bradford Hill criteria, a framework for considering whether a substance causes a disease.⁴ She opined she

⁴ The criteria are temporal relationship, strength of the association, dose-response relationship, replication of the finding, biological plausibility, consideration of alternative explanations, cessation of exposure, specificity of the association, and consistency with other knowledge. (Green et al., *Reference Guide on Epidemiology* in *Reference Manual on Scientific Evidence* (3d ed. 2011) 549, 600 (hereafter, *Reference Guide*)). Epidemiologists use

had enough information relevant to the criteria to state, to a reasonable degree of scientific and professional certainty, that genital exposure to talc causes ovarian cancer.

Dr. Jack Siemiatycki

Dr. Siemiatycki is an epidemiologist and professor at the University of Montreal and McGill University. He has over 200 peer-reviewed publications and numerous honors and awards for his work in epidemiology and biostatistics.

Siemiatycki explained several epidemiological concepts to the jury. He informed the jury that “relative risk” is the risk of developing a disease among people exposed to a particular chemical agent or toxin, divided by the risk of developing the disease among those not exposed to the same agent. He offered an example: “So if the risk of cancer in the general population . . . is 4 percent in the general population but among a group of people with a certain environmental exposure it is 6 percent, the relative risk of cancer due to that environmental exposure would be 6 percent divided by 4 percent equals 1.5.”

Siemiatycki then elaborated: “[W]hen the risk is exactly the same among the exposed and the unexposed, then the relative risk will be 1. . . . The risk among the exposed is the same. . . . And that means the agent, whatever the exposure is, has no effect on the risk of developing the disease. . . . If the relative risk is greater than 1, it means exposure to that agent increases the risk of developing the disease. If the relative risk is less than 1, so the risk among the

these factors when considering whether a statistical association reflects a causal relationship. They “reflect criteria proposed by the U.S. Surgeon General in 1964 in assessing the relationship between smoking and lung cancer and expanded upon by Sir Austin Bradford Hill in 1965” (*Ibid.*, fns. omitted.)

exposed is less than the risk among the unexposed, it means that exposure to the agent prevents the disease.”

Siemiatycki explained the related concepts of “confidence intervals” and “statistical significance.” Statistical significance concerns the question, “how solid is our belief that the relative risk that we observe in a study is really precise and accurate?” Statistical significance depends on a number of factors, including the size of the study. Siemiatycki provided the jury with an example in which a study estimated a relative risk of 1.2, with a 95 percent probability that the true estimate is between 1.1 and 1.3. “That’s a pretty tight interval, and we call that a confidence interval. We call it a 95 percent confidence interval when we calculate it in such a way that it covers 95 percent of the underlying relative risks that are compatible with this estimate from this study.” If the results of a study have a confidence interval that includes relative risk numbers under 1—reflecting decreased risk—they are not statistically significant. In those cases, the results could be due to chance. However, Siemiatycki disagreed that a study with a nonstatistically significant result must be disregarded. Such studies still contain information that may be useful when combined with evidence from other studies.

Siemiatycki chaired the 2006 IARC working group on talc. The group concluded the association between perineal talc use and ovarian cancer could have other possible explanations. The available evidence was not strong enough to exclude chance, bias, and confounding—the presence of another factor that may be causing the disease—as explanations for the association that had been observed between talc and ovarian cancer.

Siemiatycki’s current opinion is that it is more likely than not genital talc use can cause ovarian cancer. His change of opinion was based in part on a 2013 study which, he testified, showed a

dose-response pattern—increased risk with increased exposure—that was missing in earlier studies. Siemiatycki opined the 2013 study, as well as studies published in 2015 and 2016, led him to conclude the statistical evidence associating genital talc use and ovarian cancer is now much stronger than it was 10 years earlier.

Siemiatycki also conducted a meta-analysis using existing talc literature to develop an opinion for the litigation. His analysis of 28 or 29 studies led him to believe there is a “very, very strong statistical association between use of talc and ovarian cancer.” The analysis resulted in a relative risk of 1.28, with a confidence interval of 1.18 to 1.38, rendering the results highly statistically significant. In other words, Siemiatycki found a 28 percent greater risk of ovarian cancer among women who used talc compared to women who had not used talc.

Siemiatycki evaluated the Hill factors and concluded they support an opinion that there is a causal relationship between genital talc use and ovarian cancer. He testified that for as many as half of the known carcinogens for which there is epidemiologic data, the data show relative risk estimates less than 2.0. Like Plunkett, Siemiatycki testified epidemiologists typically do not write articles stating “this causes that.” He explained “that sort of communication tends to come from authoritative agencies who have the capacity to integrate the viewpoints of multiple experts and, preferably, multiple experts from multiple disciplines.”

General Causation: Defendants’ Expert Testimony

Dr. Alan Andersen

Dr. Andersen is a former director of the CIR. He described the CIR as an independent review group, but also admitted an industry trade group is the CIR’s sole funder. Andersen testified the group’s mission is to review and assess the safety of ingredients

in an “open, unbiased, and expert manner,” and to publish the results in peer-reviewed scientific literature. In 2011, a CIR panel began a review of the safety of talc and concluded, in 2013, that talc is safe.

The CIR panel determined available data “did not reliably demonstrate” talc could migrate from the perineal area into the ovaries. The panel concluded the epidemiological data did not consistently reveal statistically significant positive associations between talc use and ovarian cancer; there were uniformly small risk ratio estimates; and other plausible alternative explanations of the association had not been ruled out. The panel did not see a consistent dose-response pattern reflected in the available literature. The panel also concluded there was no plausible biological mechanism to explain how genital talc use could cause ovarian cancer. It found a “lack of credible defensible evidence of carcinogenicity from the results of epidemiological studies of occupational exposures and animal bioassays.” The panel determined the available cellular studies were “unremarkable,” meaning there were no adverse cellular effects relating to talc.

Dr. Douglas Weed

Dr. Weed, medical doctor and epidemiologist, is a former chief of the office of preventive oncology at the National Cancer Institute, and currently a consultant. Based on his review of the scientific literature and the Hill criteria, Weed opined it has not been established that talc use causes ovarian cancer. In his evaluation of the epidemiological literature, he concluded the published cohort studies show no association between genital talc use and ovarian cancer. The case-control studies establish only a “weak” association

reflected in a relative risk estimate of 1.3.⁵ Weed opined the studies do not establish a dose-response pattern.

Weed further testified that some studies call into question the proposed biological mechanism of migrating talc particles causing inflammation. For example, although one would expect that women who used genital talc but had tubal ligation or hysterectomies would experience a reduced risk of ovarian cancer, Weed testified studies reveal “a mix of results.” Similarly, studies show no uniformly reduced risk of ovarian cancer in women who use medications that reduce inflammation. Weed also indicated studies have not established genital talc use increases the risk of other kinds of cancer in the female genital tract.

Pathology: Plaintiff's Expert Testimony

Dr. John Godleski

Dr. Godleski is a professor of pathology, recently retired from Harvard Medical School and the Harvard School of Public Health, where he continues to consult on research programs. He has close to 150 peer-reviewed publications, including a case report regarding the presence of talc particles in the lymph nodes of a woman diagnosed with ovarian cancer who had used genital talc for over 30 years.

⁵ Case-control and cohort studies are two types of epidemiological observational studies. In case control studies, researchers take two groups of people, one with the disease and one without, and both groups are asked about exposures they have had. In cohort studies, researchers study two groups, one whose participants have been exposed to the studied agent and an unexposed group. Researchers then observe and measure the incidence of the disease in both groups. (*Reference Guide, supra*, at pp. 556-559.)

Godleski examined slides of Echeverria's gynecologic tissue, using electron microscopy and x-ray analysis to identify talc particles. He found 11 talc particles and fibers in the examined tissues—eight particles of talc in ovarian tissue, and three talc particles in pelvic peritoneum and omentum tissue. Godleski opined that finding 11 particles in a small sample indicated there was a "substantial burden of talc" in Echeverria's tissue. He was "convinced" the particles were present as the result of perineal talc use.

Godleski admitted his expert reports submitted before trial did not mention that he observed inflammation in Echeverria's tissues. However, at trial Godleski testified he observed a talc particle, and other particles with characteristics of talc, near or "involved with" macrophages, which are cells that are signals of an inflammatory reaction. Godleski believed this suggested the occurrence of a chronic inflammatory process. The talc particle involved with a macrophage was from a slide of Echeverria's ovarian tissue. The other particles and cells were from a slide of Echeverria's pelvic peritoneum tissue. Godleski testified "to a reasonable degree of medical certainty that the presence of talc found in a woman's ovarian tissue can be contributory evidence for a causal link between the presence of talc and the development of a woman's ovarian cancer."

Pathology: Defendants' Expert Testimony

Dr. Juan Felix

Dr. Felix is the former director of gynecologic pathology at the University of Southern California (USC) Keck Medical Center. He is currently a professor and the director of anatomic pathology at the Medical College of Wisconsin. Felix testified that 75 to 80 percent of cases of ovarian cancer have an unknown cause. He

also testified exposure to talc “guarantees” there will be chronic inflammation in the body, and talc in a woman’s peritoneal cavity will produce inflammation and chronic toxicity. However, he opined the inflammation would take the form of adhesions and granulomas, neither of which causes ovarian cancer.

Felix reviewed Echeverria’s tissue slides and found no inflammation or evidence of the inflammatory reaction Godleski described. Felix testified that macrophages do not cause or contribute to the growth of ovarian cancer. He has seen hundreds of cases in which inflammation caused cancer and, in those cases, the inflammation was everywhere, not hidden or in an isolated area. He testified the presence of a tumor would not obscure the presence of talc-induced inflammation.

Specific Causation: Plaintiff’s Expert

Dr. Annie Yessaian

Dr. Yessaian is a double board-certified gynecologic oncologist at USC. She handles over 150 surgeries each year and also teaches and supervises medical students. Yessaian began treating Echeverria in 2007.

Yessaian conducted a “differential diagnosis” to form an opinion for the litigation about the cause of Echeverria’s cancer.⁶

⁶ “Differential diagnosis, or differential etiology, is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated. . . . [Citation.] . . . [¶] The first step in the diagnostic process is to compile a comprehensive list of hypotheses that might explain the set of salient clinical findings under consideration. [Citation.] The issue at this point in the process is which of the competing causes are *generally* capable of causing the patient’s symptoms or mortality. . . . [¶] After the expert rules in all of the potential hypotheses that might explain a patient’s symptoms, he or

Yessaian considered several “protective factors,” which “are very well known and established to reduce a woman’s risk of developing ovarian cancer.” These were parity—how many children a woman has delivered to term, use of oral contraception, bilateral tubal ligation, and breastfeeding. Echeverria had one child, so Yessaian considered this “a factor.” Echeverria used oral contraception very briefly, breastfed her daughter very briefly, and did not have tubal ligation.

Yessaian considered genital talcum powder. She took note that Echeverria used talcum powder two or three times a day for over 40 years, resulting in over 30,000 genital applications in her lifetime. Yessaian reviewed migration studies establishing there is a biologically plausible way for talc to go from the external environment to the peritoneal cavity. She looked at “other evidence” relating to a mechanism of “talc sitting in the peritoneal cavity” and “participating in that whole cascade of process from inflammation to malignant transformation to leading to cancer.” Yessaian did not have specific evidence of this mechanism taking place in Echeverria. However, she considered Godleski’s findings that talc was present in Echeverria’s ovary, omentum, and peritoneal cavity, all places where cancerous tumors were found.

Yessaian also considered numerous epidemiological studies. At trial, she discussed studies that found 20, 40 and 60 percent increases in the risk of serous ovarian cancer in women exposed to talc. She also indicated she relied on four studies with odds ratios

she must then engage in a process of elimination, eliminating hypotheses on the basis of a continuing examination of the evidence so as to reach a conclusion as to the most likely cause of the findings in that particular case.” (*Clausen v. M/V New Carissa* (9th Cir. 2003) 339 F.3d 1049, 1057-1058.)

or relative risk estimates above 2.0.⁷ A 1982 study showed an odds ratio of 3.28, while a 1992 study resulted in an odds ratio of 4.8.⁸ A 1999 study showed an overall odds ratio of 2.15, with a stratified result of 1.70 for serous ovarian cancer. A 2009 study showed an overall odds ratio of 2.08, and a 1.70 estimate for the serous subtype. Yessaian believed the results of the 2009 study suggested Echeverria was at an even higher risk than the overall risk estimate reflected in the study, given the extent of her talc use. All four studies had statistically significant results. Yessaian further testified about four studies that provided evidence of dose response.

Yessaian also “evaluated . . . 13 factors that could have an implication in ovarian cancer in general.” She considered genetic mutation as a potential cause and ruled it out. During the course of treating Echeverria, Yessaian ordered genetic testing on multiple occasions. The testing revealed no abnormalities in the mismatch

⁷ Before trial, the court ruled Yessaian’s testimony would be allowed, provided she could opine based solely on studies showing risk estimates greater than 2.0. As discussed in greater detail below, the court relied on cases concluding only epidemiological studies with relative risk estimates greater than 2.0 (“doubling the risk”) are useful to the jury as support for a specific causation opinion. These cases reason “a relative risk of 2.0 implies a 50% probability that the agent at issue was responsible for a particular individual’s disease. This means that a relative risk that is greater than 2.0 permits the conclusion that the agent was more likely than not responsible for a particular individual’s disease. [Citation.]” (*In re Silicone Gel Breast Impl. Prod. Liab. Lit.* (C.D.Cal. 2004) 318 F.Supp.2d 879, 893.)

⁸ In case-control studies, the association between the exposure to an agent and the disease is reflected as an odds ratio rather than as a relative risk. (*Reference Guide, supra*, at pp. 568-569.)

repair genes known to increase the risk of ovarian cancer and no clinically significant gene mutations.

Yessaian considered and ruled out fertility medications and hormone replacement therapy as Echeverria had not used either one. She considered endometriosis and polycystic ovarian syndrome and ruled both out; Echeverria did not suffer from either condition. Yessaian considered tobacco and alcohol use since Echeverria had used both for a short time. Yessaian ruled out tobacco, indicating the data on tobacco and ovarian cancer are “inconclusive at best, especially if you look at for serous.” Yessaian also ruled out alcohol use, concluding Echeverria’s alcohol consumption was not significant enough to cause her ovarian cancer.

Yessaian considered family history. Echeverria’s mother had pancreatic cancer. Her aunt had colon cancer. No family members had ovarian or breast cancer. Yessaian noted the aunt with colon cancer was diagnosed in her 80’s and genetic testing had established Echeverria’s cancer was not genetically related. Yessaian thus ruled out family history of cancer.

Yessaian considered Echeverria’s age. She believed 52 to be an average age for ovarian cancer incidence and therefore not a likely cause.

She considered menarche, the age at which Echeverria had her first menstrual period, and menopause. Yessaian explained: “The idea is if a woman gets her periods so, so young and then gets her menopause so, so late, she has all these long, long years of ovulation. One of the theories is that with every ovulation the surface of the ovary has an injury. And when the body tries to repair that injury—cancer is kind of like a repair gone wrong. . . . So that’s why the more ovulations you had, like early—you know, they start their periods at nine and they are menopausal at like 55 and beyond, they’ve had so much more ovulations, more chances of

damage to the surface, more damage or repair process that could go off, so that's why. And [Echeverria] was so average in her age of menarche and also her age at menopause. She was menopausal before I saw her." Yessaian thus ruled out menarche and menopause, or the number of ovulatory cycles, as a cause.

Yessaian considered and ruled out Echeverria's obesity. She explained obesity is a standard risk factor for uterine cancer: "[T]he more estrogen you have through these cells producing more estrogen in the fatty tissue, the more likely you are to get uterine cancer and breast cancer. The data on these two are very, very solid." Yessaian testified there is no similar "solid evidence" identifying obesity as a risk factor for ovarian cancer. Yessaian had reviewed the available literature and found no correlation between obesity and serous ovarian cancer.

Yessaian thus concluded "talc was more probable than not the causing agent in Ms. Echeverria's developing high-grade serous ovarian cancer," and that it is more probable than not that but for her use of talc, she would not have developed the cancer. Yessaian testified her opinion was not based on a single study, factor, or element. Rather it was the "totality of all the evidence and the factors" she considered.

On cross-examination, Yessaian admitted she did not have any evidence there was inflammation in Echeverria's ovarian tissue. If Echeverria had been over 60 years old, Yessaian would have attributed the cancer to aging and would have concluded it was more than 50 percent likely that advancing age and the corresponding accumulation of "genetic hits" caused the cancer. Since Echeverria was younger—52 when diagnosed—Yessaian found age less likely to be the cause. Yessaian admitted no one could completely rule out age as a contributing factor but she was trying to figure out "which factor stands out."

As to a high number of ovulatory cycles, Yessaian opined it was not an “independent risk factor for postmenopausal ovarian cancer.” She testified she could not rule out the number of ovulatory cycles “as a hundred percent, but it more likely than not was not a factor.”

Yessaian agreed that in general terms for ovarian cancer, as well as other cancers, it might be true that the “biggest cause” is “unknown etiology.” She also agreed that “unknown etiology” could be a cause of Echeverria’s ovarian cancer, but opined that was “less probable than not.” She explained the statement “the leading cause of cancer is an unknown etiology” applies to everyone and ovarian cancer in general. She distinguished Echeverria’s case: “Not Ms. Echeverria’s specific serous and with everything else included in her history, having ruled out genetics, and we’ve been talking about this whole talc and migration and use and et cetera. That statement holds true as a blanket general, not for this particular—Ms. Echeverria’s case.” She later elaborated that she had “studied all the details in [Echeverria’s] particular case. And when you’re putting an etiology of all cancers, that’s for everybody else, the population of the world in general. We’re talking about how we evaluated this patient’s case in detail and studied all other factors involved. She’s not a generic part of the population. I’m talking about a case that—a patient that has been studied and evaluated in [detail].”

Defense counsel asked if Yessaian’s differential diagnosis started with the assumption that it was possible to find a cause of the cancer without considering the possibility that an unknown risk factor caused the cancer, or that it developed spontaneously. Yessaian answered: “I objectively evaluated all risk factors to the best of my knowledge and ability I did not have any preconceived conclusion for which I wanted to fit my . . . workup

. . . . I always assume unknown is part of what I do. I want to make sure—can I find something known? Because I look for what I know. I look for known. And if I don't find something known, then I say, okay, it's unknown. I mean there's no publication that says let's look at unknown—the role of unknown. We look at what we know. And we cannot find something we know, then, okay, sorry, we tried. It's unknown.”

Counsel asked for the basis for Yessaian's testimony that it is less than 50 percent likely that the cause of Echeverria's cancer is unknown. Yessaian answered: “At the risk of sounding redundant and repetitive, all the risk factors that I included, ruling in, ruling out the fact about her talc exposure, the epidemiologic data that support, the total evidence that I provided in my report and my knowledge of her Because I've studied Ms. Echeverria's case specifics. I looked at all the risk factors that applied to her. I've looked at the protective factors that could apply to her, the talc exposure, the epidemiology, . . . the migration, all of that put together. I cannot do the same assessment for every patient out there in the general population. So not all patients with cancer get that dissection of possible etiology.”

Specific Causation: Defendants' Expert

Dr. Cheryl Saenz

Dr. Saenz is a gynecologic oncologist and clinical professor at the University of California, San Diego. Saenz opined perineal use of talc does not contribute to the development of ovarian cancer. She based her opinion on her over 20 years of clinical experience treating thousands of women with ovarian cancer, a review of the literature on the topic, and the absence of evidence “that talc is a consistently credible scientific cause of ovarian cancer.” Saenz testified several factors increased Echeverria's risk for developing

ovarian cancer: her family history of cancer, even though her family members had different kinds of cancer; her morbid obesity; the fact that she had her first child late, at 36 years old; and her early menarche at age 11.

Saenz disagreed with Yessaian's opinion that vaginal talc use was more likely than not the cause of Echeverria's cancer. She testified ovarian cancer is multifactorial and there is no way for her to say exactly what causes a patient to develop the disease. Saenz does not consider unknown etiology to be a risk factor, instead "it's a fact. We don't know what causes the majority of ovarian cancers . . . over 50 percent." Saenz opined it is more likely than not talc had nothing to do with Echeverria developing ovarian cancer. She has operated on thousands of women with ovarian cancer and has never seen inflammation in any of her ovarian cancer patients.

Saenz critiqued Yessaian's method of considering epidemiological studies. She explained the epidemiological "literature is being published to try and determine whether or not there are certain associations, to try and determine whether or not there are certain relationships. It's not meant to be a mathematical model that you can then just plug your patient into and do a calculation of her individual risk."

Saenz also testified specifically about a 2016 study both she and Yessaian had cited in their reports. Saenz testified the study showed a relative risk estimate of 1.33 for serous invasive ovarian cancer, for women who, like Echeverria, were postmenopausal at the time of diagnosis and used talc more than 24 years. Yet, for women who, also like Echeverria, were postmenopausal at the time of diagnosis, did not use hormone replacement therapy, and used talc more than 24 years, the study showed a relative risk of 1,

indicating no increased risk.⁹ Both results had confidence intervals rendering them not statistically significant. Saenz continued: “So in my opinion, again, I do not think you should ever use literature to see what happened with one individual patient. But if you’re going to pull the numbers that apply to Ms. Echeverria, this paper says that she is not at an increased risk of developing ovarian cancer based on her years of talc use.”

Jury Verdict and Posttrial Motions

The jury returned a verdict finding both defendants liable for negligent failure to warn. The jury awarded Echeverria a total of \$70 million in compensatory damages; \$68 million as to Johnson & Johnson and \$2 million as to JJCI. The jury awarded \$347 million in punitive damages; \$340 million against Johnson & Johnson, and \$7 million against JJCI. Defendants filed separate motions for JNOV and a joint motion for a new trial. The trial court granted the three motions.

DISCUSSION

I. *Judgment Notwithstanding the Verdict*

A. Standard of Review

“ “A motion for judgment notwithstanding the verdict may be granted only if it appears from the evidence, viewed in the light most favorable to the party securing the verdict, that there is no substantial evidence in support. [Citation.] [¶] . . . As in the trial court, the standard of review [on appeal] is whether any substantial evidence—contradicted or uncontradicted—supports the jury’s conclusion.” ’ [Citation.]” (*Webb v. Special Electric Co., Inc.* (2016) 63 Cal.4th 167, 192.) We, like the trial court, may not reweigh the

⁹ The testimony did not indicate whether this result was stratified for serous ovarian cancer alone.

evidence or judge the credibility of witnesses. “ “ ‘If the evidence is conflicting or if several reasonable inferences may be drawn, the motion for judgment notwithstanding the verdict should be denied. . . .’ ” [¶] When an appellate court reviews an order granting JNOV, it will “ ‘resolve any conflict in the evidence and draw all reasonable inferences therefrom in favor of the jury’s verdict.’ ” [Citation.]” (*In re Coordinated Latex Glove Litigation* (2002) 99 Cal.App.4th 594, 606.)

The testimony of a single witness may be substantial evidence, including the testimony of an expert. However, “when an expert bases his or her conclusion on factors that are ‘speculative, remote or conjectural,’ or on ‘assumptions . . . not supported by the record,’ the expert’s opinion ‘cannot rise to the dignity of substantial evidence’ [Citations.]” (*Wise v. DLA Piper LLP (US)* (2013) 220 Cal.App.4th 1180, 1191-1192; *Jennings v. Palomar Pomerado Health Systems, Inc.* (2003) 114 Cal.App.4th 1108, 1117-1118.)

**B. No Substantial Evidence Supported
the Jury’s Verdict as to Johnson & Johnson**

Johnson & Johnson stopped producing Johnson’s Baby Powder in 1967. The trial court concluded there was no substantial evidence that Johnson & Johnson knew of any risk of harm from perineal use of talc prior to 1967, there was no evidence at trial sufficient to find the company directly liable after that time, and no substantial evidence to find Johnson & Johnson vicariously liable for any JJCI tort.

On appeal, Echeverria argues the trial court misinterpreted the law and ignored evidence supporting the jury’s findings. We find no merit in these arguments.

1. Failure to warn

A manufacturer has a duty to warn of facts which make a product dangerous or likely to be dangerous. “[A] product ‘likely’ to

be dangerous will ‘in all probability’ or ‘probably’ be dangerous.” (*Valentine v. Baxter Healthcare Corp.* (1999) 68 Cal.App.4th 1467, 1483 (*Valentine*)). To establish a negligent failure to warn claim, the plaintiff must prove “ ‘that a manufacturer or distributor did not warn of a particular risk for reasons which fell below the acceptable standard of care, i.e., what a reasonably prudent manufacturer would have known and warned about.’ ” (*Carlin v. Superior Court* (1996) 13 Cal.4th 1104, 1112 (*Carlin*)). “[A] reasonable manufacturer [is] not charged with knowing more than what would come to light from the prevailing scientific and medical knowledge.” (*Valentine*, at pp. 1483-1484.) “The manufacturer has no duty to warn of risks that are ‘merely speculative or conjectural, or so remote and insignificant as to be negligible.’ [Citation.]” (*T.H. v. Novartis Pharmaceuticals Corp.* (2017) 4 Cal.5th 145, 164 (*Novartis*)).

Under California law, a manufacturer generally has no duty to warn of risks from another manufacturer’s product, and is typically liable only for harm caused by its own product. (*O’Neil v. Crane Co.* (2012) 53 Cal.4th 335, 349, 365; *Taylor v. Elliott Turbomachinery Co., Inc.* (2009) 171 Cal.App.4th 564, 593-596.) It was undisputed that Johnson & Johnson ceased manufacturing Johnson’s Baby Powder after 1967. Echeverria was required either to establish that Johnson & Johnson breached a duty to warn between 1965 and 1967, or to advance and prove a theory under which the company could be liable even after it stopped manufacturing the product.

**2. *There was no substantial evidence
Johnson & Johnson breached a duty to warn
prior to 1967***

Echeverria contends Johnson & Johnson knew or should have known Johnson’s Baby Powder was unsafe by 1967 and it breached

its corresponding duty to warn consumers. There was no substantial evidence to support this theory. According to Echeverria's evidence at trial, the first epidemiological study to investigate a link between perineal use of talc and ovarian cancer was published in 1982, 15 years after Johnson & Johnson ceased manufacturing the product. On appeal, Echeverria refers to a 1971 study as evidence of Johnson & Johnson's knowledge of the dangerousness of talc. Yet, plaintiff's experts identified a 1982 study as the "first" epidemiological study to address the issue. The 1971 study was only obliquely mentioned when referenced in other documents. In any event, the 1971 study does not assist Echeverria's argument since it was published four years after JJCI became responsible for Johnson's Baby Powder. There was no evidence that Johnson & Johnson knew or should have known of the study or its results prior to the 1971 publication date.

The only pre-1967 evidence Echeverria offered to support her claim was the 1964 internal memo, in which the scientist Ashton wrote that Dry Flo had replaced talc as a condom lubricant "because it was found to be absorbed safely in the vagina whereas, of course, talc was not." There was no evidence providing the context of this statement, no evidence that anyone had raised concerns regarding a link between talc and ovarian cancer by 1964, and no further explanation of the memo.¹⁰

¹⁰ During the cross-examination of a defense expert, the jury was shown a 1996 article from the "Jersey Journal," reporting that condom makers were no longer using talc due to "women's health concerns." The article stated: "Concern about talc as an ovarian carcinogen goes back 50 years in the medical literature." The trial court instructed the jury it was not to consider the statements in the article for their truth. The article was not admitted into evidence. The statements in the article cannot support Echeverria's

Even if the jury could reasonably infer from the 1964 memo that Johnson & Johnson knew talc posed some danger to consumers because it was not safely absorbed into the vagina, this is a far cry from knowledge that perineal talc use created a risk of ovarian cancer. (*Carlin, supra*, 13 Cal.4th at pp. 1112, 1116 [manufacturer must warn of particular risk]; see also *Mitchell v. City of Warren* (6th Cir. 2015) 803 F.3d 223, 230 [jury may not speculate that a manufacturer should have known about one risk because a separately known risk revealed the mere possibility of the first].) While inferences may support a judgment, “ ‘the inference must be a reasonable conclusion from the evidence and cannot be based upon suspicion, imagination, speculation, surmise, conjecture or guesswork. [Citation.]’ ” (*Joaquin v. City of Los Angeles* (2012) 202 Cal.App.4th 1207, 1219.) The jury could not reasonably infer from the 1964 memo that Johnson & Johnson was aware at that time of a risk of ovarian cancer from genital talc use.

Echeverria argues the jury could infer from later documents that Johnson & Johnson knew or reasonably should have known in earlier years of the risks of genital talc use. But the next document admitted from defendants’ files, which referenced “the talc/ovary problem,” dated from 1975, eight years after Johnson & Johnson ceased manufacturing baby powder, and over a decade after Ashton wrote the 1964 memo. No document admitted at trial referred to the 1964 memo or cast any light on its interpretation. There was no legitimate basis for the jury to conclude from later documents, which reflected later developments in scientific knowledge about a link between talc and ovarian cancer, that Johnson & Johnson had similar knowledge in 1964. Indeed, Echeverria’s own expert,

claims that the 1964 Ashton memo reflected an awareness that genital talc use created a risk of ovarian cancer.

Dr. Plunkett, testified that the fact that “talc is dangerous and capable of causing cancer” was likely to have been known since the early 1990’s; over two decades after Johnson & Johnson stopped producing Johnson’s Baby Powder.

Echeverria further argues the trial court erred in requiring evidence that Johnson & Johnson “knew or should have known prior to 1967 that talc more probably than not caused ovarian cancer.” But, in our view, the most salient portion of the trial court ruling is the conclusion that “[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.” We agree with the trial court that there was no evidence indicating a link between ovarian cancer and talc was even suspected by 1967. Based on the evidence at trial about what was known or reasonably knowable by 1967, a risk of ovarian cancer from perineal talc use would have been entirely speculative and conjectural, and Johnson & Johnson had no duty to warn of such risks.

3. *There was no legal basis for the jury to find Johnson & Johnson liable for breaching a duty to warn after it ceased manufacturing the product*

Echeverria argues that even if Johnson & Johnson did not breach a duty to warn while it was manufacturing Johnson’s Baby Powder, a manufacturer has a continuing duty to warn after it stops making a product, and it remains liable even after a third party begins manufacturing the product. However, the authorities Echeverria cites for these propositions do not support her argument.

For example, in *Novartis*, the court held a prescription drug maker that negligently fails to warn while it is producing a drug may be liable when the plaintiff is harmed by another manufacturer’s generic bioequivalent. Liability may continue even

after the original drug maker sells its rights in the brand-name drug to a successor. (*Novartis, supra*, 4 Cal.5th at p. 156.) Yet, the *Novartis* court's reasoning and analysis are inextricably tied to the "distinctive legal framework governing labeling for brand-name and generic pharmaceuticals." (*Ibid.*) Federal regulations governing prescription drug labeling require the makers of generic bioequivalents, and successor manufacturers, to match the original brand-name manufacturer's warning label as a default. (*Id.* at pp. 157-158, 182-183.) As a result, the original brand-name manufacturer's failure to issue an adequate warning label may have foreseeable effects on consumers using another manufacturer's generic bioequivalent, and on consumers who use the drug after a successor manufacturer takes over production and sales. (*Id.* at pp. 174, 182-183, 192.)

This case presents no such unique circumstances that would take it outside of the general rule that a manufacturer has no duty to warn of risks posed by another manufacturer's product. (*O'Neil v. Crane Co., supra*, 53 Cal.4th at pp. 364-366; *Taylor v. Elliott Turbomachinery Co., Inc., supra*, 171 Cal.App.4th at pp. 593-596.) Further, as to successor prescription drug manufacturers, the *Novartis* court held "a brand-name manufacturer's sale of the rights to a drug does not, as a matter of law, terminate its liability for injuries foreseeably and proximately caused by *deficiencies present in the warning label prior to sale.*" (*Novartis, supra*, 4 Cal.5th at p. 191, italics added.) *Novartis* concerned continuing liability for a negligent failure to warn in labeling that occurred prior to a manufacturer divesting itself of the rights to the drug. (*Id.* at pp. 183, 188, fn. 9 [court's holding would not prevent the manufacturer in a given case from arguing it did not breach its duty given the scientific knowledge at the time].) This holding is of no assistance to Echeverria because there was no substantial evidence that

Johnson & Johnson negligently failed to warn prior to 1967, when it was manufacturing Johnson's Baby Powder. *Novartis* does not support Echeverria's argument.

The other authorities Echeverria cites are equally inapt. *Hernandez v. Badger Construction Equipment Co.* (1994) 28 Cal.App.4th 1791, and *Balido v. Improved Machinery, Inc.* (1972) 29 Cal.App.3d 633, concerned the manufacturers' alleged negligence in failing to correct a defect affecting an earlier model of a product still in use. Neither case addressed a duty to warn after the manufacturer has stopped making the product altogether, when the original product is no longer in use, or when the plaintiff alleges she was harmed by the product a different entity manufactured and sold.

Echeverria did not argue that Johnson & Johnson had a separate duty to take corrective efforts as to the product it manufactured prior to 1967. (See, e.g., CACI No. 1223 [instructions for theory a defendant was negligent because it failed to recall/retrofit the product].) There was no evidence that Echeverria was using talcum powder Johnson & Johnson manufactured, i.e., before 1967, years later. Indeed, such an inference would be unreasonable in light of the evidence regarding her frequency of use. (*Valentine, supra*, 68 Cal.App.4th at p. 1482 [jury properly instructed that manufacturer's duty to warn is a continuous duty which lasts as long as the product is in use; under the instructions given "as more information about adverse effects develops over time, the manufacturer must continue to provide physicians with warnings, at least so long as it is manufacturing and distributing the product"].) Echeverria did not present a legal theory to the jury that allowed it to find Johnson & Johnson liable for breaching a duty to warn that continued even after it stopped manufacturing the product, or after the product was no longer in use.

In her reply brief, Echeverria cites several cases from other jurisdictions espousing theories of products liability applicable to nonmanufacturers, such as “apparent manufacturer” liability, or the liability of a trademark licensor. Echeverria did not advance any such theory at trial. She tried the case on a negligent failure to warn theory only, not on a version of nonmanufacturer products liability represented in the cases she now cites on appeal. The jury’s verdict cannot be upheld based on legal or factual theories that were not advanced below. (*Rayii v. Gatica* (2013) 218 Cal.App.4th 1402, 1409; *Richmond v. Dart Industries, Inc.* (1987) 196 Cal.App.3d 869, 874.) Nor was the jury required to make findings that would have been necessary for such a theory, even if it applied to Echeverria’s negligent failure to warn claim. (See *Bay Summit Community Assn. v. Shell Oil Co.* (1996) 51 Cal.App.4th 762, 778 [factors necessary for strict liability of defendant outside of vertical distribution chain but involved in the production and marketing enterprise of a defective product]; *Kasel v. Remington Arms Co.* (1972) 24 Cal.App.3d 711, 725-726; cf. *Cleveland v. Johnson* (2012) 209 Cal.App.4th 1315, 1334 [verdict alternatively affirmed on ground for which the jury made necessary findings in association with another issue].)

4. *There was no evidence to support a finding of liability arising out of Johnson & Johnson’s continued involvement in talc issues or based on it “directing” JJCI*

Echeverria contends the jury could reasonably find Johnson & Johnson had a continuing duty to warn because it played an active role in efforts to denigrate or conceal a link between talc and ovarian cancer. She asserts several documents from defendants’ files that concerned talc referred to “Johnson & Johnson” only, suggesting the parent company’s involvement. She also points to

evidence that Johnson & Johnson was a member of the CTFA and it agreed to support a talc task force,¹¹ and communications about talc included both Johnson & Johnson and JJCI employees. Echeverria argues this evidence showed the parent company was “directly involved” in failing to warn of the risks of Johnson’s Baby Powder.

We disagree. The relevant question for purposes of the negligence claim is whether Johnson & Johnson, no longer the manufacturer of the injury-causing product, had a duty to Echeverria after 1967. (*Ladd v. County of San Mateo* (1996) 12 Cal.4th 913, 917-918.) Evidence that Johnson & Johnson took actions to defend talc, to participate in industry trade groups, or to avoid a NTP or IARC characterization of talc as a carcinogen, does not in itself create a basis to hold Johnson & Johnson liable to Echeverria for negligence. Echeverria has failed to articulate a *legal theory*, supported by substantial evidence, that would have allowed the jury to find Johnson & Johnson had and breached a duty to Echeverria, even though JJCI was responsible for the product she used. Indeed, Echeverria’s failure to cite any legal authorities to support her theory—either below or on appeal—arguably waives this argument altogether. (*Ewald v. Nationstar Mortgage, LLC* (2017) 13 Cal.App.5th 947, 948.)

Similarly, Echeverria contends the evidence showed Johnson & Johnson was “directing” JJCI’s actions, without citing legal authorities to specify her underlying legal theory. Nonetheless, the trial court considered Echeverria’s arguments to reflect an agency or alter ego theory of liability. The court concluded there was no substantial evidence to support either theory. We agree. JJCI is a

¹¹ There was evidence that a JJCI executive signed an agreement committing “Johnson & Johnson” to contribute funds for a CTFA task force.

wholly owned subsidiary of Johnson & Johnson, but evidence of a legal relationship between the two corporations is not, without more, sufficient for Johnson & Johnson to be held liable for JJCI's actions. (*Institute of Veterinary Pathology, Inc. v. California Health Laboratories, Inc.* (1981) 116 Cal.App.3d 111, 119.) Ambiguity arising out of similar company names is also not enough to establish liability. The record is devoid of any evidence of the relationship between Johnson & Johnson and JJCI, beyond the fact of the parent-subsidary relationship and interaction of some employees. (*Santa Clarita Organization for Planning & Environment v. Castaic Lake Water Agency* (2016) 1 Cal.App.5th 1084, 1106 [having some common personnel is not enough to show subsidiary is alter ego of parent].)

The trial court properly rejected Echeverria's claims that internal documents showed Johnson & Johnson directed or controlled JJCI. At most, the documents established Johnson & Johnson was involved in issues related to talc, sometimes in coordination with JJCI. The documents failed to create an inference that any such coordination was in fact control, or that Johnson & Johnson treated JJCI as merely a conduit or instrumentality of itself. (*Santa Clarita Organization for Planning & Environment v. Castaic Lake Water Agency, supra*, 1 Cal.App.5th at pp. 1104-1106; *Sonora Diamond Corp. v. Superior Court* (2000) 83 Cal.App.4th 523, 541-542.)

There was no substantial evidence to support a finding that Johnson & Johnson was liable to Echeverria for negligently failing to warn of the risks of perineal talc use. The trial court properly granted JNOV to Johnson & Johnson.

C. Substantial Evidence Supported the Jury's Finding That JJCI Breached Its Duty to Warn

In its motion seeking JNOV, JJCI argued the evidence did not show that the prevailing scientific knowledge established talc to be dangerous by 2007, when Echeverria was diagnosed with ovarian cancer. The trial court rejected this theory as a ground for JNOV because defendants had not requested an equivalent jury instruction. On cross-appeal, defendants argue this was error and the trial court should have granted JNOV to JJCI on this alternative ground. Echeverria contends there was substantial evidence that JJCI breached a duty to warn.

We need not decide if the trial court erred in concluding defendants' failure to request a jury instruction on "prevailing scientific knowledge" prevented any consideration of the argument as a basis for JNOV. Even if this was error, substantial evidence supported the jury's finding that JJCI breached a duty to warn of the risks of ovarian cancer from genital talc use, even with a 2007 cutoff date.

"Negligence law in a failure-to-warn case requires a plaintiff to prove that a manufacturer or distributor did not warn of a particular risk for reasons which fell below the acceptable standard of care, i.e., what a reasonably prudent manufacturer would have known and warned about." (*Anderson v. Owens-Corning Fiberglas Corp.* (1991) 53 Cal.3d 987, 1002.) As explained above, there is no duty to warn of risks that are merely speculative or conjectural. A manufacturer is "not charged with knowing more than what would come to light from the prevailing scientific and medical knowledge." (*Valentine, supra*, 68 Cal.App.4th at pp. 1483-1484.) But the evidence as it applied to JJCI was sufficient to allow the jury to conclude the known risks of genital talc use were concrete enough

that it was unreasonable for JJCI to fail to warn consumers of them.

The evidence established that between 1967 and 2007, there were several epidemiological studies finding a statistically significant association between genital talc use and ovarian cancer, as well as studies concluding talc can migrate to the ovaries. Internal documents reflected JJCI's knowledge of the studies and of the evidence of increased risk of ovarian cancer associated with perineal talc use. The 1997 outside consultant letter reported to JJCI that by November 1994 "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," and that several independent reports provided a basis to conclude talc is capable of migrating to the ovaries. The evidence also established JJCI knew of the possibility the NTP or the IARC might designate talc as a carcinogen, and JJCI worked to avoid such a designation.

JJCI argues the scientific evidence was inconclusive and did not establish a causal connection between talc and ovarian cancer. The jury could reasonably conclude the risks were significant and well-documented enough that JJCI had a duty to warn consumers. Studies had repeatedly shown an association between perineal talc use and ovarian cancer and there was evidence supporting a biological mechanism. A 1992 study recommended that women not use genital talc due to the risk of ovarian cancer. A 1999 study suggested women should be warned of the risks of ovarian cancer from genital talc use. In 2004, Luzenac was communicating its concern about the different pieces of evidence that together suggested a causal connection between perineal talc use and ovarian cancer. In 2006, Luzenac added a warning on its MSDS about the IARC 2B designation. That no regulatory or scientific

organization has conclusively identified talc as causing ovarian cancer is relevant, but not dispositive on the question of whether JJCI acted as a reasonably prudent manufacturer in deciding not to warn.

Relying on *Valentine*, JJCI further argues there is no duty to warn unless it is *probable*, rather than *possible*, that the defendant's product causes harm, and there was no evidence by 2007 that talc was a probable cause of ovarian cancer.

In *Valentine*, the court considered the difference between strict liability and negligent failure to warn claims to determine whether a jury's conclusion that the defendant was not liable for strict liability failure to warn necessarily exonerated the defendant on a negligent failure to warn theory. (*Valentine, supra*, 68 Cal.App.4th at pp. 1480-1481, 1482.) The court concluded the instructions given in the case on strict liability failure to warn subsumed the elements of a negligent failure to warn claim.

The *Valentine* court reasoned: "The manufacturer's duty, per strict liability instructions, to warn of *potential* risks and side effects envelopes a *broader* set of risk factors than the duty, per negligence instructions, to warn of facts which make the product '*likely to be dangerous*' for its intended use. A 'potential' risk is one 'existing in possibility' or 'capable of development into actuality,' while a product 'likely' to be dangerous will 'in all probability' or 'probably' be dangerous. Stated differently, if [the defendant] adequately warned of potential risks and side effects, it of necessity warned of facts likely to render the product dangerous to the user. But, conversely, one could discharge the duty to warn of likely risks without discharging the duty to warn of potential risks. In sum, the manufacturer's strict liability duty to warn is greater than its duty under negligence, and thus negligence requires a greater showing

by plaintiffs.” (*Valentine, supra*, 68 Cal.App.4th at p. 1483, fns. omitted.)

Here, there was substantial evidence that, if credited, allowed the jury to find that by 2007, a reasonable manufacturer would conclude there were facts showing genital talc use was likely to be dangerous, or “probably” dangerous. As noted above, there was evidence of repeated studies showing a statistical association between perineal talc use and ovarian cancer, evidence of migration of talc to the ovaries, and, according to the IARC designation, a credible but inconclusive causal interpretation of the observed association between talc use and increased risk of ovarian cancer.

Moreover, as it concerned JJCI, this was not a case in which the evidence established the alleged danger was unknown or unknowable because of lack of scientific knowledge. Instead, the evidence presented a question of whether what was known was significant enough that JJCI acted unreasonably in failing to give an appropriate warning. What was known by 2007 went beyond, for example, “[k]nowledge of a potential side effect which is based on a single isolated report of a possible link between a prescription drug and an injury” (*Finn v. G.D. Searle & Co.* (1984) 35 Cal.3d 691, 701.) While the evidence may not have been definitive or overwhelming, it was not so limited that we may determine the *only* reasonable conclusion was the risk of ovarian cancer from perineal talc use was unknown or unknowable in light of the prevailing scientific and medical knowledge.

“The question whether there has been a breach of duty is usually a fact issue for the jury and may be resolved only as a matter of law if the circumstances do not permit a reasonable doubt as to whether the defendant’s conduct violates the degree of care exacted of [it]. [Citations.] If there is room for honest difference of opinion . . . as to whether there has been a breach of duty, the

question becomes one of fact for the jury.” (*Putensen v. Clay Adams, Inc.* (1970) 12 Cal.App.3d 1062, 1077; *Carlin, supra*, 13 Cal.4th at p. 1116; *Finn v. G.D. Searle & Co., supra*, 35 Cal.3d at p. 700 [jury determines the reasonableness of the manufacturer’s conduct in negligent failure to warn cases]; see also *Saller v. Crown Cork & Seal Co., Inc.* (2010) 187 Cal.App.4th 1220, 1239.) There was substantial evidence to support the jury’s finding that a reasonably prudent manufacturer would have known about the risk of ovarian cancer from genital talc use, and would have warned about that risk. (*Carlin*, at p. 1115; *Anderson v. Owens-Corning Fiberglas Corp., supra*, 53 Cal.3d at p. 1002.)

D. Substantial Evidence Supported the Jury’s Finding on Specific Causation

The trial court ruled Yessaian’s specific causation opinion was insufficient as a matter of law, identifying two main deficiencies in the testimony. First, the court reasoned Yessaian relied on epidemiological studies that did not support her opinion and she had no other basis for her conclusions. Second, the court found Yessaian purported to rule out other potential causes of Echeverria’s cancer but she either failed to completely eliminate alternative causes, or she did so based on speculation alone. Echeverria argues these conclusions misconstrued the record and were legal error. Keeping in mind the standard of review, we conclude the evidence was sufficient to support the jury’s causation finding.

“ ‘Causation’ is an essential element of a tort action. Defendants are not liable unless their conduct . . . was a “legal cause” of plaintiff’s injury. [Citations.]’ [Citation.] ‘Generally, the burden falls on the plaintiff to establish causation. [Citation.] . . . In the context of products liability actions, the plaintiff must prove that the defective products supplied by the defendant were a

substantial factor in bringing about his or her injury. [Citations.]” (*Whiteley v. Philip Morris, Inc.* (2004) 117 Cal.App.4th 635, 696.) A defendant’s negligence is not a substantial factor in bringing about harm if the plaintiff would have sustained the injury without the defendant’s negligence. (*Viner v. Sweet* (2003) 30 Cal.4th 1232, 1240-1241.)

“[I]n a personal injury action causation must be proven within a reasonable medical probability based upon competent expert testimony. Mere possibility alone is insufficient to establish a prima facie case. . . . There can be many possible ‘causes,’ indeed, an infinite number of circumstances which can produce an injury or disease. A possible cause only becomes ‘probable’ when, in the absence of other reasonable causal explanations, it becomes more likely than not that the injury was a result of its action.” (*Jones v. Ortho Pharmaceutical Corp.* (1985) 163 Cal.App.3d 396, 402-403; *Sparks v. Owens-Illinois, Inc.* (1995) 32 Cal.App.4th 461, 476-477.)

1. *Yessaian's Reliance on Epidemiological Studies Supported Her Opinion*¹²

The trial court relied in part on *Daubert v. Merrell Dow Pharmaceuticals, Inc.* (9th Cir. 1995) 43 F.3d 1311 (*Daubert II*), in evaluating the sufficiency of Yessaian's opinion. In *Daubert II*, the plaintiffs alleged the drug Bendectin caused their limb reduction birth defects. However, every published study had concluded the drug was not a teratogen. Epidemiological studies reported no statistical association between the drug and birth defects. (*Id.* at

¹² The trial court framed this issue as a lack of evidence to “rule in” talc as part of the differential diagnosis. We question what appears to be the combination of two distinct methods of proving specific causation—the use of epidemiological studies alone and the use of a differential etiology. The “ruling in” step of a differential diagnosis involves creating a list of causes that are *generally* capable of causing the disease. (*Clausen v. M/V New Carissa, supra*, 339 F.3d at pp. 1057-1058.) In contrast, the 2.0 relative risk threshold is typically invoked with regard to specific causation—whether the agent caused an individual plaintiff's disease. (*In re Silicone Gel Breast Impl. Prod. Liab. Lit., supra*, 318 F.Supp.2d at p. 893 [relative risk of 2.0 not necessary to establish general causation]; *King v. Burlington Northern Santa Fe Ry.* (Neb. 2009) 762 N.W.2d 24, 46-47 [declining to set 2.0 relative risk threshold for general causation].) In fact, the *Reference Guide* suggests “[d]ifferential etiologies are most critical when the agent at issue is relatively weak and is not responsible for a large proportion of the disease in question.” (*Reference Guide, supra*, at p. 618.) The *Reference Guide* also notes ruling out known causes may allow a relative risk under 2.0 to support an inference that the agent more likely than not caused the plaintiff's disease. (*Id.* at pp. 616-618.) However, we need not take up this issue. Whether as part of the differential diagnosis or as a separate means of proof, we conclude Yessaian's reliance on epidemiological studies was a valid basis for her ultimate opinion.

p. 1314.) The court concluded the plaintiffs' expert testimony on whether the drug was capable of causing limb reduction birth defects did not reflect findings that were derived by the scientific method and did not amount to "good science." (*Id.* at pp. 1315-1316, 1319-1320.)

The court further held that even if the plaintiffs could show their experts' findings were in fact derived by the scientific method, the plaintiffs still could not establish causation. Statistical probabilities derived from epidemiological studies were the *only* evidence the plaintiffs offered to show the drug caused their individual injuries. (*Daubert II, supra*, 43 F.3d at p.1320.) The plaintiffs had to establish that their mothers' use of the drug more than doubled the likelihood of birth defects because "only then can it be said that Bendectin is more likely than not the source of their injury." (*Ibid.*) The *Daubert II* court thus held that "[f]or an epidemiological study to show causation under a preponderance standard, 'the relative risk of limb reduction defects arising from the epidemiological data . . . will, at a minimum, have to exceed "2".' [Citation.] That is, the study must show that children whose mothers took Bendectin are more than twice as likely to develop limb reduction birth defects as children whose mothers did not." (*Id.* at p. 1321.)

The court noted a "statistical study showing a relative risk of less than two could be combined with other evidence to show it is more likely than not that the accused cause is responsible for a particular plaintiff's injury." (*Daubert II, supra*, 43 F.3d at p. 1321, fn. 16.) This was of no help to the *Daubert II* plaintiffs, however, since their experts did not seek to differentiate the plaintiffs from the subjects of the statistical studies they relied on. The court concluded "[t]he studies must therefore stand or fall on their own." (*Ibid.*)

In *Cooper v. Takeda Pharmaceuticals America, Inc.* (2015) 239 Cal.App.4th 555 (*Cooper*), a panel of this court adopted the *Daubert II* reasoning that only studies showing relative risk estimates greater than 2.0 are useful to the jury and may properly be used to “extrapolate from generic population-based studies to conclusions about what caused a specific person’s disease.” (*Cooper*, at p. 593.) However, the studies at issue in *Cooper* had relative risk estimates greater than 2.0. (*Id.* at pp. 562-564.) The court had no occasion to consider what role, if any, studies with lower relative risk estimates may play in an expert’s opinion.¹³

a. Yessaian relied on studies with risk ratios greater than 2.0

Here, Yessaian relied on four studies which reported risk ratios greater than 2.0. The trial court rejected Yessaian’s reliance on the two studies that reported a 1.7 odds ratio for the serous histologic subtype. Still, the court acknowledged that left two studies with odds ratios greater than 2.0. These studies reported

¹³ Numerous commentators have criticized the use of a 2.0 relative risk threshold as a prerequisite to establishing specific causation. (See, e.g., Egilman et al., *Proving Causation: The Use and Abuse of Medical and Scientific Evidence Inside the Courtroom—An Epidemiologist’s Critique of the Judicial Interpretation of the Daubert Ruling* (2003) 58 Food & Drug L.J. 223; Geistfeld, *Scientific Uncertainty and Causation in Tort Law* (2001) 54 Vand. L.Rev. 1011; Finley, *Guarding the Gate to the Courthouse: How Trial Judges Are Using Their Evidentiary Screening Role to Remake Tort Causation Rules* (1999) 49 DePaul L.Rev. 335; Greenland, *Relation of Probability of Causation to Relative Risk and Doubling Dose: A Methodologic Error That Has Become a Social Problem* (1999) 89 Am.J. Public Health 1166.) The validity of a 2.0 threshold is not before us as Echeverria argues Yessaian in fact relied on epidemiological studies showing risk estimates greater than 2.0.

the risk of ovarian cancer among genital talc users to be over three and over four times greater than the risk in the unexposed. The trial court discounted Yessaian's reliance on these studies because the results were not stratified by histologic subtype. However, there was no evidence offered at trial indicating study results were categorically irrelevant unless they showed stratified results for the serous subtype. Yessaian explained why she thought these particular risk estimates were appropriate when considering Echeverria's case. The jury could accept her explanations.

The lack of stratification for serous ovarian cancer in these two studies could certainly affect the *weight* of the evidence. Indeed, the trial court appeared to weigh the evidence when concluding that, "[i]n light of the other studies presented," including the studies showing 1.7 odds ratios for serous ovarian cancer, and one study in which "no increased risk was shown," the two studies with risk estimates greater than 2.0 were not substantial evidence supporting Yessaian's opinion. But we may not weigh the evidence at this stage. We have no basis to conclude Yessaian's reliance on the two "greater than 2.0" studies was invalid. Yessaian had epidemiological support for her opinion that talc was more likely than not responsible for causing Echeverria's ovarian cancer, based on odds ratios greater than 2.0.

- b. Yessaian's reliance on studies with risk estimates less than 2.0 provided additional support for her opinion

We also conclude Yessaian's reliance on epidemiological studies with risk estimates less than 2.0 offered additional support for her opinion. Several courts have held, consistent with *Daubert II*, that while studies reporting relative risk estimates under 2.0 may not on their own establish specific causation, they may be combined with other evidence to provide proof of causation,

or to render an expert's testimony sufficiently reliable to be admissible. (See, e.g., *Ambrosini v. Labarraque* (D.C. Cir. 1996) 101 F.3d 129, 135 [exclusion of expert testimony not warranted because it failed to "establish the causal link to a specified degree of probability"]; *In re Joint Eastern & Southern Dist. Asbestos Lit.* (2d Cir. 1995) 52 F.3d 1124, 1134 [declining to set standard mortality ratio "floor" as a matter of law]; *Landrigan v. Celotex Corp.* (N.J. 1992) 605 A.2d 1079, 1087 [under some circumstances a study with relative risk less than 2.0 could support specific causation finding; 2.0 relative risk is "not so much a password to a finding of causation as one piece of evidence, among others" for court to determine whether expert has used a sound methodology]; Carruth & Goldstein, *Relative Risk Greater Than Two in Proof of Causation in Toxic Tort Litigation* (Winter 2001) 41 *Jurimetrics J.* 195 [collecting cases between 1982 and 1999]; see also *In re Hanford Nuclear Reservation Litigation* (9th Cir. 2002) 292 F.3d 1124, 1136-1137 [district court erred in requiring threshold level of radiation creating relative risk greater than 2.0 without regard to individualized factors].)

Similarly, here, Yessaian did not rely on epidemiological studies with risk estimates under 2.0 alone to conclude talc was a substantial factor in causing Echeverria's ovarian cancer. As explained above, she relied on studies with greater than 2.0 odds ratios. Yessaian also considered the dose-response relationship reflected in at least four studies, as well as Echeverria's history of using talc for over 40 years, two or three times each day. Moreover, Yessaian did not only rely on epidemiological studies. She considered the migration studies and evidence regarding the general processes of inflammation and resulting carcinogenesis, in combination with the evidence of talc particles in Echeverria's ovarian tissues and other areas where the cancer was found. Her

differential diagnosis evaluated and ruled out other known causes and risk factors. It was therefore permissible for Yessaian to also rely in part on epidemiological studies with risk ratios less than 2.0.

2. *Yessaian's Opinion Was Not Invalid for Failure to Rule Out Other Known Causes or the Possibility of an Unknown Cause*

The trial court concluded Yessaian did not properly employ the differential diagnosis methodology because her opinion ruling out age and the number of ovulatory cycles was speculative. The court also found Yessaian only "discounted" certain risk factors rather than eliminating them. The court additionally concluded Yessaian merely speculated when opining Echeverria's cancer was not idiopathic. Echeverria asserts these conclusions ignored the evidence and misapplied the law. We conclude the entirety of the evidence established Yessaian's methodology was not fatally flawed and her opinion was sufficiently supported.

Cooper instructs our analysis. In *Cooper*, the plaintiff alleged the defendant's drug caused his bladder cancer. (*Cooper, supra*, 239 Cal.App.4th at p. 561.) Following a jury verdict in the plaintiff's favor, the trial court struck the specific causation expert's testimony as speculative and lacking foundation, and granted JNOV. (*Ibid.*) The expert had conducted a differential diagnosis based on his review of the plaintiff's medical records, review of the relevant literature, and his own scientific research. (*Id.* at pp. 566-567.) He ruled out numerous potential causes and risk factors, eventually concluding the defendant's drug was the " 'most substantial causative factor.' " (*Id.* at pp. 567-570, 583.)

The reviewing court held the trial court erred when it ruled the expert's testimony was inadmissible because he failed to "adequately consider and definitively rule out" potential causes of the cancer other than the defendant's drug. (*Cooper, supra*, 239

Cal.App.4th at p. 577.) The court explained: “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 a performance of a differential diagnosis.” (*Id.* at p. 578, original italics.)

The defendant did not identify any relevant evidence about other causes it claimed the expert overlooked. The *Cooper* court reasoned the “critical point” was the defendant could not point to any substantial evidence to indicate that the expert ignored another cause of bladder cancer, other than the drug, such that his opinion was unreliable. (*Cooper, supra*, 239 Cal.App.4th at p. 585.)

The *Cooper* expert acknowledged there are many possible causes of bladder cancer and much still unknown about the etiology of the disease. This was not a proper basis for exclusion of the testimony in the absence of any substantial evidence to support the proposition that other possible causes in fact affected the plaintiff. (*Cooper, supra*, 239 Cal.App.4th at pp. 585-586.) The court reasoned: “California has rejected the notion that an expert must ‘exclude all “possibilities” ’ in reaching a specific causation opinion. [Citation.] 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.” (*Ibid.*)

In this case, the trial court concluded Yessaian did not sufficiently rule out age and number of ovulatory cycles. Our review of the record reveals that Yessaian considered these two risk factors and explained her decision to rule each factor out. As to age, Yessaian explained that while half of all women who get ovarian cancer do so between the ages of approximately 52 to 60 years old, Echeverria was on the younger side of that range. Were Echeverria

older at the time of diagnosis, Yessaian said she would have identified age—and the larger number of accompanying “genetic hits”—as a more likely cause of the cancer. But since Echeverria was at the younger end of the spectrum, Yessaian found age to be an unlikely cause.

As to the number of ovulatory cycles, Yessaian explained that Echeverria’s age at menarche and menopause were both average. She described the risk related to ovulatory cycles as involving abnormally long periods of ovulation that occur when a woman has early menarche and late menopause. She did not believe Echeverria fit into this category, later noting Echeverria was menopausal at age 48, younger than the average age of menopause in American women. She also testified that she relied on several studies, included in her report, which informed her opinion that menarche at age 11 was not young enough to conclude early menarche was a cause of the cancer. She additionally opined that the number of ovulatory cycles is not an independent risk factor for postmenopausal ovarian cancer, referencing a particular study to support that opinion.

Yessaian considered both age and number of ovulatory cycles and explained why she found them improbable as independent causes of Echeverria’s ovarian cancer. This was adequate. Yessaian was not required to conclusively exclude other potential causes for her testimony to be sufficiently reliable to support her opinion. (*Cooper, supra*, 239 Cal.App.4th at pp. 585-586; see also *Johnson v. Mead Johnson & Co., LLC* (8th Cir. 2014) 754 F.3d 557, 563 [experts not required to rule out all possible causes when performing differential etiology; such considerations go to the weight of the evidence]; *Messick v. Novartis Pharmaceuticals Corp.* (9th Cir. 2014) 747 F.3d 1193, 1198 [expert must provide reasons for rejecting alternative hypotheses using scientific methods and

not based on speculation or subjective beliefs; expert may rely on clinical experience and need not identify sole cause for opinion to be reliable]; *Westberry v. Gislaved Gummi AB* (4th Cir. 1999) 178 F.3d 257, 265-266 [causation opinion not inadmissible for failure to rule out every possible alternative cause unless expert offers *no* explanation for why she has concluded an alternative cause was not the sole cause]; *Heller v. Shaw Industries, Inc.* (3d Cir. 1999) 167 F.3d 146, 156-157 [same].)

Defendants argue for a restrictive reading of Yessaian's testimony, taking isolated portions to conclude she "discounted" alternative causes rather than eliminating them. This approach conflicts with the standard of review we must apply. Yessaian used varying language to describe her process of rejecting other risk factors as the cause of Echeverria's cancer. Taken as a whole, however, and drawing all inferences in favor of the verdict, the record supports the conclusion that Yessaian did "rule out" alternative causes, either concluding they were not independent risk factors, or explicitly testifying that in her opinion these other factors were not a cause. As in *Cooper*, defendants did not point to any substantial evidence to indicate Yessaian ignored age or number of ovulatory cycles, such that her opinion was unreliable or mere conjecture. (*Cooper*, 239 Cal.App.4th at p. 585; see *King v. Burlington Northern Santa Fe Ry., supra*, 762 N.W.2d at pp. 50-51 [expert did not fail to consider other possible hypotheses; defendant's alternative suggestions for cause of disease affected weight of testimony only].) Defendants challenged Yessaian's explanations on cross-examination and offered competing expert testimony. It was appropriate for the *jury* to determine the credibility of Yessaian's testimony and to weigh it against contradictory evidence.

We also find the reasoning of *Cooper* instructive when considering “unknown causes.” There was no substantial evidence that unknown, yet-to-be-identified causes of ovarian cancer acted on Echeverria and provided an alternative explanation for her disease. As the court explained in *Cooper*, something more than bare conceivability or plausibility of other causes is required before another cause must be chosen as a matter of law as a cause in fact over the defendant’s conduct. (*Cooper, supra*, 239 Cal.App.4th at p. 581.)

As to the largely idiopathic nature of ovarian cancer, Yessaian testified the statement that “unknown etiology is the leading cause of cancer” is a general statement, applicable to the population as a whole. Her entire opinion was directed to answering the question of whether Echeverria’s cancer had a known cause or, in other words, that the cancer was not idiopathic. Yessaian’s testimony indicated she did not ignore idiopathy but instead determined there was in fact a known cause of the cancer, based on the factors she described. The credibility of her explanation was for the jury to determine. (See *Wendell v. GlaxoSmithKline LLC* (9th Cir. 2017) 858 F.3d 1227, 1237 [expert not required to eliminate all other possible causes of a condition for the testimony to be reliable; true in patients with multiple risk factors and in cases where there is a high rate of idiopathy]; *In re Diet Drugs* (E.D.Pa. 2012) 890 F.Supp.2d 552, 562 [experts not required to exclude unknown or idiopathic causes for differential diagnosis to be reliable basis for their opinions].)

The authorities defendants cite do not mandate a different result. In each case cited, the court first concluded the plaintiff failed to provide evidence of general causation. Stated otherwise, the plaintiffs’ experts failed to provide any admissible evidence that the defendants’ products were capable of causing the disease at

issue, in anyone. Without any evidence demonstrating the alleged toxin was even capable of causing disease, the experts could not reliably conclude the toxin caused the *plaintiff's* disease, even if other known causes were ruled out. (*Tamraz v. Lincoln Elec. Co.* (6th Cir. 2010) 620 F.3d 665, 674-675 [expert had no nonspeculative basis to identify manganese exposure as a cause of the plaintiff's parkinsonism]; *Henricksen v. ConocoPhillips Co.* (E.D.Wa. 2009) 605 F.Supp.2d 1142, 1162-1163, 1169-1170 [expert's opinion that exposure to benzene in gasoline could cause AML was not supported by reliable studies and was based on assumptions only]; *Doe v. Ortho-Clinical Diagnostics, Inc.* (M.D.N.C. 2006) 440 F.Supp.2d 465, 477 [expert testimony was inadmissible to establish general causation and differential diagnosis was therefore inappropriate].)

Here, defendants have not argued there was no substantial evidence of *general* causation. We have also concluded Yessaian's use of epidemiological and other scientific evidence to support her opinion identifying talc as the cause of Echeverria's cancer was proper. (Compare *Hall v. Conoco Inc.* (10th Cir. 2018) 886 F.3d 1308, 1312-1316 [errors and inconsistencies in calculating plaintiff's exposure to benzene invalidated expert's opinion ruling it in as potential cause and differential diagnosis unreliable for largely idiopathic disease]; *Milward v. Rust-Oleum Corp.* (1st Cir. 2016) 820 F.3d 469, 475-476 [expert had no scientifically valid basis to rule in benzene and could not use differential diagnosis to rule out idiopathic diagnosis], with *Wendell v. GlaxoSmithKline LLC, supra*, 858 F.3d at pp. 1234, 1237 [opinion not pure conjecture that patient with obvious and known risk factors led to assumption that those risk factors were the cause instead of idiopathy]; *In re E.I. DuPont de Nemours and Company* (S.D. Ohio 2016) 342 F.Supp.3d 773, 783-787 [rejecting a rule that plaintiff may not rely on differential diagnosis when cause of disease is unknown in majority of cases;

expert opinion that plaintiff's disease had a known cause sufficiently reliable to be admitted].)

In addition, while Yessaian was the sole specific causation expert, other evidence admitted at trial was relevant to the issue. Godleski, for example, opined there was evidence of a chronic inflammatory process in Echeverria's tissues. In addition to providing a general causation opinion, Siemiatycki proffered an opinion that epidemiological evidence established a dose-response pattern, thus corroborating Yessaian's opinion related to dose-response data.

We consider whether there is any substantial evidence, contradicted or uncontradicted, to support the jury's verdict. Yessaian's opinion had multiple elements. One was the differential diagnosis ruling out other known causes. Another was epidemiological evidence in the form of studies showing risk ratio estimates greater than 2.0. Yet another was the evidence of dose response, evidence of Echeverria's consistent and long years of heavy exposure, and the evidence of talc in her ovarian and other tissues. While a differential diagnosis alone may be insufficient as the sole basis for an opinion on the etiology of a largely idiopathic disease, that is not the situation before us. (See *In re Diet Drugs*, *supra*, 890 F.Supp.2d at p. 563; *Henricksen v. ConocoPhillips Co.*, *supra*, 605 F.Supp.2d at pp. 1162-1163 [not impossible to prove specific causation in cases where most diagnoses are idiopathic but "in those cases, analysis beyond a differential diagnosis is required"].)

Taken together, Yessaian's specific causation opinion was supported by the epidemiological literature, including studies showing risk ratios greater than 2.0, her testimony regarding the biological mechanism in general and the presence of talc in Echeverria's ovarian tissue and other areas where the cancer was

present, her clinical experience and treatment, her explanations addressing and ruling out other known risk factors and causes, and portions of the testimony of the other experts. (*In re Joint Eastern & Southern Dist. Asbestos Lit.*, *supra*, 52 F.3d at pp. 1132-1133 [admissibility assessments concern individual pieces of evidence, but a sufficiency inquiry asks whether the collective weight of a litigant's evidence is adequate to present a jury question; the issue is whether epidemiological and clinical data already in evidence was sufficient to justify the jury's verdict finding causation].)

The weaknesses in Yessaian's testimony affected the weight of the evidence. They did not represent fundamental methodological flaws that rendered her testimony conjectural or insufficient as a matter of law. We may not reweigh the evidence, make credibility determinations, or disregard reasonable inferences that may be drawn in favor of the verdict. Substantial evidence supported the jury's finding that talcum powder was a substantial factor in causing Echeverria's cancer.

**E. The Trial Court Properly Granted JNOV
in Favor of JJCI as to Punitive Damages**

Echeverria contends the trial court erred in granting JNOV as to punitive damages. We find no error.

Under Civil Code section 3294, a plaintiff may recover punitive damages by proving, by clear and convincing evidence, that the defendant acted with malice, fraud, or oppression. (Civ. Code, § 3294, subd. (a).) Malice "means conduct which is intended by the defendant to cause injury to the plaintiff or despicable conduct which is carried on by the defendant with a willful and conscious disregard of the rights or safety of others." (*Id.*, subd. (c)(1).)

When there is no evidence the defendant intended to harm the plaintiff, there must be evidence of conduct that is both willful and despicable. (*Lackner v. North* (2006) 135 Cal.App.4th 1188,

1211, 1213.) Conscious disregard for the safety of another may be found “ ‘where the defendant is aware of the probable dangerous consequences of his or her conduct and he or she willfully fails to avoid such consequences.’ ” (*Pfeifer v. John Crane, Inc.* (2013) 220 Cal.App.4th 1270, 1299. (*John Crane*)). “ ‘Despicable conduct’ is conduct that is “so vile, base, contemptible, miserable, wretched or loathsome that it would be looked down upon and despised by ordinary decent people.” ’ [Citation.] Such conduct has been described as having the character of outrage frequently associated with crime.” (*Butte Fire Cases* (2018) 24 Cal.App.5th 1150, 1159; *College Hospital Inc. v. Superior Court* (1994) 8 Cal.4th 704, 725.)

“[S]ince the jury’s findings were subject to a heightened burden of proof, we must review the record in support of these findings in light of that burden. In other words, we must inquire whether the record contains ‘substantial evidence to support a determination by clear and convincing evidence’ [Citation.]” (*Shade Foods, Inc. v. Innovative Products Sales & Marketing, Inc.* (2000) 78 Cal.App.4th 847, 891 (*Shade Foods*)). JNOV was proper on the issue of punitive damages if no reasonable jury could find Echeverria’s evidence provided clear and convincing proof of malice. (*Hoch v. Allied-Signal, Inc.* (1994) 24 Cal.App.4th 48, 60-61.)

Viewed in the light most favorable to Echeverria, the evidence established JJCI was aware of studies showing an association between talc and ovarian cancer, studies showing talc could migrate from the vagina to the ovaries, and the theory and corresponding research suggesting talc caused inflammation, eventually leading to ovarian cancer. The evidence further established that, at least between the 1990’s and 2006, JJCI’s response to these studies was to mount a defense against them. In attempts to influence or persuade agencies such as the NTP and IARC, and in response to media or governmental inquiry, JJCI’s strategy was to describe the

flaws of these studies, point out inconclusive results, and highlight the absence of any established causal link. The jury could reasonably infer that, faced with the possibility that talc might be shown to cause ovarian cancer, JJCI's response was focused solely on avoiding such a conclusion.

However, it was also undisputed that there has not been direct, conclusive evidence establishing genital talc use causes ovarian cancer. While various entities have conducted evaluations of the entire body of relevant evidence, these have resulted in conclusions that fall short of a declaration that perineal use of talc is carcinogenic. The evidence demonstrated it is not universally accepted in the scientific or medical community that talc is even a significant risk factor for ovarian cancer. We note that despite the published cell, epidemiological, and animal studies, as well as the IARC 2B designation, Yessaian, a highly experienced gynecologic oncologist, had not warned her patients or their family members away from genital talc use until this litigation. She neither asked Echeverria about her talc use, nor advised her to stop using it.

There was no evidence JJCI had any information about the dangers or risks of perineal talc use that was unavailable to the scientific or medical community. The company's critiques of available evidence were largely consistent with third party entities' evaluations of the same studies, including nontrade groups such as the IARC and the FDA. (Cf. *Boeken v. Philip Morris* (2005) 127 Cal.App.4th 1640, 1652-1655.)

Echeverria's epidemiological expert, Dr. Siemiatycki, testified that in 2006, when he chaired the IARC working committee on talc, he and the committee did not believe the available evidence was sufficient to conclude perineal use of talc caused ovarian cancer. Although there was evidence that JJCI attempted to "defend talc" and to avoid a carcinogenic designation by the IARC committee,

there was no evidence JJCI's efforts had any impact on the committee's ultimate conclusion that perineal talc use was *possibly* a carcinogen. Siemiatycki testified his changed opinion about perineal talc use was driven in large part by a study published in 2013, six years after Echeverria was diagnosed with ovarian cancer, which he believed provided dose-response data that was previously absent.

A defendant's entire course of conduct may be considered for purposes of assessing punitive damage awards, including post-injury conduct. (*Butte Fire Cases, supra*, 24 Cal.App.5th at p. 1176; *Hilliard v. A.H. Robins Co.* (1983) 148 Cal.App.3d 374, 399-401.) We disagree, however, that JJCI's actions or omissions in response to studies published *after* Echeverria incurred her injuries, which have offered *new* evidence or analysis, demonstrate a pattern or course of conduct that establishes the company's ongoing conscious disregard of the safety of others that would apply equally to Echeverria. Scientific evidence developed post-injury did not create a reasonable inference that JJCI was acting with malice, pre-injury, in failing to warn of probable dangerous consequences of the product. Further, the post-injury conduct continued to fall short of establishing clear and convincing evidence of malice.

Siemiatycki testified he believed the evidence of causation had grown stronger than it was in 2006. Yet, he also admitted the 2013 study he relied upon for evidence of dose response included two analyses, one which showed a dose response and one which did not. There was further undisputed evidence that epidemiological studies published in 2016 and 2017 showed statistical associations no greater, and in some cases weaker, than those of earlier studies. Echeverria offered no evidence of any growing general scientific consensus that talc causes ovarian cancer. (Cf. *John Crane, supra*, 220 Cal.App.4th at p. 1302 [malice shown where it was widely

accepted during relevant time period that product was carcinogenic; causal connection at significant exposure levels not disputed].)

Defendants point out that the FDA has not concluded there is a causal link between talc and ovarian cancer. A defendant's compliance with, or actions consistent with, governmental regulations or determinations about a product do not necessarily eviscerate a claim for punitive damages. (*John Crane, supra*, 220 Cal.App.4th at pp. 1301-1302.) But, here, the evidence showed the IARC has identified genital use of talc as possibly causing ovarian cancer and the statistical association between talc and ovarian cancer remains under scientific investigation. (See *Satcher v. Honda Motor Co.* (5th Cir. 1995) 52 F.3d 1311, 1316-1317 [no evidence to support punitive damages where there was a genuine dispute in scientific community about the benefit of the proposed safety measure, no independent organization required it, industry as a whole rejected the safety measure, and there were no definitive conclusions about effectiveness of the measure].) The evidence established that JJCI has refused to draw a causal connection between perineal talc use and ovarian cancer before experts in the relevant fields have done so. The jury could reasonably conclude this was unreasonable and negligent. But it is not clear and convincing evidence of "despicable conduct," that is, conduct " "[having] the character of outrage frequently associated with crime." [Citation.] " (*American Airlines, Inc. v. Sheppard, Mullin, Richter & Hampton* (2002) 96 Cal.App.4th 1017, 1050.)

In *Shade Foods*, the court noted "[a] record that presents a close case with regard to the sufficiency of the evidence of bad faith will inevitably provide a tenuous basis for supporting an award of punitive damages, since both the bad faith and punitive damage findings rest on inferences to be drawn from the same evidence." (*Shade Foods, supra*, 78 Cal.App.4th at p. 893.) Similar reasoning

applies here, since the failure to warn and punitive damages findings both rested on inferences to be drawn from the same evidence about the strength of the causal connection between talc and ovarian cancer, what JJCI knew about the risks of perineal talc use, when it obtained such knowledge, and what its legal responsibilities were with the information available. As in *Shade Foods*, while we have concluded there was sufficient evidence to support the jury's finding that JJCI breached its duty to warn of the risks of perineal talc use, we do not take the further step of upholding the jury's finding that JJCI acted with malice. (*Ibid.*) There was no substantial evidence to support a finding, by clear and convincing evidence, of despicable conduct which JJCI carried out with a willful and conscious disregard of the safety of others. (Civ. Code, § 3294, subd. (c).)

II. *The Trial Court Did Not Abuse Its Discretion in Granting JJCI's Motion for New Trial*

The trial court granted defendants' motion for new trial on the grounds of insufficiency of the evidence (Code Civ. Proc., § 657(6)), errors in law (*id.*, § 657(7)), jury misconduct (*id.*, § 657(2)), and excessive damages (*id.*, § 657(5).) Echeverria contends the trial court erred as to each ground. We find no abuse of discretion in the trial court order granting the new trial motion on the ground of insufficiency of the evidence.

A. *Standard of Review*

In her appellate briefing, Echeverria largely asserts the JNOV and new trial order must be reversed for the same reasons. Although we have concluded the JNOV in favor of JJCI as to liability must be reversed because there was substantial evidence to support the jury's verdict, we apply a different standard of review when considering the trial court's order granting a new trial. The California Supreme Court explained the differing standards in *Lane*

v. Hughes Aircraft Co. (2000) 22 Cal.4th 405 (*Lane*). In *Lane*, the trial court granted JNOV and, alternatively, a motion for new trial based on insufficiency of the evidence. The new trial order cross-referenced findings the trial court made in granting the JNOV. (*Id.* at p. 413.) The appellate court reversed the JNOV, finding substantial evidence supported the verdict. The court then determined it did not need to consider whether the evidentiary record supported the new trial order since it had analyzed whether sufficient evidence supported the verdicts with respect to the JNOV. (*Id.* at p. 411.) Our high court held the appellate court erred in applying the same standard when reviewing the JNOV and new trial order. (*Id.* at pp. 415-416.)

As the *Lane* court explained, “an order granting a new trial under [Code of Civil Procedure] section 657 ‘must be sustained on appeal unless the opposing party demonstrates that no reasonable finder of fact could have found for the movant on [the trial court’s] theory.’ [Citation.] Moreover, ‘[a]n abuse of discretion cannot be found in cases in which the evidence is in conflict and a verdict for the moving party could have been reached’ [Citation.] In other words, ‘the presumption of correctness normally accorded on appeal to the jury’s verdict is replaced by a presumption in favor of the [new trial] order.’ [Citation.]” (*Lane, supra*, 22 Cal.4th at p. 412.) Since the evidence in *Lane* could have supported a defense verdict, the appellate court erred in reversing the new trial order.

This case presents similar procedural circumstances. Thus, although we have determined the JNOV in favor of JJCI as to liability must be reversed, we separately analyze the new trial order. “We defer to the trial court’s resolution of conflicts in the evidence if the decision is supported by substantial evidence and reverse only if there is no reasonable basis for the court’s decision or the decision is based on a legal error. [Citations.] [¶] An order

granting a new trial 'will not be disturbed unless a manifest and unmistakable abuse of discretion clearly appears. . . . So long as a reasonable or even fairly debatable justification under the law is shown for the order granting the new trial, the order will not be set aside.' [Citation.]" (*Bell v. Bayerische Motoren Werke Aktiengesellschaft* (2010) 181 Cal.App.4th 1108, 1122.)

B. Discussion

In granting the motion for new trial on the ground of insufficient evidence, the trial court concluded that, "[s]itting as the thirteenth juror, the Court is of the firm conclusion that the evidence of specific causation is not sufficient to support the verdict, for the reasons set forth above respecting the JNOV . . . and for the additional reason that Yessaian did not consider all available epidemiology and apply it to the facts relative to Echeverria except when it favored Echeverria." The court found evidence of both specific and general causation was "lacking," citing the "lack of anything other than a hypothesis about causation and the nature of the epidemiological evidence presented"

We find no abuse of discretion. We reject Echeverria's argument that the court made legal errors that require reversal of both the order granting JNOV in favor of JJCI and the order granting a new trial. In our view, the trial court's ruling granting JNOV to JJCI as to liability must be reversed because the trial court weighed the evidence and made credibility determinations when rejecting and evaluating aspects of Yessaian's testimony. In ruling on the new trial motion, however, the court was permitted to assess the credibility of witnesses, weigh the evidence, and draw inferences from the evidence different from those the jury may have drawn. (*Licudine v. Cedars-Sinai Medical Center* (2016) 3 Cal.App.5th 881, 900; *Fountain Valley Chateau Blanc*

Homeowner's Assn. v. Department of Veterans Affairs (1998) 67 Cal.App.4th 743, 751.)

The causation evidence was in significant conflict. For every plaintiff's expert, there was a defense expert who offered opposing testimony, based on his or her own significant experience and review of the same or similar evidence and scientific literature. With respect to specific causation, the trial court found Yessaian "cherry picked" the studies without sufficient justification and the weight of the epidemiological evidence undermined her opinion. There was evidence to support this finding, namely, the testimony of defense experts Weed and Saenz, whose evaluation of the epidemiology conflicted with that of Yessaian. Although Yessaian did not rely on epidemiological studies alone, they remained an important basis of her opinion.

The trial court also found there was no evidence of inflammation present in Echeverria's tissue, rejecting Godleski's testimony and inferences that could be drawn from it. While we have concluded a trier of fact could credit Godleski's opinion that he observed a chronic inflammatory process in Echeverria's tissues, a reasonable trier of fact could equally have determined defense expert Felix's testimony was the more credible. Based on his examination of Echeverria's tissue slides, Felix opined he saw no evidence of cancer-causing inflammation and, had it been present, it would have been easy to find.

A reasonable jury could have given more weight to the defense interpretations of the epidemiology, rejected Yessaian's interpretation of the literature as overly narrow or biased, questioned Godleski's testimony and credited Felix's testimony, and concluded the evidence did not sufficiently establish talc was a substantial factor in causing Echeverria's cancer.

The evidence also supported the trial court's reasoning on general causation. While Plunkett offered an opinion that talc causes ovarian cancer, a reasonable trier of fact would have been entitled to discredit or reject her testimony, in view of the limitations and critiques of several studies she relied upon. The weaknesses in the studies and her opinion were highlighted in her own testimony on cross-examination, and brought out in Andersen's and Weed's testimony. Weed also testified the available epidemiological and other scientific evidence did not support the conclusion that talc causes ovarian cancer. He, too, applied the Hill criteria and found the evidence did not support the factors sufficiently to state the "weak" statistical association between talc and ovarian cancer reflects a causal relationship.

Despite the conclusive nature of Plunkett's ultimate opinion, other evidence indicated no governmental or scientific agency has reached similar conclusions, and medical institutions have not uniformly taken steps to identify genital talc use as even a risk factor for ovarian cancer. Indeed, there was evidence that a 2017 National Cancer Institute physician data query concluded the weight of the evidence did *not* support an association between perineal talc use and ovarian cancer.

The evidence at trial would have supported a verdict in JJCI's favor. The trial court did not abuse its discretion in granting the motion for new trial on the ground of insufficiency of the evidence. (*McFarland v. Voorheis-Trindle Co.* (1959) 52 Cal.2d 698, 707.) We need not address the additional grounds on which the trial court granted the motion.

DISPOSITION

The judgment and the trial court order granting Johnson & Johnson judgment notwithstanding the verdict are affirmed. The portions of the court's judgment and order granting JJCI judgment notwithstanding the verdict as to punitive damages are affirmed. The portions of the judgment and order granting JJCI judgment notwithstanding the verdict as to liability are reversed. The trial court's order granting a new trial to JJCI is affirmed. The matter is remanded for further proceedings consistent with this opinion. The parties shall bear their own costs on appeal.

CERTIFIED FOR PUBLICATION.

ADAMS, J.*

We concur:

LAVIN, Acting P.J.

EGERTON, J.

* Judge of the Los Angeles Superior Court, assigned by the Chief Justice pursuant to article VI, section 6 of the California Constitution.

CERTIFICATE OF SERVICE

COURT: Supreme Court of the State of California

Case Nos.: Court of Appeal, Second Appellate District, Division Three,
No. B286283

Superior Court, County of Los Angeles

Civil Case No. BC628228, JCCP No. 4872

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. On August 9, 2019, I served the documents described as:

PETITION FOR REVIEW

on the parties and entities below as follows:

[X] BY ELECTRONIC SERVICE TO INTERESTED PARTIES: I further declare that I caused the document(s) listed above to be served on all interested parties via email addresses listed below.

3. On August 12, 2019, I caused the document(s) listed above to be served on:

[X] FEDEX TO COURTS: I placed the document(s) listed above in a sealed overnight courier envelope addressed to the parties below and routing the envelope for pick up by Federal Express on that same day in the ordinary course of business, with charges fully prepaid for next day delivery.

CLERK OF THE COURT
Spring Street Courthouse

Document received by the CA Supreme Court.

Hon. Maren E. Nelson Superior Court of the State of California
County of Los Angeles
312 North Spring Street
Los Angeles, CA 90012

Court of Appeal, Second Appellate District, Division Three
Ronald Reagan State Building
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[X] PERSONAL SERVICE:

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Room 1295
San Francisco, CA 94102-4797

I declare under penalty of perjury under the laws of the State of California
that the foregoing is true and correct.

Executed on August 9, 2019 at Newport Beach, California.

/s/ Donna Hosea
Donna Hosea

Document received by the CA Supreme Court.

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