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SUPERIOR COURT OF THE STATE OF CALIFORNIA
FOR THE COUNTY OF LOS ANGELES

Coordination Proceeding
Special Title (Rule 3.550)

JOHNSON & JOHNSON TALCUM POWDER CASES

This document relates to:

Charmaine Lloyd, et al., v. Johnson & Johnson, et al., Los Angeles County Superior Court, Case No. BC628228

Plaintiff Eva Echeverria ONLY

Case No. BC628228
JCCP NO. 4872

DEFENDANT JOHNSON & JOHNSON CONSUMER INC.'S MOTION FOR JUDGMENT NOTWITHSTANDING VERDICT; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT THEREOF

Judge: Hon. Maren E. Nelson
Dept.: 307

Hearing: October 12, 2017, 10:00 a.m.

NOTICE OF MOTION AND MOTION

TO THE COURT AND ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that, on October 12, 2017, at 10:00 a.m., or as soon thereafter as the matter may be heard, in Department 307 of the above-referenced court, located at 600 Commonwealth Ave., Los Angeles, CA 90005, Defendant Johnson & Johnson Consumer Inc., by and through its counsel of record, will and hereby does move this Court for an Order setting aside the judgment entered against it and in favor of Plaintiff Eva Echeverria on August 21, 2017, and entering judgment in favor of Defendant notwithstanding the verdict, pursuant to Code of Civil Procedure section 629.

The motion is based on the ground that there is no substantial evidence to support the verdict on liability, including insufficient evidence of causation and/or to support a duty to warn during the relevant time. In the alternative, Defendant seeks partial judgment notwithstanding the verdict as to liability for punitive damages because there was no clear and convincing evidence of malice by a director, officer, or managing agent acting on behalf of Defendant.

The motion is based upon this Notice of Motion and Motion; each Defendant's previously filed "Notice of Motion and Motion for Judgment Notwithstanding the Verdict"; the evidence presented at trial; all pleadings, papers, files, and records in this action; the minutes of the Court; the Memorandum of Points and Authorities attached hereto; the Declaration of Bart Williams submitted herewith and the exhibits thereto; the Compendium of Trial Transcript Excerpts submitted herewith; and upon any such further evidence and argument that may properly come before the Court at the hearing to be set by the Court pursuant to Code of Civil Procedure sections 660 and 661.

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Where, as here, a party moves for both new trial and JNOV as alternative remedies, the Court must rule on both motions at the same time. Civ. Proc. Code § 629. The Court's power to grant these motions expires 60 days after service of notice of entry of judgment, which took place on August 21, 2017. Accordingly, the last day for the Court to rule on the Motions is October 20, 2017.

DATED: September 15, 2017

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INTRODUCTION

No peer-reviewed study, regulatory body, or public health organization has ever found that talc use causes ovarian cancer. Nonetheless, a divided 9-3 jury found not only that talc is capable of causing ovarian cancer but that it more likely than not caused Plaintiff Eva Echeverria's cancer, and it awarded an exorbitant $417 million in compensatory and punitive damages as a result. No substantial evidence supports this astounding verdict. Four critical points stand out from trial as undisputed and, on the record here, necessarily defeat Plaintiff's claim.

First, no epidemiological study has ever shown a statistically significant relative risk above 2.0 for Plaintiff's characteristics and type of ovarian cancer (serous invasive ovarian cancer). In its July 18, 2017 pre-trial ruling, the Court allowed Plaintiff's specific causation expert Dr. Annie Yessaian to testify, so long as four epidemiology studies constituted her "sole basis" for ruling in talc as the probable cause of Plaintiff's disease. As the trial testimony from Dr. Yessaian and other experts revealed, *none* of those studies—or any other study—met the 2.0 threshold for serous, as necessary to imply "a 50% probability that the agent at issue was responsible for a particular individual's disease." *Cooper v. Takeda Pharms. Am., Inc.*, 239 Cal. App. 4th 555, 593-94 (2015). Because the epidemiology studies cannot provide the "sole basis" for ruling in talc as the probable cause—as Dr. Yessaian was required to show—JNOV should be granted on this basis alone.

Second, testimony from Dr. Yessaian and others established that most ovarian cancer cases are of unknown etiology (idiopathic). This undisputed fact further confirms Plaintiff's inability to prove causation. As reflected in the Restatement (Third) of Torts, courts and commentators recognize that a differential etiology, like that employed by Dr. Yessaian, can become speculative when most cases of the disease are idiopathic. On the facts here—where the epidemiology fails to show any "doubling of the risk" for Plaintiff and there was no evidence of inflammation in Plaintiff's ovaries—Dr. Yessaian's inability to account for unknown causes renders her opinion inherently speculative. Even if talc were a possible risk factor, there was no substantial evidence to find that that talc was a probable cause of Plaintiff's cancer.

Third, the undisputed testimony—including from Plaintiff's expert Dr. Siemiatycki—is that the scientific literature did not establish a probable causal link between talc use and ovarian cancer

prior to 2007, when Plaintiff was diagnosed with cancer. Because there was no substantial evidence of a probable link, there was no duty to warn.

Fourth, at a minimum, there is no clear and convincing evidence of malice so as to warrant punitive damages when Defendant's conduct has been consistent with the prevailing views of the scientific and medical community and regulatory bodies.

Accordingly, Defendant Johnson & Johnson Consumer Inc. ("JJCI") thus respectfully requests that the Court grant its motion for judgment notwithstanding the verdict.

LEGAL STANDARDS

A motion for JNOV challenges the legal sufficiency of the evidence at trial and may be granted even when motions for nonsuit or directed verdict were denied. *See* Civ. Proc. § 629; *Beavers v. Allstate Ins. Co.*, 225 Cal. App. 3d 310, 328, 333 (1990). Although evidentiary conflicts must be resolved in favor of the prevailing party, "this does not mean [it] must blindly seize any evidence" to uphold the judgment. *Kuhn v. Dep't of Gen. Servs.*, 22 Cal. App. 4th 1627, 1633 (1994). Nor may it "consider only supporting evidence in isolation, disregarding all contradictory evidence." *Rivard v. Bd. of Pension Comm'rs*, 164 Cal. App. 3d 405, 412 (1985). This Court's "substantial evidence" review must be "based on the whole record," *id.* (emphasis added) and consider relevant, uncontradicted evidence that supports the position of the moving party, *Osborn v. Irwin Mem'l Blood Bank*, 5 Cal. App. 4th 234, 275, 284 (1992). "Substantial evidence is not synonymous with 'any' evidence. To constitute sufficient substantiality to support the verdict, the evidence must be reasonable in nature, credible, and of solid value; it must actually be substantial proof of the essentials which the law requires in a particular case." *Id.* at 284 (quotation omitted).

ARGUMENT

I. PLAINTIFF LACKED SUBSTANTIAL EVIDENCE THAT TALC USE MORE PROBABLY THAN NOT CAUSED HER CANCER.

For the jury's verdict to stand, causation must have been "proven within a reasonable medical probability based upon competent expert testimony. Mere possibility alone is insufficient to establish a prima facie case." *Jones v. Ortho Pharm. Corp.*, 163 Cal. App. 3d 396, 402 (1996). "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. This is the outer limit of inference upon which an issue may be submitted to the jury." *Id.* at 403. To support the jury's verdict, expert testimony must be both "reasonably reliable" and "establish[] a reasonably probable causal connection between an act and a present injury." *Id.* If the "probabilities" that talc did or did not cause Plaintiff's ovarian cancer "are at best evenly balanced, [then] it becomes the duty of the court to direct a verdict for the defendant." *Jennings v. Palomar Pomerado Health Sys., Inc.*, 114 Cal. App. 4th 1108, 1118 (2003) (quotation marks and emphasis omitted).

To prove specific causation at trial, Plaintiff relied solely on the testimony of her treating physician, Dr. Annie Yessaian, who performed a version of a "differential etiology" (or "differential diagnosis"). Under this methodology (and based on the Court's *Sargon* order), Dr. Yessaian relied on four epidemiology studies and purported to "rule in" talc as the more-likely-than-not cause of Plaintiff's cancer compared to other known or unknown factors. *E.g.*, Tr.2811:24-2817:24; Ex. PP.[1]

The context for Dr. Yessaian's reliance on the four epidemiology studies is critical. In its pre-trial ruling, the Court reviewed in detail the potential bases for Dr. Yessaian's opinion. The "bottom line," the Court concluded, was that four specific epidemiology studies—Cramer 1982, Rosenblatt 1992, Cramer 1999, and Wu 2009—"constitute the sole basis that Dr. Yessaian has for 'ruling in' talc as the cause of Echeverria's cancer and ruling out the fact that the cancer may be idiopathic [of unknown origin]." Ex. D, at 11. The Court precluded Dr. Yessaian from, among other things, testifying as to a specific odds ratio above 2.0 for Plaintiff or speculating that talc had caused inflammation in Plaintiff's ovaries (because there was "no evidence" of it). *Id.* at 10-11. The Court called it "exceedingly close" but decided that Dr. Yessaian's opinion would "not be excluded at this point"—that is, pre-trial under a *Sargon* analysis—"provided that she can opine based solely on the studies cited and no other matter." *Id.* at 11 (emphasis added).

Now that the trial has taken place, two undisputed facts preclude Dr. Yessaian's testimony from serving as the lone support for the jury's verdict. First, no epidemiology study—including

[1] "Tr." cites are to the trial transcripts included in the Compendium of Trial Transcript Excerpts. All "Ex." cites are to the exhibits attached to the currently filed Declaration of Bart Williams.

the four studies on which Dr. Yessaian was permitted to rely—has shown a risk ratio above 2.0 for Plaintiff's subtype of cancer. That prevents the epidemiology studies from being the "sole basis" for ruling in talc as the probable cause of Plaintiff's serous invasive ovarian cancer. Second, the record is clear that idiopathic causes account for not just some but a majority of ovarian cancer cases. Because Dr. Yessaian has "no other matter" to "rule in" talc use over idiopathy (or other known causes) as the probable cause of Plaintiff's cancer, her application of the differential etiology method is speculative. Where an expert bases her "conclusion upon assumptions which are not supported by the record, upon matters which are not reasonably relied upon by other experts, or upon factors which are speculative, remote or conjectural," as did Dr. Yessaian, "then [her] conclusion has no evidentiary value." *In re Lockheed Litig. Cases*, 115 Cal. App. 4th 558, 563 (2004) (quotation omitted); *see Sargon Enterp., Inc. v. Univ. of S. Cal.*, 55 Cal. 4th 747, 769-80 (2012) (analogizing trial court's "gatekeeping" function to role of trial courts in vacating judgments based on insufficient evidence).

A. As a Matter of Law, the Epidemiology Studies Cannot Constitute the Sole Basis for Proving Specific Causation Because No Study Showed an Odds Ratio Above 2.0 for Plaintiff's Subtype of Cancer.

The Court has recognized that California law requires that "'[w]hen statistical analyses or probabilistic results of epidemiological studies are offered to prove specific causation . . . those analyses must show a relative risk greater than 2.0.'" *Cooper*, 239 Cal. App. 4th at 593 (quoting *Daubert v. Merrell Dow Pharms. Inc.*, 43 F.3d 1311, 1320 (9th Cir. 1995)). *Cooper* explains the reason for this requirement as follows:

> This is so, because a relative risk greater than 2.0 is needed to extrapolate from generic population-based studies to conclusions about what caused a specific person's disease. When the relative risk is 2.0, the alleged cause is responsible for an equal number of cases of the disease as all other background causes present in the control group. Thus, 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.

Id. at 593-94 (emphasis omitted), *quoted at* Ex. D, at 3-4 (Yessaian Order). Conversely, "[a] relative risk of less than two . . . actually tends to disprove legal causation, as it shows that [the agent] does not double the likelihood of [harm]." *Daubert*, 43 F.3d at 1321 (emphasis in original);

see also In re Breast Implant Litig., 11 F. Supp. 2d 1217, 1225-28 (D. Colo. 1998) (rejecting specific causation testimony because epidemiology studies did not show "doubling of risk"); *Sanderson v. IFF*, 950 F. Supp. 981, 1000 (C.D. Cal. 1996) ("None of plaintiff's other experts even says that the relative risk is more than two, so their testimony, even if totally reliable, would actually tend to disprove legal causation, just as in *Daubert on remand.*") (emphasis in original).

As noted, the basis for Dr. Yessaian's opinion was limited to four epidemiological studies: Cramer 1982, Rosenblatt 1992, Cramer 1999, and Wu 2009. Tr.2670:16-2673:9, 2820:1-10; Ex.D, at 11. To prove causation, those studies must do more than find a relative risk (or "odds ratio") above 2.0 for some population subset—the data must be relevant to Plaintiff, meaning it should be "as close as possible to Ms. Echeverria's serous subtype of ovarian cancer." Tr.2896:1-4; *see also, e.g.*, Tr.2834:27-2835:12 (Yessaian agreeing that data should closely match Plaintiff's situation and that she "wanted to look at data that focused on the serous histological subtype"); *Reference Manual on Scientific Evidence, Third Edition*, 613 & n.195 (2011) (hereinafter "Reference Manual") (study subjects must be representative of plaintiff for the risk estimate to be valid as applied to the individual); *In re Silicone Gel Breast Implants Prods. Liab. Litig.*, 318 F. Supp. 2d 879, 893-94 (C.D. Cal. 2004) (to show specific causation, a risk factor greater than 2.0 is required and "the plaintiff [must be] comparable to the subjects of the epidemiological study").

It is undisputed that none of the epidemiology studies on which Dr. Yessaian relied—or any other epidemiology study, for that matter—has shown a statistically significant odds ratio above 2.0 for serous ovarian cancer. The Cramer 1982 and Rosenblatt 1992 studies did not provide odds ratios specific to serous invasive cancer. Tr.2670:28-2672:4. Dr. Yessaian said on direct examination that Cramer 1999 "took a special look at the serous invasive ovarian cancer" and the relative risk was 1.7. Tr.2672:16-20. For Wu 2009, she said the subgroup for serous cancer also had a relative risk of 1.7. Tr.2673:6-9. On cross-examination, Dr. Yessaian confirmed that to the extent these and other studies provided data specific to serous, the relative risks were all under 2.0. Tr.2896:1-2897:16; *see also* Tr.2668:12-2670:15 (identifying odds ratios below 2.0 for serous in Gertig 2000, Gates 2008, and Terry 2013). Dr. Yessaian ultimately conceded that she is not aware of any studies showing a statistically significant relative risk of over 2.0 for serous invasive cancer.

Tr.2897:1-16.

Unrebutted testimony by Defendants' experts confirmed that no epidemiology study shows a risk factor over 2.0—*i.e.*, a doubling of the risk—for Plaintiff's histology and characteristics. *See* Tr.3602:19-3603:11 (Saenz explaining that, in the four studies on which Dr. Yessaian relied, "if you take those factors that are Ms. Echeverria's history and look at the odds ratio for who Ms. Echeverria was, those relative risks in those papers are not over 2. It's other characteristics that the relative risk is over 2, not a patient like Ms. Echeverria."); Tr.3717:11-17 (Weed explaining that there have been no statistically significant findings over 2.0 for serous invasive histologic subtype). A more recent study, Cramer 2016, found that the relative risk for serous was a statistically insignificant value of 1.3, and, in general, the risk factor for women who, like Plaintiff, were postmenopausal, did not have a history of using hormone therapy, and claimed more than 24 years of talc use, was 1.0—null value. Tr.3603:12-3607:4. That experts may "reasonably rely on epidemiological studies in forming opinions on causation is of no assistance" when the studies on which the expert relies provide "no reasonable basis for [that] opinion." *Lockheed*, 115 Cal. App. 4th at 565; *see also Sargon*, 55 Cal. 4th at 770-71 (courts scrutinize "whether that material actually supports the expert's reasoning").

The epidemiological data for ovarian cancer generally also does not support, and in fact undermines, Dr. Yessaian's conclusion. It is undisputed that the overall average odds ratio across studies is only around 1.3. Tr.1118:28-1119:10; 1398:1404:1, 2459:5-2461:12, 3700:10-3701:8. The Court has already found that the relative risk in such studies was "well below the 2.0 'more probable than not' criteria required for specific causation." Ex. D, at 11.[2]

Remarkably, Dr. Yessaian failed even to appreciate the significance of the fact that the

[2] Dr. Yessaian's opinion was also unsound because she cherry-picked the studies she used and, even as to those studies, cherry-picked her data and assumptions about Plaintiff's lifetime talc applications when the assumptions in her initial expert report yielded a risk ratio below 2.0 for Plaintiff. *Compare* Ex. D at 8 (pre-trial ruling explaining that Dr. Yessaian would apply the studies based on Plaintiff's history of 30,000 talc applications), *with* Tr.2908:6-2910:28 (admitting that, for Wu 2009, 30,000 genital talc applications referenced in her report would have shown a statistically insignificant relative risk). Where a witness makes "contradictory statements" at trial compared to his or her own statements in pre-trial discovery, the trial testimony can be disregarded and does not constitute "substantial evidence." *Mikialian v. City of Los Angeles*, 79 Cal. App. 3d 150, 159-60 (1978).

studies show a relative risk below 2.0—erroneously assuming that an odds ratio of 1.51 was sufficient to conclude that talc was the probable cause of Plaintiff's cancer. *Compare* Tr.2895:2-8, 2902:15-19, *with Cooper*, 239 Cal. App. 4th at 593-94; Tr.2434:2-18, 3754:24-3759:10 (Siemiatycki and Weed). An expert's reliance on false assumptions robs her opinion of any evidentiary value. *Sargon*, 55 Cal. 4th at 770-71; *Lockheed*, 115 Cal. App. 4th at 564, 565. Given that Dr. Yessaian herself did not understand why an odds ratio above 2.0 was, as a statistical matter, necessary to prove specific causation, it is unsurprising that the jury similarly failed to grasp the consequence of that fact.

Because the epidemiological data—both the studies on which Dr. Yessaian was permitted to rely and in general—show a relative risk below 2.0 for Plaintiff's characteristics, the epidemiology is insufficient as a matter of law to support the conclusion that talc more likely than not caused Plaintiff's cancer. *Cooper*, 239 Cal. App. 4th at 593-94. In fact, the epidemiology "actually tends to disprove legal causation." *Daubert*, 43 F.3d at 1321 (emphasis added in part). Because four epidemiology studies were supposed to constitute Dr. Yessaian's "sole basis" for ruling in talc as the probable cause, this failure of proof at trial precludes Plaintiff from establishing causation and requires entry of the JNOV.

B. Dr. Yessaian's Differential Etiology Was Speculative Under the Facts Here.

Plaintiff cannot show causation for an independent reason. Even if Dr. Yessaian were permitted to "rule in" talc as possible risk factor, the remainder of differential etiology—in which she purported to rule in talc over other causes, including unknown causes—was speculative and unsupported. In its pre-trial ruling, the Court declined to preclude Dr. Yessaian's opinion for failure to exclude idiopathy as a cause of Plaintiff's disease, quoting *Cooper* for the proposition that "'it is not necessary . . . to exclude every other possible cause of a plaintiff's illness.'" Ex. D at 9 (emphasis added) (quoting *Cooper*, 239 Cal. App. 4th at 578). The Court noted, however, that "[n]o party raised the idea that differential diagnosis was not appropriate unless a substantial portion of the independent causes of the disease are known." Ex. D, at 9-10 n.5 (citing Comment 4 to Restatement 3d of Torts, section 28). While it may not be necessary to exclude idiopathic causes in every case, the trial record has now made it clear that the undisputed facts of this case

implicate the *Restatement*'s rule and render Dr. Yessaian's opinion speculative.

The undisputed trial testimony established that the leading cause of ovarian cancer, including the serous subtype from which Ms. Echeverria suffers, is unknown causes. Dr. Felix, a gynecologic pathologist, testified at trial that 75-80% of ovarian cancer cases are idiopathic. Tr.3457:13-3458:5. Dr. Saenz, a gynecologic oncologist, concurred that the majority of ovarian cancers are idiopathic. Tr.3597:25-3598:17 (Saenz). Critically, Dr. Yessaian herself agreed that the leading cause of ovarian cancer was unknown and that it was "probable" "that Ms. Echeverria's ovarian cancer could have been caused by some risk factor that modern science doesn't yet know about." Tr.2864:26-2888:27.

As the Court recognized, the *Restatement (Third) of Torts* makes clear that a differential etiology analysis "is most useful when the causes of a substantial proportion of the disease are known . . . When the causes of a disease are largely unknown, however, differential etiology is of little assistance." *Restatement (Third) of Torts: Phys. & Emot. Harm* § 28 cmt. 4 (2010) (emphasis added). The Federal Judicial Center's *Reference Manual on Scientific Evidence* is in agreement:

> Although differential etiologies are a sound methodology in principle, this approach is only valid if general causation exists and a substantial proportion of competing causes are known. Thus, for diseases for which the causes are largely unknown . . . a differential etiology is of little benefit. And, like any scientific methodology, it can be performed in an unreliable manner.

Reference Manual, at p.618. Applying this logic, courts often reject differential etiologies when idiopathic causes account for a significant portion of the disease and the expert has no basis to account for that. *See id.* at 618 n.214 (collecting cases); *Perry v. Novartis Pharms. Corp.*, 564 F. Supp. 2d 452, 469 (E.D. Penn. 2008) (same).

Dr. Yessaian conceded that she made no attempt to "rule out" or account for unknown causes in this case. Tr.2887:17-2895:1. Dr. Yessaian did not even purport to rule out completely all known risk factors for Plaintiff—such as estrogen levels, diet, age, early menarche, late childbirth, or family history—although she asserted they were not probable causes. *See* Tr.2883:2-22; *see also* Tr.2867:12-2886:5, 3573:4-23, 3577:2-12, 3600:2-3601:12. Even if she could reasonably discount other known factors, that would not automatically make talc a probable cause of Plaintiff's cancer when it was uncontested that most ovarian cancers are the result of unknown

causes. In this situation, "differential etiology is of little assistance," and it is not a valid application of that methodology to conclude, to a reasonable degree of medical certainty, that talc use more likely than not caused Plaintiff's cancer. *Restatement* § 28 cmt. 4; *see also Henricksen v. Conoco Philips Co.*, 605 F. Supp. 2d 1142, 1162 (E.D. Wash. 2009) ("Standing alone, the presence of a known risk factor is not a sufficient basis for ruling out idiopathic origin in a particular case, particularly where most cases of the disease have no known cause.").

To be sure, *Cooper* states that an expert need not exclude "all" possible causes based on the "[b]are conceivability" that other causes of cancer "might have affected" the plaintiff. *Cooper*, 239 Cal. App. 4th at 585-86. In the case of ovarian cancer, however, unknown etiology is far from being a "bare conceivability;" it admittedly is the leading cause of the disease. *See supra* at 8. Moreover, the epidemiological evidence in *Cooper* showed a relative risk over 2.0, which implied that the agent being studied was the cause of cancer in the majority of cases studied and, for this reason, the probable cause of disease in any specific individual. *Cooper*, 239 Cal. App. 4th at 593-94. Here, Dr. Yessaian was unable to testify that talc doubled the risk for Plaintiff. Ex. D, at 10.

Moreover, the Court specifically precluded Dr. Yessaian from testifying "that talc caused inflammation in Echeverria's ovaries so as to link the use of talc and the development of her cancer" because that was "speculation." Ex. D, at 10-11. While Plaintiff's general causation experts hypothesized that talc-induced inflammation may cause ovarian cancer, there was no evidence of "any inflammation in Ms. Echeverria's ovarian tissue." Tr.2792:20-26; *see also* Tr.3470:1-4, 3495:1-11 (Felix); Tr.1954:4-26, 2061:16-2062:2 (Godleski admitting that his report said nothing about inflammation and would have had it been present); Ex.D at 10.[3]

In sum, the undisputed evidence is that the epidemiology studies do not show that talc doubled Plaintiff's risk of developing her cancer; there was no evidence that talc caused cancer-inducing inflammation in Plaintiff's ovaries; and Dr. Yessaian did not and cannot rule out unknown etiology—concededly responsible for a majority of ovarian cancers—as a cause of

[3] Although Dr. Godleski suggested that he saw "macrophages" in Plaintiff's tissue, Dr. Yessaian testified that macrophages are not "a type of inflammation" relevant to cancer. Tr.2789:13-26; *see also* Tr.3476:18-3479:1 (Felix). Dr. Godleski did not testify to the contrary.

Plaintiff's cancer. On these facts, even if talc were a potential risk factor, there was no basis to find that talc more likely than not caused Plaintiff's ovarian cancer. It is considerably more likely Plaintiff developed cancer for idiopathic reasons—*i.e.*, that she would have developed cancer even in the absence of her talc use. As *Cooper* makes clear, "'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.'" 239 Cal. App. 4th at 577 (quoting *Jones*, 163 Cal. App. 3d at 402-03 (emphasis added)); *see also Jennings*, 114 Cal. App. 4th at 1118 (causation is not established if "the matter remains one of pure speculation or conjecture, or the probabilities are at best evenly balanced").[4]

II. PLAINTIFF LACKED SUBSTANTAL EVIDENCE TO PROVE A DUTY TO WARN ARISING PRIOR TO 2007.

The Court should enter JNOV for an additional reason: the undisputed evidence is that the prevailing scientific knowledge in and prior to April 2007, when Plaintiff was diagnosed with ovarian cancer, did not establish a causal link between vaginal talc use and ovarian cancer. In the absence of such a link as of April 2007, there was no duty to warn as a matter of law.

A. The Duty to Warn Arises Only When a Product Is Shown to Be Dangerous or Probably Dangerous Based on Prevailing Scientific Knowledge.

To establish a duty to warn under California law, a plaintiff must prove that defendants "knew or reasonably should have known that the [product] was dangerous or was likely to be dangerous when used or misused in a reasonably foreseeable manner." CACI 1222(2) (emphasis added)). "[A] product 'likely' to be dangerous" is one that "will 'in all probability' or 'probably' be dangerous" in light of "prevailing scientific and medical knowledge." *Valentine v. Baxter Healthcare Corp.*, 68 Cal. App. 4th 1467, 1483–84 (1999) (citing *Anderson v. Owens-Corning Fiberglass Corp.*, 53 Cal. 3d 987, 1002-03 (1993), holding that a duty to warn arises as to a risk "that was known or knowable in light of the generally recognized and prevailing best scientific and

[4] For the reasons set forth in Defendants' new trial brief, the evidence is also insufficient to show a probable causal relationship between talc and ovarian cancer in the general population.

medical knowledge").[5]

The "prevailing scientific and medical knowledge" is assessed as of "the time of manufacture and distribution" of the product relevant to the plaintiff's injury. *Valentine*, 68 Cal. App. 4th at 1483; *see also Anderson*, 53 Cal. 3d at 1002-03; *Rosa v. Taser Int'l*, 684 F.3d 941, 946-48 (9th Cir. 2012) (affirming summary judgment for failure to warn because peer-reviewed articles prior to time of distribution and injury did not establish "causal link" between product and particular risk, and subsequent studies were irrelevant). Because Plaintiff was diagnosed with cancer in April 2007 (Tr. 2570:9-2577:28), she had to prove a duty to warn arose before that date.

B. Prevailing Scientific Knowledge Did Not Recognize a Causal Link Between Talc and Ovarian Cancer as of the Time Plaintiff Was Diagnosed in 2007.

There has never been a published, peer-reviewed article finding that talc causes ovarian cancer. Tr.2276:21-2277:19, 3695:19-3696:7, 3749:12-3750:1. The first study to find a statistically positive association between talc use and ovarian cancer was Cramer 1982. Tr.2347:1-7. But that study did not purport to find a causal relationship, and it was undisputed by Plaintiff's own experts that a single study is insufficient to infer causality. *See* Tr.1504:14-17 (Plunkett stating that one cannot "make any sound causal conclusions based on only two studies"); Tr.2348:13-17 (Siemiatycki agreeing that he "couldn't have concluded from that one study [Cramer 1982] that talc caused ovarian cancer"). While Plaintiff relied heavily on studies published in the 1990s—including Harlow/Cramer 1992 and Cramer 1999—those studies, too, did not establish causality Tr.1412:13-1414:22, 2351:13-2352:13, and the undisputed testimony is that a causal link remained speculative and scientifically unproven in the time period before Plaintiff was diagnosed in 2007.

1. IARC's 2006 Monograph Found the Scientific Evidence Insufficient to Classify Talc as a Known or Even Probable Carcinogen.

In 2006, the International Agency for Research on Cancer ("IARC") issued a monograph

[5] The mere possibility of risk is insufficient to trigger a duty to warn. *See Carlin v. Super. Ct.*, 13 Cal. 4th 1104, 1115-16 (1996) (explaining that failure-to-warn claim requires evaluating, among other things, "whether available evidence established a causal link," and that there is no duty to warn where the link is "speculative"). Neither California law nor public policy requires companies to warn based on "'every report of a possible risk,'" as that would lead to "'inevitably diluting the force of any specific warning given.'" *Id.* at 1115 (quoting *Finn v. G. D. Searle & Co.*, 35 Cal. 3d 691, 701 (1984)); *see also Dowhal v. SmithKline Beecham Consumer Healthcare*, 32 Cal. 4th 910, 931–32 (2004) (citing *Finn* and *Carlin* and recognizing problem of "overwarning").

classifying talc as a "Group 2B," or "possible" carcinogen. Ex. J (P-29). The "2B" classification contrasted to the classifications used for Group 1 "known" carcinogens, like cigarette smoking and benzene exposure, Tr.1177:20-1178:26, and Group "2A" "probable carcinogens," like consuming red meat or extremely hot beverages, or working night shifts. Tr.1179:1-1180:9, 1313:13-26.

IARC's talc classification was based on a thorough review of the scientific literature and reflects that there was only "limited evidence of carcinogenicity in humans and less than sufficient evidence of carcinogenicity in experimental animals." Ex. J; Tr.1181:9-1182:4. Thus, although certain epidemiology studies showed an association between talc and ovarian cancer, IARC concluded that "chance, bias, or confounding could not be ruled out with reasonable confidence." Tr.1192:11-1194:5, 1196:7-23, 1198:8-1200:2, 2162:18-2164:10, 2282:5-2284:24; *see also* Ex. J. In other words, a causal relationship between genital talc use and ovarian cancer had not been established. Tr.1199:27-1200:2, 2285:23-26, 2291:15-23; *cf.* Tr.1184:25-28 (Plunkett agreeing "association" is not causation); Tr.2488:5-2491:19 (Siemiatycki agreeing that association does not make something a carcinogen, and that positive epidemiological findings may be "false alarms").

As a matter of law, IARC's listing an agent as a "possible" carcinogen cannot trigger a duty to warn under California law because the "possible" label necessarily means the agent is not a known or probable cancer causer. The Group 2B classification means "that no one yet knows if the agent [] is actually harmful (or not)." *CTIA—The Wireless Ass'n v. City & Cnty. of San Francisco*, 827 F. Supp. 2d 1054, 1060 (N.D. Cal. 2011), *aff'd in part and vacated in part,* 494 Fed. App'x 752 (9th Cir. 2012); *see also Styrene Info. & Research Ctr. v. Office of Env't Health Hazard Assessment*, 210 Cal. App. 4th 1082, 1095, 1101 (2012) (rejecting citizen suit to include styrene and vinyl acetate on the Prop. 65 list of carcinogens based on IARC categorization).

2. Plaintiff's Expert Dr. Siemiatycki Agreed that the Evidence Was Insufficient to Show a Causal Link in or Before 2007.

Plaintiff's own expert, Dr. Jack Siemiatycki, confirms that there was no duty to warn before 2007. Dr. Siemiatycki was chair of the IARC working group when it issued its 2006 monograph and was among its authors. Tr.2280:6-2282:18. He concurred in classifying talc as a 2B "possible" carcinogen because "a causal association ha[d] not been demonstrated" when the report

was prepared. Tr.2281:5-2285:26, 2292:2-2293:2; *see also, e.g.*, Tr.2362:11-19, 2389:21-2394:1.

Dr. Siemiatycki also co-authored the "Langseth" meta-analysis, published in 2008. Tr.2296:10-2297:11; Ex. R (P-105). In that paper, he and his co-authors concluded that "[t]he current body of experimental and epidemiological evidence" was "insufficient to establish a causal association between perineal use of talc and ovarian cancer risk." Tr.2300:9-14; *see also* Tr.2300:15-19, 2362:11-22 (confirming his view that the evidence as of 2007 was insufficient). Dr. Siemiatycki co-authored a separate 2008 study that summarized in its background the scientific knowledge as presenting only "inconclusive evidence that use of cosmetic talc for feminine hygiene purposes may be associated with an increased risk of ovarian cancer." Tr.2355:24-2359:2. This statement, Dr. Siemiatycki confirmed at trial, "refer[red] to the general knowledge at that time," approximately a year after Plaintiff received her cancer diagnosis. Tr.2359:3-13, 2363:10-2364:14, 2368:11-25.

3. FDA and Other Public Health Organizations Have Rejected a Causal Association and the Need to Warn the Public.

While the views of the Food and Drug Administration ("FDA") respecting the existence of a manufacturer's duty to warn are not binding, California law mandates that they "deserve[] serious consideration," *Ramirez v. Plough, Inc.*, 6 Cal. 4th 539, 556 (1993), and "judicial deference" because "of the FDA's scientific expertise and long administrative experience," *Dowhal*, 32 Cal. 4th at 929–30). *See also Carlin*, 13 Cal. 4th at 1114 (noting relevance of FDA action "to show whether a risk was known or reasonably scientifically knowable").

In 2014, FDA responded to two citizen petitions requesting that cosmetic talc products carry a warning stating that genital application of talc would increase the risk of ovarian cancer. Ex. M (P-47). FDA refused to require the warning because it "did not find that the data submitted presented conclusive evidence of a causal association between talc use in the perineal area and ovarian cancer." *Id.* at 1. Looking at the same studies Plaintiff's experts cited, FDA explained that "[s]everal of the studies acknowledge biases in the study design and no single study has considered all the factors that potentially contribute to ovarian cancer," "[r]esults of case-controls studies do not demonstrate a consistent positive association across studies," "dose-response evidence is

lacking," and "[a] cogent biological mechanism by which talc might lead to ovarian cancer is lacking." *Id.* at 3-5.

Plaintiff introduced no evidence (because none exists) that, prior to 2007, any regulatory body, public health organization, or national medical association took the position that genital talc use was a likely or probable cause of ovarian cancer. To this day, talc is not recognized as an ovarian cancer risk factor by the Centers for Disease Control ("CDC"), American Congress of Obstetricians & Gynecologists ("ACOG"), Society of Gynecologic Oncology ("SGO"), or the current Physician Data Query issued by the National Cancer Institute ("NCI"). Tr.1619:6-1620:8, 2713:6-2721:9, 3580:9-3590:9. Talc-based body powder also is not a listed carcinogen under California's Prop. 65. Ex. K (P-31); Tr.1632:9-1633:3. Even to the extent Plaintiff identified certain websites that listed talc as a possible risk factor for ovarian cancer, those were all well after 2007. *E.g.*, Tr. 1574:6-1577:2.

C. The "Internal Documents" Fail to Show That Genital Talc Use Was a Known or Probable Cause of Ovarian Cancer Prior to 2007.

Unable to dispute the prevailing state of scientific knowledge, Plaintiff has relied on "internal documents" dating to 1964. As noted above, the first study investigating an association between talc use and ovarian cancer was not published until 1982, and Plaintiff at trial relied most heavily on studies published in the 1990s, such as Harlow/Cramer 1992 and Cramer 1999 (Exhibits P-105 and P-107). Thus, it is helpful to divide the "internal documents" into two groups: those from the 1960s-1980s, and those from the 1990s and beyond. The documents from the 1960s to 1980s cannot establish a duty to warn about talc use and ovarian cancer because they do not even reference ovarian cancer. The documents from the 1990s and beyond reflect an awareness of the scientific discussion about talc use and ovarian cancer, but nothing suggests Defendants believed, or the prevailing scientific knowledge showed, that talc causes ovarian cancer.

1. Documents Prior to the 1990s Do Not Refer to Ovarian Cancer.

The earliest "internal document" that Plaintiff relied on is P-343—a 1964 memo stating that an additive called "Dry Flo" replaced talc "as a condom lubricant . . . because it was found to be absorbed safely in the vagina whereas, of course, talc was not." Ex. W, at 3. Nothing in the memo

refers to ovarian cancer, much less that ovarian cancer can be caused by the hygienic use of body powder. Nor is it reasonable to infer that the memo was referring to ovarian cancer, given that the first study suggesting an association between genital talc use and ovarian cancer would not be published until 1982—almost two decades later—and there was no evidence of unpublished studies or even theoretical work done on the subject of talc and ovarian cancer from before that date.[6] For similar reasons, P-55—a 1975 letter with a handwritten note referring to a "talc/ovary problem"—is insufficient evidence of a duty to warn. Ex. O. Like P-343, nothing in P-55 references ovarian cancer, and there is no basis to infer that Defendant had knowledge of any potential ovarian cancer risk at that time.

Plaintiff also cited a 1986 technological forecast, which referred to safety concerns based on inhalation ("respirables"), not ovarian cancer from genital application. Ex. F (P-9). The document confirms that as of 1986 the company had concluded that "[b]ased on the scientific evidence and the extensive experience in use, we believe that cosmetic powders are safe for babies and adults. Normal use of cosmetic powders has not been related to safety concerns for humans."

Plaintiff (successfully) invited the jury to infer that these internal documents were referencing talc's supposed connection to ovarian cancer. But no evidence was introduced at trial to suggest that inference has any basis in fact. "Inferences that are the result of mere speculation or conjecture" are insufficient to uphold a verdict. *Kasparian v. Cnty. of Los Angeles*, 38 Cal. App. 4th 242, 260 (2007). Whatever concerns these early documents may reflect (*see, e.g.*, *supra* note 6), they do not refer to, or show notice of, a risk of ovarian cancer—much less that genital talc use likely caused ovarian cancer. They are not "substantial proof of the essentials which the law requires" for Plaintiff's failure-to-warn claim. *Osborn*, 5 Cal. App. 4th at 284 (quotation omitted).

2. The Remaining Documents Reflect That Defendant Followed the Studies, but Do Not Establish a Legal Duty to Warn.

The remaining documents Plaintiff has cited, from the 1990s and beyond, merely reflect

[6] There is no dispute that talc can cause adhesions within the body. But it was equally undisputed at trial that adhesions do not cause cancer. Tr.3464:23-3465:23. Plaintiff did not premise her claim on a theory that Defendants, beginning in 1964, should have warned against a risk of adhesions, and a plaintiff cannot base her failure-to-warn claim on risks unrelated to the injury she suffered. *See, e.g., Novak v. U.S.*, 865 F.2d 718, 725-26 (6th Cir. 1989).

that Defendant was monitoring the scientific literature—*i.e.*, the same studies that Dr. Siemiatycki and others found insufficient to show a causal link as of 2007.

Exhibit P-20 is a 1997 letter from Alfred Wehner, a consultant, to Michael Chudkowski, Manager of Preclinical Toxicology at JJCI, that criticizes certain public statements issued by the Cosmetics, Toiletry, and Fragrance Association ("CFTA"). The letter states there have been "'real' statistically significant associations" shown in several studies. Ex. H, at 2. It then states, however, in reference to an FDA-supported workshop, that "(1) the results of the studies were ambiguous, inconsistent, contradictory and therefore inconsistent, [and] (2) therefore hygienic use of cosmetic talc does not present a risk to the consumer." *Id.*[7] The letter's author then suggests that CTFA "use these powerful and irrefutable arguments," rather than making statements that might jeopardize its credibility. *Id.* (stating that refusal to acknowledge the studies at all "risks that the talc industry will be perceived by the public like the tobacco industry," which "would be a particularly tragic misperception in view of the fact that the industry does have powerful, valid arguments to support its position"). Nothing in P-20 constitutes an admission of JJCI itself, and the letter itself clearly states the view that "talc does not present a risk to the consumer." *Id.*

A number of documents from 2002-2005 refer to the possibility that the National Toxicology Program ("NTP") or IARC would classify talc as a carcinogen and discussed efforts to present the scientific evidence showing a lack of relationship between talc and ovarian cancer. *See, e.g.*, Ex. I, U, V, X (P-27, P-263, P-264, P-396). As the Court instructed the jury, advocacy to government agencies is protected by the First Amendment and cannot form the basis to impose liability. Tr.3933:13-21. While the documents may be evidence of Defendant's knowledge that NTP and IARC were considering talc, the documents confirm Defendant's belief that the data did not (and does not) support talc as a carcinogen. In fact, NTP never classified talc as carcinogen, and IARC's "2B" classification is insufficient to imply a duty to warn, as explained above.[8]

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[7] The letter is referring to a symposium with FDA and the International Society of Regulatory Toxicology and Pharmacology ("ISRTP") held in 1994, during which one FDA reviewer stated that "talc has proven to be among the safest of all consumer products." Tr.1251:23-1253:8.

[8] Plaintiff also introduced evidence of so-called warnings provided by others. P-37 is a Material Safety Data Sheet ("MSDS") used by Imerys in 2006, which included toxicology classifications made by various organizations, including IARC, OSHA, ACGIH, and NTP, all of which were

(cont'd)

In sum, Defendant was aware of scientific literature exploring the association between talc and ovarian cancer, but association is not causation and the prevailing scientific knowledge as of 2007 did not show a causal link between vaginal talc use and ovarian cancer. If the mere existence of studies showing a statistically significant association, or an IARC "2B" classification, were sufficient to trigger a warning, we would have cancer warnings on a wide range of products, including milk, pickled vegetables, and aloe vera. That cannot be the law. If it were, it would create "problems of overwarning," with warnings of speculative risks "crowding out necessary warnings" for known dangers. *Dowhal*, 32 Cal. 4th at 932; *see also Carlin*, 13 Cal. 4th at 1115-16.

III. AT A MINIMUM, THE COURT SHOULD GRANT PARTIAL JNOV ON THE ISSUE OF PUNITIVE DAMAGES.

A. Liability for Punitive Damages Requires Clear and Convincing Evidence of Malice, Not Merely Disagreement about the Science.

Punitive damages "are not a favorite of the law and the granting of them should be done with the greatest of caution." *Troensegaard v. Silvercrest Indus. Inc.*, 175 Cal. App. 3d 218, 227 (1985). By statute, California law narrowly defines the circumstances under which punitive damages are available and it requires that a plaintiff prove those requirements by "clear and convincing evidence." Civ. Code § 3294(a). This burden of proof is a demanding one that "requires a finding of high probability . . . 'so clear as to leave no substantial doubt'; 'sufficiently strong to command the unhesitating assent of every reasonable mind.'" *Lackner v. North,* 135 Cal. App. 4th 1188, 1211-12 (2006) (citation omitted). This heightened standard must be taken into account, meaning that the court "must inquire whether the record contains 'substantial evidence to support a determination by clear and convincing evidence.'" *Shade Foods, Inc. v. Innovative Prods. Sales & Mktg., Inc.*, 78 Cal. App. 4th 847, 891 (2000) (emphasis added).

The only basis for punitive damages submitted to the jury in this case was malice, which

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negative except for IARC's "2B" rating. Ex. L. For the reasons above, the IARC classification—as a matter of law—does not trigger a duty to warn. Moreover, on its face, the MSDS was simply relaying the findings made by different organizations and not endorsing that talc is likely carcinogenic. Plaintiff also presented evidence that two body powder bottles today have ovarian cancer warnings (while many others do not bear such a warning), but Plaintiff presented no evidence whatsoever of a custom and practice to provide warnings to consumers in or before 2007.

the California Legislature defines as "[1] conduct which is intended by the defendant to cause injury to the plaintiff or [2] despicable conduct which is carried on by the defendant with a willful and conscious disregard of the rights or safety of others." Civ. Code § 3294(c)(1) (emphasis added); Tr.3936:4-3936:28. Because Plaintiff has not contended, and presented no evidence to establish, that JJCI had any intention to cause injury to her, "'despicable conduct' must be found." *College Hosp. Inc. v. Super. Ct.*, 8 Cal. 4th 704, 725 (1994).

"Despicable" conduct requires a showing that JJCI engaged in "extreme" conduct that is "'so vile, base, contemptible, miserable, wretched or loathsome that it would be looked down upon and despised by ordinary decent people.'" *Lackner*, 135 Cal. App. 4th at 1210 (citation omitted). "Such conduct has been described as '[having] the character of outrage frequently associated with crime.'" *Am. Airlines, Inc. v. Sheppard, Mullin, Richter & Hampton*, 96 Cal. App. 4th 1017, 1050-51 (2002) (citation omitted).

It is not enough to show that a defendant "acted. . . out of a bona fide disagreement" about what the facts—here, the scientific evidence—showed. *Kendall Yacht Corp. v. United Cal. Bank*, 50 Cal. App. 3d 949, 957 (1975). There can be no willful and conscious disregard of the rights and safety of others "if the defendant's actions proceeded from . . . a sincere and reasonable difference of factual evaluation." *Kwan v. Mercedes-Benz of N. Am., Inc.*, 23 Cal. App. 4th 174, 184-85 (1994) (quoting *Lusardi Constr. Co. v. Aubry*, 1 Cal. 4th 976, 996-97 (1992)); *see also Mason v. Mercury Cas. Co.*, 64 Cal. App. 3d 471, 475 (1976) (affirming JNOV on punitive damages on bad faith insurance claim because appellant "did not adduce any evidence to show that the [defendant's] interpretation of the contract . . . was unreasonable"); *Satcher v. Honda Motor Co.*, 52 F.3d 1311, 1317 (5th Cir. 1995) (vacating punitive damages award where "there [was] a genuine dispute in the scientific community as to" the reasonableness of the challenged design).

B. There Was No Clear and Convincing Evidence of Malice.

Plaintiff's proof fell far short of these standards. She presented no sufficient evidence to permit a reasonable jury to conclude, by clear and convincing evidence, that JJCI knew and believed that its cosmetic talc products cause ovarian cancer, such that its lack of a warning

amounts to "vile, base, contemptible, miserable, wretched or loathsome" conduct that has "the character of outrage frequently associated with crime." *See supra* at 17-18.

The corporate witness testimony and internal documents cited by Plaintiff show that Defendant monitored the science, followed regulatory requirements, and reported information to FDA. *See generally* Tr. 799-982 (Telofski); Ex. Y (P-710). The documents show that Defendant believed talc was safe for normal use and was acting consistently with the prevailing views of the scientific community in interpreting the evidence as insufficient to show a causal link. *See, e.g.*, Tr.981:21-982:24 ("Thorough research and testing by the FDA and medical community does not support Cramer's hypothesis of such a link. . . . The author of the study has himself acknowledged that the evidence is rather tenuous. It does not show a cause-and-effect relationship."); Ex. F (P-9) (1986 technical forecast stating, "[b]ased on the scientific evidence and the extensive experience in use, we believe that cosmetic powders are safe for babies and adults. Normal use of cosmetic powders has not been related to safety concerns for humans"); Ex. H (P-20), at 2 (describing "powerful and irrefutable arguments" that the association shown in certain studies was not causal). Where risks were substantiated—such as the risk of inhalation by children—Defendant provided a warning on the label. Tr.875:7-20; Ex.N. None of this shows "despicable conduct."[9]

Moreover, as a matter of law, JJCI's conduct cannot be said to have been willful, loathsome, or quasi-criminal when its belief that a warning was not warranted is a reasonable one. *Cf. Satcher v. Honda Motor Co.*, 52 F.3d 1311, 1317 (5th Cir. 1995) (vacating punitive damages award where "there [was] a genuine dispute in the scientific community as to" the reasonableness of the challenged design). Viewed in the light most favorable to Plaintiff, the evidence at trial

[9] For reasons explained above and as extensively briefed during trial, Defendant's exercise of its First Amendment right to engage in advocacy before government agencies cannot be a basis for imposing liability, much less punitive damages. *See, e.g.*, Defs. Mot. for Nonsuit on All Claims, filed Aug. 10, 2017, at 27-28 (collecting cases). Nor can the filing of talc lawsuits constitute "notice" of harm to third parties, because a lawsuit is not evidence of actual harm, and Defendant cannot be punished for its decision to defend these lawsuits rather than immediately change its labeling practices. *See De Anza Santa Cruz Mobile Estates Homeowners Ass'n v. De Anza Santa Cruz Mobile Estates*, 94 Cal. App. 4th 890, 895 (2001) ("punitive damages in a tort action cannot be based on evidence of defendants' litigation conduct occurring subsequent to the underlying tort"); *Mola Dev. Corp. v. City of Seal Beach*, 57 Cal. App. 4th 405, 414 (1997) (internal quotations omitted) ("Anyone who pays a filing fee can initiate a complaint; its filing fails to show anything beyond the fact that defendant has been sued.").

established at most that there has been scientific debate over the hypothesis that genital talc use causes ovarian cancer. Some studies show a statistically significant association, while others do not, and even the studies showing a statistically significant association have not established a dose-response relationship indicative of causality. *See, e.g.*, Tr.1430:5-1438:5, 2389:21-2394:1, 2823:3-2824:9, 3182:14-3183:25, 3723:8-3736:2, 3705:9-3707:19, 3714:2-3716:28, 3176:14-3178:7. No published, peer-reviewed study finds that talc causes ovarian cancer, and Defendant's long-standing position is consistent with the views of FDA, the CDC, the National Cancer Institute's current PDQ, IARC, medical associations like ACOG and SGO, and California's Office of Environmental Health Hazard Assessment, which administers the Prop. 65 program. As of 2007—when Plaintiff was diagnosed with cancer and suffered her injury—Defendant's position was also consistent with the views of Plaintiff's own epidemiologist, Dr. Siemiatycki.

Thus, to find that the absence of an ovarian cancer warning on bottles of Johnson's Baby Powder and Shower-to-Shower constituted "despicable conduct" based on a willful and conscious disregard of others' rights would necessarily imply that each of these organizations—the FDA, NCI, CDC, ACOG, and SGO—is acting equally despicably, and in willful conscious disregard of an allegedly significant public health hazard. Each of those organizations has the mission of informing the public about health risks and, in the case of the FDA, regulating the industry directly. The NCI's PDQ, which is presented as a comprehensive source of cancer information for physicians and the public, says that "[t]he weight of evidence does not support an association between perineal talc exposure and an increased risk of ovarian cancer." Tr.1619:6-1620:8. That is not merely a "failure" to warn; the NCI is publishing an anti-warning that effectively tells physicians and patients not to worry about talc use as a risk factor for ovarian cancer.

In sum, there is no evidence of Defendant being privy to information not in the public domain, and Defendant was not acting in disregard of a consensus among scientific and medical professionals that talc causes ovarian cancer. The punitive damages award must be set aside.

CONCLUSION

For all of the foregoing reasons, Defendant Johnson & Johnson Consumer Inc. respectfully requests that the Court grant its Motion for Judgment Notwithstanding the Verdict.

Respectfully submitted,

DATED: September 15, 2017

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PROOF OF SERVICE

Johnson & Johnson Talcum Powder Cases
Los Angeles County Superior Court, Case No. JCCP No. 4872

Charmaine Lloyd, et al., v. Johnson & Johnson, et. al.
Los Angeles County Superior Court, Case No. BC628228
Plaintiff Eva Echeverria ONLY

I am employed in the County of Los Angeles. I am over the age of eighteen years and not a party to the within entitled action. My business address is 515 South Flower Street, Forty Second Floor Los Angeles, CA 90071.

On **September 15, 2017**, I served the foregoing document(s) described as: **DEFENDANT JOHNSON & JOHNSON CONSUMER INC.'S MOTION FOR JUDGMENT NOTWITHSTANDING VERDICT; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT THEREOF** on the interested party(ies) in this action through Case Anywhere. I caused the foregoing document to be transmitted to Case Anywhere for electronic service in the following manner:

(X) **BY ELECTRONIC SERVICE**: I provided the document(s) listed above electronically through the Case Anywhere website pursuant to the instructions on that website. [The document will be deemed served on the date that it was uploaded to the website as indicated by the Case Anywhere system.]

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

Executed on **September 15, 2017**, at Los Angeles, California.

Stella S. Villegas