

THE STATE OF SOUTH CAROLINA
In The Court of Appeals

APPEAL FROM RICHLAND COUNTY
Court of Common Pleas
Jean H. Toal, Circuit Court Judge

Appellate Case No. 2025-000065
Civil Action No. 2023-CP-40-04072

RECEIVED

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SC Court of Appeals

Michael L. Perry and Lonnie Long,..... Respondents,

v.

American International Industries et al.

Of whom Johnson & Johnson; LLT Management, LLC
f/k/a LTL Management, LLC; Kenvue, Inc.; and Johnson
& Johnson Holdco (NA), Inc. are the Appellants.

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I certify that this Designation does not contain any matters which are irrelevant to this appeal.

STATE OF SOUTH CAROLINA	)	IN THE COURT OF COMMON PLEAS
	)	
COUNTY OF RICHLAND	)	CIVIL ACTION NO. 2023-CP-40-04072
	)	
MICHAEL L. PERRY AND LONNIE L. LONG,	)	<i>In Re: Asbestos Personal Injury Litigation</i>
	)	Coordinated Docket
	)	
Plaintiffs,	)	
	)	
vs.	)	<u>MOTION FOR A MISTRIAL</u>
	)	
AMERICAN INTERNATIONAL	)	
INDUSTRIES, ET AL.,	)	
	)	
Defendants.	)	
	)	

Defendants Johnson & Johnson (“J&J”), LLT Management, LLC (“LLT”), Johnson & Johnson Holdco (NA), Inc., and Kenvue, Inc. (collectively “J&J Defendants”)¹ hereby move for mistrial. This motion was made necessary by a constellation of issues that have made it impossible for the J&J Defendants to get a fair trial.

ARGUMENT

A motion for mistrial is, by its nature, both an allegation of error and an allegation of prejudice sufficient to warrant a mistrial. *State v. Wilson*, 289 S.C. 579, 585 (Ct. App. 2010). The decision whether to grant a mistrial is within the trial court’s discretion. *State v. Harris*, 382 S.C. 107, 117 (Ct. App. 2009) (internal citation omitted). And “[t]he determination of prejudice must be based on the entire record and the result will turn on the facts of each case.” *State v. White*, 371 S.C. 439, 447 (2006). When comments of the Court inhibit counsel for a party from presenting a defense, a new trial should be ordered. *State v. Wright*, 248 S.E.2d 490 (1978).

¹ Holdco, LLT, and Kenvue are sued on a successor liability theory. The “J&J Defendants” moniker is used for brevity.

As recognized by one court, even well intentioned, active engagement by the trial judge is perilous:

Active involvement by a judge, however, must be done prudently. Even the most unbiased judge, by actively engaging in the trial, runs the risk of appearing to lack objectivity and may chill the attorney's capacity to represent the client's interest most effectively. A judge who makes comments that devalue a litigant's presentation midstream may not be forwarding the goals of a fair trial, but instead may lead the restricted party to believe that the judge is unwilling to listen. A judge who creates a courtroom atmosphere that appears unfair to the litigants may unintentionally cause the proceeding to become unfair. The litigants may react by abandoning *595 a planned strategy or line of questioning that could affect the result or the record. A judge's participation should not overreach and disrupt a litigant's development of the evidence. Such behavior can transcend the bounds of proper judicial conduct and can go so far as to deprive a litigant of the right to a fair trial. *Western Maryland Dairy Corporation, et al. v. Brown*, 169 Md. 257, 266, 181 A. 468 (1935).

Ricker v. Ricker, 114 Md. App. 583, 594–95, 691 A.2d 283, 289 (1997).

A trial judge must act with absolute impartiality in the performance of judicial duties. *State v. Cooper*, 334 S.C. 540, 546 (1999). A trial judge must refrain from any comment which tends to indicate her opinion as to the weight or sufficiency of the evidence, the credibility of witnesses, or any fact in controversy. *State v. Brisbon*, 323 S.C. 324, 331 (1996). And a trial judge must not make remarks that impugn the credibility of counsel and diminish her and her defense in the eyes of the jury. *State v. Simmons*, 267 S.C. 479, 483 (1975).

1. THE CHANGING RULINGS AS TO A SPOILIATION CHARGE HAVE SEVERELY PREJUDICED THE J&J DEFENDANTS' DEFENSE.

The J&J Defendants based their defense strategy for this case on the Court's pretrial ruling granting Plaintiffs' Motion in Limine No. 22 requesting entry of the *Hood-McBrayer* spoliation order in this case, an order issued by this Court in that separate case. Plaintiffs stated, in their motion in limine seeking the same order in this case, "Plaintiffs request this identical order and instruction to the jury be given in this matter." The Court indicated it would grant the same order. See *Hood-McBrayer* 11/02/2021 Spoliation Order (Ex. A), incorporated in *Perry* (7/30/2024 Tr.

150:5-156:10) (Ex. B). By its express terms, the Order is only be triggered if the J&J Defendants introduce evidence of a negative test for asbestos in their product conducted or commissioned by the J&J Defendants. *Id.* Relying upon Plaintiffs’ motion and the contents of the *Hood-McBrayer* Order, the J&J Defendants conformed their opening statement and witness examinations to the plain language of the *Hood-McBrayer* Order. That is to say, they severely curtailed the scope of their defense to avoid triggering the Order. The J&J Defendants limited their cross examination of Plaintiffs’ experts and avoided introducing any evidence of negative testing conducted or commissioned by the J&J Defendants. Indeed, the J&J Defendants were so committed to this trial strategy that counsel announced at the start of trial they would employ a trial strategy that would not trigger the Order. 08/05/2024 Trial Tr. at 39:21-23 (Ex. C) (“But I’m telling you right now that we do not intend to offer any evidence that would trigger this for the jury.”)

However, on the fourth day of trial, without warning, the Court changed course, announcing that “other” types of evidence could “open the door” to the *McBrayer* Order. 08/10/2024 Trial Tr. at 1022:24-1023:2 (Ex. D) (“And I think the door has been opened, not just on Haber, but on other things that have been done that's put before the jury.”)

The Court may not change a ruling in a manner that prejudices the J&J Defendants’ reliance expectations, which were fully announced and known to all. *See Swietlowich v. Bucks County*, 610 F.2d 1157, 1164 (3d Cir.1979) (explaining that a trial judge who “decides to change ... an earlier ruling ... must also take appropriate steps so that the parties are not prejudiced by reliance on the prior ruling” and finding that “the plaintiff suffered no prejudice at trial ... since she was fully prepared to meet the limitations defense” (emphasis added)). The Court’s mid-trial change has substantially prejudiced the J&J Defendants because their entire trial strategy was based on the language of the Motion, the Order and the Court’s pre-trial rulings. If the J&J Defendants had

been aware that other evidence could trigger the *McBrayer* charge, they would have approached trial differently. Hence, a mistrial must be declared.

2. PLAINTIFFS' COUNSEL MADE SERIOUS PERSONAL ATTACKS ON DEFENSE COUNSEL INCONSISTENT WITH SOUTH CAROLINA LAW, AND THE COURT APPEARS TO HAVE ACCEPTED PLAINTIFFS' COUNSEL'S DENIAL THAT HE MADE THE ATTACKS.

On day four of trial, while the jury was on a break, Plaintiffs' counsel repeatedly accused defense counsel and their client of being "criminals" who are "unethical" and "work for a criminal organization." 8/10/2024 Trial Tr. 1164:20-1165:15 (Ex. D). He threatened Attorney Kim Bueno that he was going to try to take her bar card. *Id.* He threatened another female trial team member that he was going to "do to you worse than what we did in *Lee*," his last trial against Johnson & Johnson. *Id.* These statements were made in an aggressive and angry manner, accompanied by body language evincing hostility and personal contempt. They were specifically meant to, and did intimidate, the trial team member who has had very limited interaction with Plaintiffs' counsel in this case. Though Mr. Adams denied making the comments when questioned by the court, much of Mr. Adams' conduct and statements were seen and heard, and can be confirmed, by third parties in the courtroom.

These types of personal attacks are not overzealous advocacy. Instead, it is unprofessional behavior designed to chill defense counsel's zealous and professional defense of their client. The behavior has no place in the courtroom. Simply put, this type of extreme personal attack is never appropriate.

Plaintiffs' counsel's actions violate the most basic standards of professionalism that are at the base of the legal profession. Indeed, the Statement of Principles adopted by the South Carolina Bar provides that "[a] lawyer should avoid all rude, disruptive and abusive behavior and should, at all times, act with dignity, decency and courtesy consistent with any appropriate response to

such conduct by others and a vigorous and aggressive assertion to appropriately protect the legitimate interests of a client.” Even though several defense attorneys, and a third party in the courtroom, heard these personal attacks, the Court asked Mr. Adams if he said “criminal” and he denied saying it. The Court then seemingly accepted this flat denial in the face of significant contrary evidence, stating that all should “turn the page.” 8/10/2024 Trial Tr. 1165:16-22. Respectfully, the Court cannot accept one party’s attorney’s statement over the other party’s numerous attorneys’ statements, as to do so necessarily creates the appearance of lack of impartiality. As Mr. Adams is an active participant in the trial, the Court should declare a mistrial. Indeed, “courts have the power, as well as the duty and responsibility, to disqualify counsel to act in the proceedings, where he is guilty of conduct which is unprofessional or otherwise improper.” 7 C.J.S. *Attorney & Client* § 58 (1980).

3. THE COURT INCORRECTLY CHARACTERIZED THE NATURE OF DR. KUFFNER’S TESTIMONY AND THE DOCUMENTS HE SOUGHT TO ADDRESS, EXCLUDING KEY EVIDENCE.

The South Carolina Supreme Court has long held that “the trial judge, of course, has the right, in his discretion, and in a proper manner, to question witnesses during a trial, in order to elicit the truth.” *Williams v. S.C. Farm Bureau Mutual Ins. Co.*, 251 S.C. 464, 163 S.E.2d 212. The discretion applies until “it appears that the manner in which the judge exercised the right tended to unduly impress the jury with the importance of the testimony elicited, or would be likely to lead the jury to suppose that the judge was of the opinion that one party rather than the other was correct upon a particular issue of fact.” *Fowler v. Laney Tank Lines, Inc.* 263 S.C. 422, 424 (1975). “In exercising discretion to question a witness, the trial judge must do so in an impartial manner that does not indicate the trial judge's opinion as to any fact or “have an unintended prejudicial effect.” *Day v. Kilgore*, 314 S.C. 365, 369 (1994). The Supreme Court has “restricted the trial judge's

power to enter the realm generally reserved for the advocate.” *Id.* at 370. Here, the Court crossed this line.

Dr. Edwin Kuffner is a medical doctor and the Chief Medical Officer of Johnson & Johnson Services, Inc. Moreover, he has significant experience in many areas related to the production and safety of Johnson’s Baby Powder, both from his professional work and his review of thousands of documents about talc and/or asbestos. J&J Defendants’ counsel attempted to discuss one of those documents with Dr. Kuffner – a 2019 Health Hazard Evaluation of Johnson’s Baby Powder (“HHE”) that he wrote, signed, and approved. Ex. E. Counsel intended to question Dr. Kuffner about this document not as an expert, but as a fact witness who was directly involved in preparing the document in the normal course of business as Chief Medical Officer. Notwithstanding his qualifications and familiarity with the document, the Court informed the jury that Dr. Kuffner is not an expert. “Ladies and gentlemen, let me put this on the record. This exhibit that Ms. Bueno had asked Dr. Kuffner about is an expert opinion. You may recall that experts get qualified in a particular subject. If they’re qualified, then they can express an opinion. Dr. Kuffner is the corporate representative. He can’t express some expert opinion.” 8/10/2024 Trial Tr. 1290:23-25 (Ex. D).

If the Court had permitted his testimony, Dr. Kuffner would have testified about the HHE, which contains a variety of information, including but not limited to, an exposure assessment which concluded that the allowable occupational asbestos exposures are at least 2 million times higher than the potential consumer exposure reported at 0.00002 percent asbestos in talc. Dr. Kuffner would have testified about the conclusion of the HHE, that consumer exposure to the FDA’s reported findings of asbestos would result in a de minimis risk to the consumer and that the use of the product was unlikely to result in adverse health consequences. Dr. Kuffner was prepared

to testify about how and why he came to that conclusion in his role as Chief Medical Officer and why that was Johnson & Johnson's conclusion in 2019. This testimony would have been offered not only for the substance of the HHE, but to establish that the J&J Defendants were diligent in their efforts to investigate the presence of asbestos and confirm the safety of Johnson's Baby Powder. This evidence thus rebuts Plaintiffs' claims that the J&J Defendants were negligent, reckless, wanton and willful in the continuation of Johnson's Baby Powder sales. This is not impermissible expert opinion testimony, but factual testimony about what Johnson & Johnson actually did—years before this case was even filed—to assure the safety of its cosmetic talc products.

This error was compounded because Plaintiffs were allowed to question Dr. Kuffner at length about the experts the J&J Defendants retained for this case. See 8/10/2024 1211:10-15 (Ex. D) (“Did you review any of the reports each of the six experts hired by Johnson & Johnson have prepared in this case? A. I -- I didn't specifically -- I know I've seen a few reports. I didn't review all the reports, no.”); *Id.* at 1210:11-16 (“And because of that, Johnson & Johnson hires experts in these cases to come defend the company, correct? A. Yes. My understanding is plaintiffs hire experts, and company [sic] hires experts, and that's my understanding of how these cases go.”). Yet, when J&J Defendants tried to address the issues raised in the expert report of one of their experts, Dr. Matt Sanchez, the Court prohibited Dr. Kuffner from discussing his independent knowledge as medical director regarding the presence of winchite in a 1940's bottle of talc likely sourced from California. J&J Defendants raised the report to provide context to claims that Plaintiffs made about Dr. Sanchez's testing during the re-direct examination of their testing expert, Dr. William Longo. *See generally id.* at 1210:10-1212:25. By excluding this testimony from Dr.

Kuffner, J&J Defendants were not provided with an opportunity to rebut information obtained for the first time in a re-direct examination of Dr. Longo.

Moreover, the Court interrupted J&J Defendants' questioning of Dr. Kuffner, voicing her (incorrect) understanding of a document that was being offered: "He's already told you that they withdrew from the market or recalled – I don't know exactly how they determined it – one lot consisting of many cases in a particular talc that had been tested. They withdrew it from the market the October 19, 1994, I believe it was." *Id.* at 1291:6-8. Then the Court implied that it was Defense counsel who had misrepresented the nature of Defendants' 2020 business decision to decommercialize Johnson's Baby Powder, referring to it as a recall. *Id.* at 1286:7-1291:21.

Not only did the Court inform the jury that Dr. Kuffner was not an expert (he is a doctor), and confuse the issue about when and why Johnson's Baby Powder was manufactured, but also *sua sponte* interjected and struck the question and answer when Dr. Kuffner attempted to discuss winchite, the type of asbestos fiber Plaintiffs' claim was found by Dr. Longo in Mr. Perry's lung tissue samples. Dr. Kuffner, as the CMO overseeing the safety of Johnson's Baby Powder, was familiar with possible talc contaminants including winchite, where it might originate, the mines Johnson & Johnson used, and whether asbestos had ever been found in Johnson's Baby Powder, or their competitors' talc products. Having Dr. Kuffner testify about what the company knows, and what he personally knew as CMO, about winchite and what its presence means, was essential to the J&J Defendants' case after the court permitted Plaintiffs to admit the late tissue digestion report². Dr. Kuffner would have explained that winchite is a form of asbestos associated with isolated mines in the United States – but not the mines used by the J&J Defendants when Mr. Perry was using Johnson's Baby Powder. He would also have addressed Plaintiffs' prior submission of

² The report was admitted over objection.

Dr. Sanchez’s finding of winchite in a 1940’s bottle of Johnson’s Baby Powder (Ex. F, Sanchez Report on Longo Samples), which Dr. Kuffner had reviewed. Ex. G, Longo Affidavit at 19; Ex. H, PowerPoint Slides (Kuffner-1940s Talc). And Dr. Kuffner would have explained, as Dr. Longo had speculated, for a brief period in the 1940s during World War II, Johnson’s Baby Powder talc had likely been sourced from California mines. Ex. I, 8/7/2024 Tr. Transcript (Longo) at 900.

But the Court prohibited all of this crucial defense testimony: “That’s why – what I’m going to do is strike any testimony by him about the geological arguments, winchite, or whether it – whether it occurs in various mines. He’s not being offered for this. . . . But I direct you to move on, not ask him any further questions about the presence of winchite or anything.” *Id.* at 1293:15-1294:1³. When counsel for the J&J Defendants explained that her question only sought to illicit facts the corporate representative was familiar with, the Court stated in front of the jury that “I am not going to allow you to get around a ruling by saying ‘as a corporate representative are you aware...’” *Id.* at 1294:11-13.

The jury respects the Court, which is the very reason for the restrictions set forth in *Day v. Kilgore, supra*. As a result, the jury looks to the Court’s every word and gesture for guidance. Without question, the effect of the Court’s commentary and incorrect ruling was to diminish Dr. Kuffner’s experience and judgment in the eyes of the jury, as well as painting J&J’s counsel in a negative light. This is why judges must “be cautious to see that such questions are propounded in a fair and impartial manner, and should not express or indicate to the jury the judge’s opinion as to the facts of the case or the weight or sufficiency of the evidence.” *Williams v. S.C. Farm Bureau*

³ Plaintiffs’ counsel had not objected.

Mut. Ins. Co., 251 S.C. 464, 472 (1968). This exchange and the limitations on the witness's testimony has unquestionably marred the testimony of the J&J Defendants' primary witness.⁴

4. CUMULATIVELY, THE COURT HAS APPLIED A DIFFERENT STANDARD TO PLAINTIFFS AND J&J DEFENDANTS AND INHIBITED COUNSEL FROM PRESENTING DEFENSES.

Outside the presence of the jury, the J&J Defendants feel that the Court has applied a different standard to evidence offered by J&J Defendants than evidence offered by Plaintiffs. Further, and cumulatively, some of the Court's statements during both pre-trial and trial have inhibited J&J Defendants counsel from presenting the case for the defense, in violation of *State v. Wright, supra*.

First, while discussing a motion related to evidence of LTL's bankruptcy, the Court repeatedly stated or suggested that the bankruptcy proceeding was illegitimate. (*See, e.g.*, 7/30/2024 Hr'g Tr. 174:13-175:2 (Ex. B) ("Well, why did they engage in this type of restructuring? To avoid liability. That's the only reason they did it. I was here with a bunch of these J&J cases on my docket when all of that came down. And all of them were stopped and stayed by a bankruptcy that turned out to be not legitimate. And then we went through the Texas two-step. That turned out not to be legitimate. These -- these corporations weren't established for some theoretical idea of restructuring. They were structured to try to throw all the liability into a corporation that had no assets so J&J can go on their merry way forward."); 153:18-154:4 ("[Y]our client has jumped through every hoop imaginable from the Texas two-step to Lord knows what to put a stop on the trial of Johnson & Johnson cases in state court, and that includes in this court");

⁴ By contrast, when Plaintiffs' primary witness, Dr. Longo, was preparing to testify, the Court seemingly endorsed his importance and very broad-ranging forthcoming testimony to the jury as Plaintiffs' primary witness. Ex. I 08/07/2024 806:8-11 ("Just for a preview then, members of the jury, one of the plaintiffs' principal witnesses is appearing live here, and he'll be lengthy.")

172:21-173:7 (“[Y]ou all are the ones that created this monster with this bankruptcy, that was later dismantled, and with this Texas two-step and all the rest of it.”); 175:21-24 (“Legitimate bankruptcies cannot be the basis of a fraud. This didn’t turn out to be in that conventional framework.”)

These statements by the Court are simply not factually accurate. Contrary to the Court’s statement that LTL had “no assets” or somehow constituted a ploy to “avoid liability,” the Third Circuit found the exact opposite. It dismissed the bankruptcy because LTL had **too many** assets and acknowledged the irony that its ruling essentially stemmed from the fact that the company was structured in a manner **too generous** to talc claimants. *See In re LTL Mgmt., LLC*, 64 F.4th 84, 110-11 (3d Cir. 2023) (“We do not duck an apparent irony: that J&J’s triple A-rated payment obligation for LTL’s liabilities, which it views as a generous protection it was never required to provide to claimants, weakened LTL’s case to be in bankruptcy.”)

The Court also sharply criticized other actions taken by the J&J Defendants and others in the cosmetic industry, for instance referring to ordinary (and constitutionally-protected) public relations and government engagement as “shenanigans... to hide the ball from the public to pressure the governmental entities.” 7/30 Hr’g Tr. 74:3-5 (Ex. B); *see also id.* 78:9-13 (making unsupported claim that FDA testing was “wrong” and “influenced” by the cosmetic industry to justify hiding it from the jury) And the Court asserted as a fact that “it was known for years [talcum powder] had asbestos in it” (*id.* 191:3-5), essentially announcing its views on a central merits question at the trial.

Second, the Court repeatedly seemed to disparage the J&J Defendants’ expert witnesses in a manner that suggested it had already adopted Plaintiffs’ view of contested scientific issues.⁵ While it is reasonable for the Court to comment on science when exercising its role as the gatekeeper of expert evidence, the Court’s comments went beyond evaluation of expert methodology under Rule of Evidence 702. For instance, the Court claimed it to be “common knowledge” that “talc with asbestos causes mesothelioma,” which is the Plaintiff’s theory of the case and is opposed by the J&J Defendants. The J&J Defendants do not believe this is true, nor is it common knowledge. *Id.* 217:11-20. The Court’s seeming embrace of Plaintiffs’ theory of the case before trial creates an appearance of lack of impartiality.

As another example, the Court referred to Dr. Sanchez’s definition of asbestos (to include only asbestiform minerals) as “totally discredited . . . in this day and age” and “mind-boggling” “nonsense.” *Id.* at 114:24-115:2, 120:7, 124:21-125:4; *see also id.* 123:9-15 (claiming definition of asbestos was “thoroughly discounted” and had been invented by a J&J contractor); *Id.* at 116:14-25 (“nothing to do with the asbestos properties that are identified by most experts”) The Court went on to claim there is “a vast amount of material . . . that says that talc does have asbestos in it.” *Id.* 218:9-12. The Court also suggested that Dr. Sanchez’s testimony would be unhelpful because “you got a guy who defines asbestos in a very different way.” *Id.* 125:2-4. However, no defense expert defines asbestos differently than Dr. Sanchez. Unlike Plaintiffs’ advocated definitions, Dr. Sanchez’s definition of asbestos is consistent with the one used by federal

⁵ The Court also disparaged defense attorneys. For instance, in discussing a defense motion, the Court referred to the Reptile Theory, which by most accounts was popularized in a book by and for plaintiffs’ lawyers, as “that crazy thing that the defense invented as a scare tactic.” (Ex. B 7/30 Hr’g Tr. 160:1-4.) At another point the Court said it was “ashamed of [counsel] for making” an argument. (*Id.* 155:23.) This comment chilled defense counsel from making legitimate arguments consistent with this Court’s previous orders.

regulatory agencies, such as the Occupational Safety Hazard Administration and Environmental Protection Agency, and accepted by the International Agency for Research on Cancer. Finally, while discussing trial length, the Court referenced the duration of Dr. Sanchez's testimony in a previous trial and promised it would "never repeat that again." *Id.* 114:10-12. The Court then went so far as to state that if any expert attempted to explain asbestos detection in talc as "lab contamination" the Court would likely strike all of the testimony and "instruct the jury to draw an adverse inference." A key part of Dr. Sanchez's testimony was describing the various ways of detecting asbestos in talc, including false positives and times when his lab has detected false positives in Johnson's Baby Powder due to contamination. Faced with the improper threat of an adverse inference, J&J Defendants had no choice but to pull that expert from trial. This violates the principles set forth in *State v. Wright, supra*. No similar statements have been made about Plaintiffs' experts.

The Court granted Plaintiffs' motion to compel regarding Defendants' corporate witness who had already been deposed for four days on the successor liability issues in this case. The Court ruled that an additional deposition was required to take place over the weekend between trial days because Plaintiffs were entitled to additional discovery of evidence of Defendants' financial transactions. This Order contrasts the Court's ruling allowing Plaintiffs' expert, Dr. Longo, to offer new opinions about a previously undisclosed tissue digestion. J&J Defendants found out about the existence of this new test just before opening statements and were not provided information about the findings at that time. (8/5/2024 Trial Tr. 72:3-6.) When counsel for the J&J Defendants reacted, understandingly, with surprise and concern over the lack of disclosure, the Court stated: "And you're going to, I think, pretty well be able to **guess** what he found" in the tissue digestion. (8/5 Trial Tr. 147:25-148:2.) (emphasis added). J&J Defendants moved to exclude the

tissue testing for these reasons and the fact that their experts did not have time to complete a proper tissue digestion, which the court improperly denied. Only after the J&J Defendants were forced in their opening to “guess” how the tissue digestion might impact their case did Plaintiffs produce the tissue digestions results and present Dr. Longo for deposition – at night – in the middle of trial. Plaintiffs, on the other hand, were granted sanctions against Holdco and LLT Management LLC for purportedly failing to sufficiently answer some questions during the course of **four days** of corporate representative deposition testimony prior to trial. The continuing depositions of Holdco and Kenvue are going on today. The J&J Defendants thus believe that they have not been treated similarly to plaintiffs, culminating in the improper interjection of questioning by the Court of Dr. Kuffner, the corporate representative, and they have been inhibited from putting on a defense. As a result, a mistrial should be granted.

CONCLUSION

For the foregoing reasons, the Court should grant a mistrial.

(Signature Page Follows)

Respectfully submitted,

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Columbia, South Carolina

August 10, 2024

Exhibit A

STATE OF SOUTH CAROLINA	)	IN THE COURT OF COMMON PLEAS
	)	
COUNTY OF CHARLESTON	)	NINTH JUDICIAL DISTRICT
	)	
ANGELA M. HOOD , Individually and as	)	C/A No. 2020-CP-10-03946
Personal Representative of the Estate of	)	
MARY B. MCBRAYER ,	)	In Re: Asbestos Products
	)	Liability Litigation
Plaintiff,	)	
	)	
vs.	)	
	)	<u>ORDER</u>
ACME MARKETS, INC. , et al.	)	
	)	
Defendants.	)	

Before the Court is Plaintiff's Consolidated Motion for Evidentiary Sanctions Against Johnson & Johnson Based on Spoliation of Evidence.¹ The Court received briefs from Plaintiff and from Johnson & Johnson and heard extensive argument from the parties on October 28, 2021. The motion is granted in part and denied in part.

BACKGROUND

Since at least the 1950s, Johnson & Johnson has itself tested or directed others to test several hundred samples of its talcum powder products and the talc sources from which those products are made. For most of those tests, only summary reports of the results are available. In most cases, no underlying data remain that describes or depicts what the analyst saw during the test. These materials have been destroyed or discarded or were never collected. In addition, the talc samples that were tested have been destroyed and discarded.

¹ Plaintiff originally made this motion against Johnson & Johnson Consumer, Inc. ("JJCI"), but proceedings against that entity have been stayed by the bankruptcy court. This order is not directed at JJCI.

Plaintiff argues that Johnson & Johnson is guilty of spoliation through its failure to preserve (1) underlying data that support (or fail to support) test reports, (2) control blanks or documentation about control blanks that would show whether laboratory air was contaminated with asbestos fibers, and (3) historical talc samples in its possession. Based on this alleged spoliation, Plaintiff has requested certain evidentiary sanctions in the form of jury instructions that the jury may presume that, when Johnson & Johnson is responsible for missing evidence, the missing evidence would not have supported Johnson & Johnson's position. Plaintiff also asks that Johnson and Johnson be precluded from arguing that the causation opinions of Plaintiff's experts are supported by tests of insufficient or unrepresentative talc samples.

THE MISSING DATA

Documentation of Testing and Analysis

Testing for asbestos often requires a complex and multilayered analysis. The analyst will collect several types of data during the process, including: (a) "bench sheets" or "count sheets," (b) photographs and/or (c) chemical analysis such as EDS data. Bench sheets report each particle examined: its chemistry (whether it is one of the asbestos types and which one), length, width, aspect ratio, and other features. Photographs show the particle's length and width, but also its shape, such as potential curvature, bundling, etc. And tests such as EDS data provides information on the chemical elements of the particle. The elemental makeup can then be compared to the reference standard for identification.

The parties and their experts have fundamental disagreements about the proper (1) definition for asbestos in the context of evaluating health effects, (2) methodology to detect the presence of trace levels of asbestos in talc and (3) interpretation of the data generated, including the chemistry, crystal structure, size and shape of the particles or structures examined. These disagreements can lead experts to reach different conclusions based on review of the same

evidence. In fact, Plaintiff presented evidence that Johnson & Johnson and its consultants recognized in the 1970s that this underlying data was “vital information” and interpretation of the data would vary based on the expertise and interest of the analyst.

Plaintiff argues that, without the underlying data for Johnson & Johnson’s tests, it is impossible to determine what the results would have been if a different definition were applied, different methodology used, and/or different interpretation made. For example, as to methodology, evidence was presented that Johnson & Johnson instructed its testing consultants to use a counting protocol that permitted the presence of asbestos to be reported in a sample only if five fibers of the same type were counted, and Johnson & Johnson directed its testing consultants on the language to be used in testing reports.

Johnson & Johnson has not argued that this underlying data are unimportant. In fact, the evidence presented demonstrate that Johnson & Johnson testing consultant RJ Lee Group has taken the position that, to evaluate the accuracy of another analyst’s report, it would need information on the number, chemistry, crystal structure, size, and shape of the particles. Rather, Johnson & Johnson argues that, because Plaintiff has the examples she used in making this motion, any other evidence she could obtain through the missing data would be cumulative.

Laboratory Control Blanks

Another type of data that is collected for such testing is data on control blanks. It is standard practice for laboratories to use “blanks” to control for possible contamination. A blank is a filter placed near talc samples being tested to capture any contaminants in the air. The practice allows labs to rule out the possibility that asbestos fibers found in the sample came from an outside source since any contamination from an outside source would appear in both the sample and in the blanks.

Johnson & Johnson required the use of blanks, but the testing data provided by Johnson & Johnson in discovery virtually never includes documentation concerning blanks.

Plaintiff argues that Johnson & Johnson and its experts sometimes take the position that asbestos found in samples are the result of laboratory contamination. Plaintiff has identified specific instances in which documentation of blanks was available and did not support a finding of laboratory contamination. Johnson & Johnson argues that it should be allowed to use language in test reports that attribute asbestos to laboratory contamination without documentation of empty control blanks because (1) Plaintiff assumes that blanks were used, and (2) there is no evidence the blanks were in Johnson & Johnson's possession, custody, or control. However, Plaintiff provided evidence that Johnson & Johnson required the use of blanks, and Plaintiff does not appear to seek the physical blanks themselves, but rather documentation of their contents—as with the count sheets.

Talc Samples

Johnson & Johnson did not maintain the talc samples after they were tested. Its testing consultant McCrone offered to return the samples to Johnson & Johnson, but Johnson & Johnson did not take possession of the samples or ask that they be preserved. It is clear this offer had been made repeatedly and was made again in 1987. Plaintiff makes the point that Johnson & Johnson had access to the bulk of its product samples, and samples of its talc sources, but it chose to discard those products.

Plaintiff claims that Johnson & Johnson generally attacks the number, diversity, and source of the talc samples that Plaintiff's experts rely on as insufficient in number or not representative. Plaintiff points out that Johnson & Johnson has also attempted to challenge reliance on samples of

Johnson's Baby Powder not obtained from it by claiming insufficient chain-of-custody and/or asbestos contamination during maintenance.

Johnson & Johnson argues that there is no evidence that these samples were ever its custody after they went out for testing, and it had no responsibility to reclaim them. Johnson & Johnson also argues that Plaintiff is not prejudiced by not having access to the lost samples, which will be discussed below.

JOHNSON & JOHNSON'S KNOWLEDGE OF AND RESPONSE TO
PENDING OR ANTICIPATED LITIGATION

In 1969, Johnson & Johnson's Medical Director Dr. T.M. Thompson (a) advised Johnson & Johnson of the danger of inhaling "needle-like" tremolite, (b) recognized that "trace" amounts of tremolite in Johnson's Baby Powder were "unavoidable" and (c) noted that "furor" might arise if the public learned Johnson's Baby Powder "contained any significant amount of tremolite." He predicted Johnson & Johnson "could become involved in litigation" for pulmonary fibrosis and recommended Johnson & Johnson's "Law Department" evaluate the "defensibility of our position." Johnson & Johnson's privilege log asserts privilege based on pending or ongoing talc litigation as early as 1971 and throughout the 1970s. Johnson & Johnson argues that these early cases involved industrial talc rather than cosmetic talc and did not include allegations of mesothelioma. Johnson & Johnson asserts that the first mesothelioma case against it alleging exposure to Johnson's Baby Powder was in 1996.

Johnson & Johnson's corporate representative John Hopkins testified that the company knew since 1971 that asbestos-related diseases were latent and might not be diagnosed until decades after exposure. Plaintiff argues that, because Johnson & Johnson knew consumers would not develop disease until decades after using its product, it also knew that the talc samples in its possession might remain one of the only sources for vintage samples by the time an individual was

diagnosed with cancer. Johnson & Johnson's privilege log reveals that, as early as February 1971, Johnson & Johnson was communicating with its attorneys about talc samples in connection with both ongoing and anticipated litigation. Despite ongoing litigation and the depth of its knowledge, Johnson & Johnson failed to institute preservation policies until far too late.

The evidence shows that Johnson & Johnson did not institute a records retention policy until 1997. Johnson & Johnson also has no evidence that a legal hold was put in place for any talc litigation before the late 1990s, and Johnson and Johnson's position is that any legal hold would apply only to a single talc case. Although Johnson & Johnson sought and was unable to obtain talc samples for use in litigation from its talc supplier Luzenac in 1994 because of Luzenac's retention policy, Johnson & Johnson did not institute a legal hold on talc samples in its possession until 2017.

Johnson & Johnson's corporate designee on its discovery responses Nancy Musco testified that Johnson & Johnson was asked repeatedly in discovery for "any evidence" that the talc in Johnson's Baby Powder (*i.e.*, Johnson's Baby Powder or its talc sources) contained asbestos. Musco testified that Johnson & Johnson would respond with the company position, "That there is no asbestos in the cosmetic talc used for Johnson's Baby Powder." Musco testified that Johnson & Johnson could not identify a case prior to 2017 in which it had produced evidence related to the testing of its talc.

ANALYSIS

"The courts of South Carolina have long recognized that a party is entitled to favorable presumptions [in civil cases] about the contents of missing evidence when an opponent is responsible for the destruction of evidence that might otherwise be expected to have been relevant." *State v. Reaves*, 414 S.C. 118, 128, 777 S.E.2d 213, 218 (2015) (quoting Kevin R. Eberle, *Spoliation in South Carolina*, 19 S.C. LAWYER 26, 28 (2007)); *see also Gathers ex rel.*

Hutchinson v. S.C. Elec. & Gas Co., 311 S.C. 81, 83, 427 S.E.2d 687, 689 (Ct. App. 1993) (“when a party loses or destroys evidence, an inference may be drawn that the destroyed or lost evidence would have been adverse to that party.”). Just as a defendant should be allowed “to exculpate itself from liability because the plaintiff has barred it from obtaining evidence,” *Cole Vision Corp. v. Hobbs*, 394 S.C. 144, 153, 714 S.E.2d 537, 542 (2011) (quoting Robert L. Tucker, *The Flexible Doctrine of Spoliation of Evidence: Cause of Action, Defense, Evidentiary Presumption, and Discovery Sanction*, 27 U. TOL. L. REV. 67, 75 (1995)), a defendant should not be allowed to escape liability by denying the plaintiff access to evidence.

The Duty to Preserve

The evidence supports the conclusion that a duty to preserve evidence was triggered by 1971 at the latest, when Johnson & Johnson had already been sued for personal injury caused by its talc. Two years before, Johnson & Johnson had been warned by its medical director that it faced the risk of litigation from tremolite fibers in Johnson’s Baby Powder and that the Law Department should be informed. Also in 1971, Johnson & Johnson knew that the FDA was concerned about the presence of asbestos in talc and considering regulation of the talc industry, and Johnson & Johnson was also aware by this time that asbestos disease was latent, so that consumers using its product in 1971 would not develop asbestos-related cancers for decades.

Johnson & Johnson argues spoliation sanctions are normally applied in the context of discrete events, such a car accident where the plaintiff allows the car to be destroyed or where a furnace is destroyed after an accident. Johnson & Johnson argues that applying the doctrine in to conduct over decades and in the absence of a discrete event would be unfair. However, the analogy falls flat where Johnson & Johnson, with knowledge of the danger and the latency of asbestos-

related disease, sold its product to hundreds of thousands of consumers over the lengthy period of time at issue here.

Johnson & Johnson also argues that it cannot be guilty of spoliation going back to 1969 or 1971 because it was not sued in a mesothelioma case for exposure to Johnson's Baby Powder until 1996. But Johnson & Johnson's argument that the litigation must be identical to give rise to a duty to preserve evidence is not persuasive. Whether the talc at issue was industrial grade or cosmetic grade, Johnson & Johnson's corporate representative testified that it came from the same talc ore body. And any distinction between cancer in one part of the body versus another part of the body is inconsequential when both are triggered by asbestos. Any lawsuit alleging asbestos-related disease from exposure to its talc should have alerted Johnson & Johnson of the duty to preserve evidence related to asbestos in its talc sources and its talc products, particularly when Johnson & Johnson knew that asbestos had been found in its products and that low dose exposure to asbestos could cause latent disease.

Relevance and Prejudice

Plaintiff has demonstrated that the missing testing data is relevant and that she is prejudiced by its absence. Even Johnson & Johnson and its experts have expressed in the past that this evidence is essential to evaluating test results. Plaintiff has presented examples based on the few sample documents in Plaintiff's possession that show (1) some tests that report no quantifiable asbestos actually show that the analyst found an asbestos fiber in the sample, and (2) some tests where the analyst blamed asbestos in a sample on laboratory contamination had no asbestos in any laboratory blank and so no evidence to support the conclusion of laboratory contamination. The underlying test data, including documentation of blanks, is relevant and its absence is prejudicial

to Plaintiff. Johnson & Johnson's argument that any additional data would simply be cumulative is not credible. Underlying data for each test is necessary to evaluate the results of that test.

Johnson & Johnson has argued, however, that Plaintiff is not prejudiced by the absence of additional talc samples because she and plaintiffs generally have a sufficient representative number of samples available to test. Johnson & Johnson cites the testimony of Plaintiff's expert Dr. William Longo that sufficient talc samples were available to him for testing. Based on Johnson & Johnson's representations, I find that the absence of additional talc samples from Johnson & Johnson's historical testing does not prejudice Plaintiff.

Appropriate Sanctions

An appropriate sanction must "serve to protect the rights to discovery provided by the Rules." *Downey v. Dixon*, 294 S.C. 42, 46, 362 S.E.2d 317, 319 (Ct. App. 1987). "In determining the appropriateness of a sanction, the court should consider such factors as the precise nature of the discovery and the discovery posture of the case, willfulness, and degree of prejudice." *Griffin*, 334 S.C. at 199, 511 S.E.2d at 719.

Plaintiffs have demonstrated substantial prejudice and that the conduct at issue has been going on for decades. Even after Johnson & Johnson admits it was involved in litigation with a plaintiff who alleged mesothelioma caused by exposure to Johnson's Baby Powder in 1996, Johnson & Johnson continued to deny that its product had ever contained asbestos and did not disclose its historical testing in discovery until 2017.

Johnson & Johnson argues that the loss of this evidence was not intentional, and so it should not be subject to what it claims is the equivalent of granting judgment by default or dismissal. First, Johnson & Johnson overstates the scope of Plaintiff's motion. Plaintiff seeks an instruction only as to the testing done by or at the direction of Johnson & Johnson since 1971. It does not

apply to any testing done by Johnson & Johnson's suppliers, for example, and the evidence shows that hundreds of such tests exist. Nor does it apply to any test performed or commissioned by Johnson & Johnson before 1971. The proposed instructions are not the equivalent of death penalty sanctions.

While there is some evidence that Johnson & Johnson acted in bad faith in relation to certain matters connected to the reporting and preservation of its testing, Plaintiff need not prove that the spoliation was intentional to justify an adverse inference instruction. *See Kershaw Cnty. Bd. of Educ. v. U.S. Gypsum Co.*, 302 S.C. 390, 395, 396 S.E.2d 369, 372 (1990) (upholding trial court's spoliation instruction as appropriate sanction because there was no evidence of undue prejudice or intentional misconduct); *Stokes v. Spartanburg Reg. Med. Ctr.*, 368 S.C. 515, 521, 629 S.E.2d 675, 678–79 (Ct. App. 2006) (finding it reversible error to not include adverse inference instruction when two pieces of evidence were missing from hospital records, even though there was no evidence hospital acted intentionally and one of the records may never have been generated).

For these reasons, the Court **GRANTS** Plaintiff's motion for an adverse inference instruction concerning underlying testing data and blanks, and **IT IS HEREBY ORDERED** that the jury will be instructed that it may presume:

- 1) That when Johnson & Johnson introduces a test result, for tests performed by Johnson & Johnson or commissioned by Johnson & Johnson, that is negative for asbestos, reports "no quantifiable asbestos," or contains similar language, if the evidence shows Johnson & Johnson destroyed or unreasonably failed to preserve underlying data related to the test, the jury may presume that the missing data showed asbestos fibers were present.
- 2) When Johnson & Johnson argues any positive tests for asbestos, for tests performed by Johnson & Johnson or commissioned by Johnson & Johnson, were the result of lab contamination but Johnson & Johnson failed to retain evidence related to the "blanks" used as a control for such contamination, the jury may presume the blanks were free from asbestos.

These instructions are directly connected to the missing evidence and what it appears likely the evidence would have shown.

In addition, **IT IS HEREBY ORDERED** that Johnson & Johnson, its lawyers, or its experts are precluded from suggesting limitations to positive testing due to lack of underlying data when the underlying data does not exist because of Johnson & Johnson's conduct.

Finally, Plaintiff is instructed to inform defense counsel of what tests Plaintiff contends are included in the scope of this order in sufficient time for Johnson & Johnson to review before trial. Should the parties require any further clarity on import of this order, it can be discussed in context of specific testing.

Finally, the Court **DENIES** Plaintiff's with regard to talc samples. It is not clear whether these samples were within Johnson & Johnson's possession, custody, or control. Moreover, the Court notes Johnson & Johnson's argument that Plaintiff has access to sufficient and representative talc samples for testing.

AND IT IS SO ORDERED.



Charleston Common Pleas

Case Caption: Angela M Hood , plaintiff, et al VS Acme Markets Inc , defendant, et al
Case Number: 2020CP1003946
Type: Order/Other

So Ordered

Jean H. Toal

Electronically signed on 2021-11-05 12:32:07 page 12 of 12

Exhibit B

STATE OF SOUTH CAROLINA IN THE COURT OF COMMON PLEAS
COUNTY OF RICHLAND FOR THE FIFTH JUDICIAL
CIRCUIT

-----X
MICHAEL L. PERRY and :
LONNIE L LONG, : C/A No.
 :
 Plaintiff(s), : 2023-CP-40-04072
 :
 vs. :
 :
AMERICAN INTERNATIONAL :
INDUSTRIES, et al., :
 :
 Defendant(s). :
-----X

Pre-Trial Hearing

BEFORE: HONORABLE JEAN H. TOAL

LOCATION: Richland County Judicial Center
 1701 Main Street
 Columbia, South Carolina 29201

DATE TAKEN: Tuesday, July 30, 2024

TIME BEGAN: 11:07 a.m.

TIME ENDED: 5:39 p.m.

REPORTED BY: Corinne J. Blair,
 Certified Real-Time Reporter
 Certified Court Reporter
 Registered Professional Reporter
 Certified Live-Note Reporter

 EveryWord, Inc.
 P.O. Box 1459
 Columbia, South Carolina 29202
 803-212-0012

1 THE COURT: Well, if we're going to get
2 into that, we're going to impeach the CFTA and
3 all the shenanigans they went through to hide
4 the ball from the public to pressure the
5 governmental entities not to put -- to put out
6 the warnings they wanted to put out. I mean,
7 that's a slippery slope.

8 MS. BUENO: Well, I disagree, Your Honor,
9 with that characterization. I don't think that
10 what you just said is going to be in evidence,
11 because I don't think it's factual, but you are
12 correct that I am sure the plaintiffs will seek
13 to offer such evidence. But the evidence --

14 THE COURT: -- offered it before in cases
15 I've tried.

16 MS. BUENO: As defendants have offered
17 evidence about the FDA citizen's petitions and
18 responses and the like.

19 THE COURT: I'm not going to spend this
20 very limited amount of time we have with this
21 trial, and we talked about how long this trial
22 is going to be after awhile, but I'm not going
23 to spend it having a back and forth and back
24 and forth about the FDA and all that kind of
25 thing. EPA is something that is a little bit

1 means it's safe.

2 MS. BUENO: No, I'm not going to say that
3 means it's safe. I'm going to say that's what
4 they found at that time. This is what they
5 said when they said, "We do not need a warning
6 label."

7 THE COURT: Right.

8 MS. BUENO: This is not a health hazard.

9 THE COURT: Then we're going to have to
10 get into a thing of why the testing that they
11 did was wrong, how it was influenced very much
12 by the cosmetic, talc, fragrance association
13 and all that other thing. I'm not going to
14 have a trial within a trial about something
15 this minor.

16 MS. BUENO: Okay. So this is not minor,
17 Your Honor, from defendant's perspective.

18 What the FDA was doing at the time that
19 the plaintiffs' accused us of the fraudulent
20 behavior, that is very significant; what the
21 FDA was doing to test; what the FDA was doing
22 to pull the industry together and have
23 conversations.

24 THE COURT: Okay. I -- I understand your
25 position. Ms. McVey.

1 that, they better back it up, otherwise the
2 penalties are going to be severe.

3 MR. ADAMS: Understood, Your Honor. Thank
4 you.

5 THE COURT: Sixteen, plaintiffs' motion in
6 liminé to exclude the testimony of Dr. Matthew
7 Sanchez. I got a lot of questions here.

8 And I'll tell you another thing.
9 Dr. Sanchez, we're going to talk about how long
10 this trial's going to take. I spent four days
11 listening to McCrone and Dr. Matthew Sanchez.
12 I will never repeat that again. Yes, ma'am.

13 MS. GROSS: I'm going to try to go through
14 this as quickly as I can.

15 THE COURT: Yes, ma'am.

16 MS. GROSS: Okay. So our ask is that we
17 would like Your Honor to strike Dr. Sanchez in
18 his entirety. Not partially; entirely. For
19 these reasons that were outlined in our brief,
20 so I'm not going to hem and haw over them. I'm
21 just going to hit the high points.

22 The first is Dr. Sanchez cannot define
23 what his definition of asbestos is.

24 THE COURT: Yeah. He's an asbestiform
25 guy, and that is totally discredited as a means

1 of isolating asbestos from what I can tell in
2 this day and age.

3 MS. GROSS: And we're going to talk to you
4 about the two main points under that, but the
5 real main point under that is this whole
6 population requirement that I'm going to
7 explain to you in a minute.

8 THE COURT: I know --

9 MS. GROSS: You know --

10 THE COURT: I know this. I don't need to
11 have instruction. It's 3:15 and I don't need
12 to spend an hour on Dr. Sanchez.

13 MS. GROSS: The next is, he uses the bulk
14 building testing method, and sort of
15 extrapolates it to look at talc under a
16 microscope with a completely different
17 microscope and there's all -- we walked through
18 it all. There's all the peer review
19 publications that say you can't do that. It's
20 bad signs.

21 And then the third, and perhaps the most
22 damning, is when he applies his definition of
23 population asbestos as a ratio using this bulk
24 building method looking under the microscope
25 and looks at photos of raw tremolite, the raw

1 mix-standard tremolite, he says almost a
2 hundred percent of the time, it's not asbestos.

3 And then when you follow up with a
4 question, if you had a hundred of them that
5 look exactly like that, it's still not asbestos
6 for a variety of reasons. We put the whole
7 chart in there. I brought them to hand them to
8 Your Honor. It's kind of small. If you want
9 to see the photos blown up, I can hand them to
10 you. But what the Watson case --

11 THE COURT: But his definition of asbestos
12 in the final analysis, he's a geologist.

13 MS. GROSS: That's correct.

14 THE COURT: So his definition of asbestos
15 has nothing to do with the asbestos properties
16 that are identified by most experts. He says
17 that it's cleavage fragments versus
18 asbestiform. Everything is to be divided in
19 those two ways. I don't know of anybody else
20 that does it that way.

21 And he denominates -- he further
22 denominates, if you really want to drill him
23 down, that chrysotile is a cleavage
24 fragment-type asbestos, so it really isn't
25 asbestos.

1 THE COURT: It might be. But everything
2 that's happened since then is a huge variance
3 with the concept that asbestiform, as Matthew
4 Sanchez defines it in these slides,
5 characterizing it that way as a comparison with
6 cleavage fragments, that's the other thing so
7 mind-boggling about this thing.

8 He kind of works backwards to it. He
9 takes these cleavage fragments. And he takes
10 these cleavage fragments, slaps them on
11 something, then he works back to it. These
12 other things, well, they got to be something
13 else. They're not cleavage fragments. Oh,
14 well, I guess they're asbestiform. Then he
15 goes through all this malarkey about how
16 asbestiform works.

17 MR. COWAN: I don't think that I will be
18 convincing Your Honor anything about
19 Dr. Sanchez today, but I will say that if
20 plaintiff believes there has been this c-change
21 (ph) in what is and what is not asbestos, then
22 they are more than capable of cross-examining
23 Dr. Sanchez on his -- on his opinions. And I
24 think I'll just leave it at that.

25 THE COURT: Okay.

1 THE COURT: Yeah, 98 percent of raw
2 asbestos. Not asbestos, if you use Sanchez's
3 approach.

4 MS. GROSS: That's correct.

5 THE COURT: And the only question I got is
6 this, you know, it's the battle of the experts.
7 You know, they're going to be doing the same,
8 you know, attack on your experts.

9 I am -- as I say, I am very, very
10 questionable about Sanchez and this aspect
11 ratio is not supported now by anybody. McCrone
12 use to be -- they were the big defenders of
13 J&J. They came up with all this business.
14 It's now been thoroughly discounted by later
15 expert examination.

16 I don't know. I'm very hesitant about it.

17 MR. COWAN: Your Honor, may I at least
18 address the --

19 THE COURT: I mean, you know, one thing
20 that's said about Sanchez, if you're using PLM,
21 and you're using it in bulk materials, then his
22 thing may have some pertinence, but that's not
23 what we're talking about here. We're talking
24 about the much finer expert examination of
25 processed and marketed talcum powder and

1 whether it has asbestos in it. And his methods
2 simply don't get in the hemisphere of dealing
3 with the sophisticated determinations you have
4 to make in this thing. He's way back in the
5 geology of it and some kind of very basic, much
6 more basic world.

7 I mean, my family was in the sand-mining
8 business for many, many years. And so I am
9 sensitive to mining techniques and what you can
10 use to examine them.

11 We used a lot of sophisticated glass
12 capacitor and other kind of uses, because we
13 have very high ISO and very low FE. But the
14 way you examine those kind of minerals is about
15 the way he's examining this stuff, and it's a
16 much grosser examination to yield results.
17 And, you know, something like sand, even very
18 fine mill sand, then it is a sophistication it
19 takes to look at talc, and, particularly,
20 cosmetic talc.

21 And that's what's got me about taking this
22 very gross measuring device of Sanchez and
23 particularly taking up a bunch of court time
24 with all this nonsense when it really doesn't
25 have much ability to look at and tease out

1 whether there is or there isn't asbestos in
2 cosmetic talc. And particularly when you got a
3 guy who defines asbestos in a very different
4 way.

5 MR. COWAN: May I respond, Your Honor?

6 THE COURT: Yes, of course.

7 MR. COWAN: I'm not sure if you want me at
8 the --

9 MS. GROSS: I had a couple -- I had a
10 couple of quick points.

11 THE COURT: Let Mr. Cowan do it.

12 MR. COWAN: I'll be very brief.

13 THE COURT: Let him respond.

14 MR. COWAN: I don't think she needs to be
15 convincing you anymore. I think I need to get
16 up here for a moment.

17 Your Honor, I understand the point about
18 R-93 and your concerns there. The issue,
19 though, is that Dr. Sanchez does not just look
20 at these samples but the PLM, using that EPA
21 R-93. He uses XRD. He uses R-93 on the PLM.
22 He uses 22662-1 TEM. He used a different
23 methodology in his previous iterations of
24 reports, and then switched to the ISO.

25 Regardless, he is using all three.

1 Mr. Bernardo, and we argued about documents
2 that have been spoliated. And you entered an
3 order which Johnson & Johnson has. And I just
4 handed the order to you.

5 Nothing at all has changed since that
6 order was entered. So we would ask you to
7 enter the same order in the Perry case and give
8 the same spoliation charge.

9 MR. COWAN: Your Honor, I'm not going to
10 re-litigate this at all, but I would like to
11 put something on the record.

12 THE COURT: Do what?

13 MR. COWAN: I'm not going to re-litigate
14 this at all. I understand your prior order,
15 Your Honor. I just would like to put something
16 on the record just very briefly because --

17 THE COURT: Okay.

18 MR. COWAN: We understand the order.
19 Obviously, we respectfully disagree with the
20 order, but we've incorporated our McBrayer
21 briefing in our response we filed with the
22 Court. If the Court grants the relief,
23 however, if the Court signs the same order,
24 defendants note that the Court's order has
25 previously stated "requires plaintiff to inform

1 defense counsel of what tests plaintiff
2 contends are included in the scope of the
3 order." I think it's the last page of the
4 order, Your Honor.

5 And it requires that be done in a
6 sufficient time before trial. We are now less
7 than a week --

8 THE COURT: Hold on a minute. I'm
9 looking.

10 MR. COWAN: Yes, Your Honor.

11 THE COURT: Is what you're talking about,
12 "In addition, it is hereby ordered that Johnson
13 & Johnson and its lawyers and experts are
14 precluded from suggesting limitations to kinds
15 of testing due to lack of underlying data when
16 the underlying data does not exist because of
17 J&J's conduct"?

18 MR. COWAN: No. I believe it comes right
19 after that. If I could take a look at the
20 order you're looking at?

21 THE COURT: Oh, it's, "Finally, plaintiff
22 is instructed to inform defense counsel for
23 what tests plaintiff contends were included in
24 the scope of this or in a sufficient time
25 period to review before trial"?

1 MR. COWAN: Correct. So I'm referring to
2 that provision.

3 THE COURT: Right, right.

4 MR. COWAN: So that provision provides
5 that they need to provide notice of the tests
6 that they believe are within the scope of the
7 order.

8 McBrayer's order was signed and entered
9 nearly three years ago, obviously, before this
10 case was even filed. But it's fair to say that
11 when it got filed, this case, that plaintiff
12 was pretty sure they were going to be trying to
13 get this order, again, understandably, because
14 they were before the same judge.

15 So I would respectfully submit that, at a
16 minimum, they could have identified these tests
17 three weeks ago when they filed this motion for
18 entry of this order. We are now less than a
19 week away from trial and we have not been told
20 what tests that they believe are within the
21 scope of this order.

22 So my suggestion is that Your Honor --
23 that this order can be signed, but it's too
24 late. The time has elapsed. We don't have
25 enough time to be dealing with which tests are

1 you going to be claiming today, and, by the
2 way, what evidence are you going to be putting
3 on that proves that that particular underlying
4 data from McCrone, R.J. Lee, wherever it's
5 from, that we, Johnson & Johnson, ever had the
6 underlying data to begin to preserve --

7 THE COURT: Well, that's just an argument
8 against the whole law.

9 MR. COWAN: No, no. It's not, Your Honor,
10 because if we had enough time, they could tell
11 us what the evidence was. They could tell us
12 what the test was. And then we could have time
13 to prepare a response.

14 THE COURT: Well, let me tell you this:
15 This order, which is an order involving Johnson
16 & Johnson, was signed by me in --

17 MR. COWAN: 2021.

18 THE COURT: -- 2021. All right. Your
19 client has known about this for a very long
20 time. That's one.

21 Number 2, your client has jumped through
22 every hoop imaginable from the Texas two-step
23 to Lord knows what to put a stop on the trial
24 of Johnson & Johnson cases in state court, and
25 that includes in this court. Now, suddenly,

1 you come up at the last minute with an issue
2 that has been around a long time and try to put
3 it back on the plaintiff that you have been
4 surprised by what's going on here.

5 MR. COWAN: I'm not surprised at all. The
6 issue is --

7 THE COURT: Well, then, if you're not
8 surprised, I don't get the problem.

9 MR. COWAN: May I -- may I respond? The
10 problem is that it is plaintiff's burden under
11 that order to provide us the tests. They have
12 failed to do so.

13 THE COURT: I haven't signed the order
14 yet. That's the first thing.

15 MR. COWAN: I totally understand, but the
16 issue is that they sought the entry of this
17 order at the end of the -- right before the
18 beginning of trial.

19 THE COURT: Mr. Cowan, let me see what
20 Ms. McVey has to say about that.

21 MR. COWAN: Thank you, Your Honor.

22 MS. McVEY: Your Honor, they know exactly
23 what tests we're talking about. They answered
24 discovery where they said whether they got the
25 underlying data for each of these tests or not.

1 If they need to give you a list of the stuff
2 they've already provided to us, then I'm sure
3 we can do that. But this is not that kind of
4 issue. This order, by the way, was right
5 before they felt like this for the first time.
6 Do you remember that?

7 THE COURT: Yes, I do.

8 MS. McVEY: And so it's now been years
9 that they've known about this. It's not a
10 surprise what tests we're talking about, but
11 certainly if they need us to give them a list,
12 we'll give them a list. But they know. They
13 answered discovery.

14 THE COURT: Yeah. That's very much my
15 feeling about the matter.

16 MR. COWAN: Can we get a deadline by which
17 we can get that list?

18 MS. McVEY: We'll reproduce your discovery
19 responses to you on Thursday.

20 THE COURT: I'm not going back and forth
21 on this, Mr. Cowan. Really, this whole shock
22 and surprise of "they're treating us so bad,"
23 I'm frankly ashamed of you for making that kind
24 of argument here. Johnson & Johnson well knows
25 about this stuff. Y'all have been back and

1 forth about this stuff many a time. This is no
2 magic or mystery here going on.

3 MR. COWAN: Your Honor, I'll sit down.

4 THE COURT: Good.

5 Ms. McVey, get your order form. I'll sign
6 it --

7 MS. McVEY: Yes, ma'am.

8 THE COURT: -- and then provide the
9 materials for him as quickly as you can.

10 MS. McVEY: I will do that.

11 THE COURT: All right. Twenty-three, to
12 exclude expert hearsay opinions.

13 MS. McVEY: Your Honor, I think we agree
14 on that one.

15 MS. BUENO: We do.

16 THE COURT: All right. Now, what is 24?

17 MS. McVEY: That's it, Your Honor.

18 (A discussion was held
19 off-the-record.)

20 THE COURT: This is motion in liminé by
21 the defense now to exclude or partially exclude
22 certain opinions of Dr. Longo.

23 We're not going to spend all day on this.
24 I'm not going to do it. I'll send you a list
25 of my rulings.

1 THE COURT: The Reptile Theory is that
2 crazy thing that the defense invented as a
3 scare tactic, if you were going to talk about
4 the Reptile Theory.

5 MS. McVEY: Right. I can do it the way
6 the motion is written, if you're granting it.
7 We're allowed to ask safety questions,
8 obviously. Companies have duties to put out
9 safe products and do safe things. And so we
10 want to be able to ask those questions, which
11 you've allowed us to do in every case.

12 THE COURT: All I'm doing is ruling out
13 the Reptile Theory, which is the level of
14 reptilian bar that's appealed to by certain
15 arguments. That has nothing to do with safety.
16 Safety is always something you can ask about.

17 I grant it on the basis of the Reptile
18 Theory and Golden Rule. And our state enforces
19 the Golden Rule, and I do, too. All right.

20 Johnson & Johnson Motion in Liminé
21 Number 2, exclude each and every exposure from
22 cumulative dose, causation --

23 FEMALE SPEAKER: I think you skipped 1C.

24 THE COURT: Where?

25 MS. BUENO: 1C through G.

1 quote, Given that all relevant evidence is
2 admissible, plaintiff asks this Court to allow
3 them to introduce evidence of LLT bankruptcy
4 proceedings only to explain historical context
5 relating to LLT's existence and liabilities and
6 its relevance in this litigation. Unless J&J
7 opens the door and calls into question the
8 purpose of LLT bankruptcy proceedings,
9 plaintiffs do not intend to introduce evidence
10 showing J&J orchestrated the corporate
11 restructuring, sham bankruptcies and subsequent
12 events to avoid and limit its talc liabilities.

13 In other words, plaintiffs seek to admit
14 evidence relating to LLT bankruptcy proceedings
15 only to provide context and explain to the jury
16 how and why LLT is liable, not to show J&J is a
17 bad actor. That is the way plaintiffs
18 initially responded, and then rescinded by
19 amending and taking --

20 THE COURT: Let me tell you what's going
21 to happen here. They sued -- you all are the
22 ones that created this monster with this
23 bankruptcy, that was later dismantled, and with
24 this Texas two-step and all the rest of it. So
25 you created all these other corporations;

1 therefore, they had to sue all of the other
2 ones or you would have tried to step out of it
3 on the basis that they didn't sue the real
4 responsible party. So they sued all of them.

5 Now you don't want them to tell the jury
6 anything about these corporations and what they
7 are and when they were created and why.

8 MS. BUENO: Two responses: First of all,
9 Johnson & Johnson has never sought to avoid
10 liability. We have been front and center in
11 every single trial.

12 THE COURT: I'm not even going there.

13 MS. BUENO: Every single trial that has
14 gone to trial has been Johnson & Johnson
15 involved, not just these other entities.

16 But, number 2, we are absolutely willing
17 to enter into a stipulation, as we've done in
18 other cases, including the one that the same
19 plaintiff's counsel just tried in Oregon called
20 the Lee case, where we entered into a
21 stipulation to read the jury about what LLT
22 was. And we worked on language of that to talk
23 about the corporate structure, when the company
24 was created, what the purpose of it was, why
25 the name change was, et cetera.

1 We're very willing to enter into a similar
2 stipulation to provide that information. And
3 that answer is exactly what plaintiffs had
4 originally responded about seeking to admit
5 evidence only to provide context to explain to
6 the jury how and why LLT is liable. We will
7 stipulate to those type of corporate
8 restructuring and things about LLT. There's no
9 reason not to do it.

10 What we're seeking to avoid by this motion
11 is a side show of argument about why Johnson &
12 Johnson engaged in this type of restructuring.

13 THE COURT: Well, why did they engage in
14 this type of restructuring? To avoid
15 liability. That's the only reason they did it.
16 I was here with a bunch of these J&J cases on
17 my docket when all of that came down. And all
18 of them were stopped and stayed by a bankruptcy
19 that turned out to be not legitimate. And then
20 we went through the Texas two-step. That
21 turned out not to be legitimate.

22 These -- these corporations weren't
23 established for some theoretical idea of
24 restructuring. They were structured to try to
25 throw all the liability into a corporation that

1 had no assets so J&J can go on their merry way
2 forward.

3 MS. BUENO: And, Your Honor, obviously,
4 Johnson & Johnson disagrees with that
5 characterization. We have it in our briefing.
6 I know you've read it. The bankruptcy was
7 created to bring some certainty.

8 THE COURT: Bring some certainty? It was
9 created to stop all the litigation.

10 MS. BUENO: To bring certainty --

11 THE COURT: If you call that a euphuism
12 for bring certainty, that's what it was -- the
13 certainty that they wouldn't have to try these
14 cases that had been pending on dockets all over
15 the country.

16 MS. BUENO: Obviously, we disagree.
17 Plaintiffs have a fraud claim here.

18 THE COURT: Yes.

19 MS. BUENO: Bankruptcies cannot form the
20 basis of a fraud claim.

21 THE COURT: Well, there's some exceptions
22 to that now. Legitimate bankruptcies cannot be
23 the basis of a fraud. This didn't turn out to
24 be in that conventional framework.

25 MS. BUENO: Well, as addressed in our

1 projection and image did you put before the
2 public about the reliability and trust that you
3 can put in the product, when it turned out in
4 your internal records it was known for years it
5 had asbestos in it.

6 So -- and your own records say, we've got
7 to be sure this doesn't get out because our
8 image is the mother-child image that we are
9 projecting. You have internal records that say
10 that. They're going to be able to use that.

11 MS. BUENO: Your Honor, I hear you, and I
12 hear your ruling. I would disagree with the
13 fact that there is any document that says we
14 have to be careful this doesn't get out,
15 because Johnson & Johnson was not aware of
16 these allegations at that time. We were aware
17 of the allegations, but there is nothing to
18 suggest there was knowledge of asbestos in talc
19 that we were trying to hide or conceal. I know
20 Your Honor disagrees. I know Your Honor
21 disagrees.

22 THE COURT: It was brought to my attention
23 here, and in other cases I've tried, that talk
24 about that, specifically, in the internal
25 memos, about what to be sure is kept

1 mesothelioma. That's a step too far. He's a
2 statistician.

3 He can talk about what the epidemiology
4 says. He can talk about the powers of those
5 studies and everything else, as he's done in
6 the past, but this new opinion where he's
7 taking a leap, where he's now saying, "I can
8 opine on general causation," that's too far for
9 a statistician.

10 THE COURT: You know, I just don't see
11 this as some great big problem. I mean, the
12 majority of people that have looked at this
13 issue at any time in the recent past have come
14 to the conclusion that exposure to talc with
15 asbestos causes mesothelioma, or can cause
16 mesothelioma. And the question is levels of
17 exposure and how that increases the probability
18 or possibility that someone develops
19 mesothelioma. I don't see this as some great
20 big deal. That's kind of common knowledge now.

21 MS. BUENO: Well, I hear what Your Honor
22 is saying, but Dr. Madigan is a perfect
23 example, because what he relies on in his
24 charts and his report, do you know what they
25 are? They're asbestos studies. So I think it

1 is common knowledge. And I think nobody would
2 disagree that if you're exposed to asbestos --

3 THE COURT: Well, that's what he's being
4 asked to talk about.

5 MS. BUENO: It's different when you start
6 talking about cosmetic talc, because there's a
7 genuine disagreement. There is a genuine
8 disagreement --

9 THE COURT: Well, yes, ma'am, but there is
10 a vast amount of agreement -- there's a vast
11 amount of material, in which anyone can rely,
12 that says that talc does have asbestos in it.

13 You and J&J continue to insist that talc
14 does not have asbestos in it. It all has to do
15 with the way you define asbestos. And I get
16 all of that, but I am not going to exclude
17 Madigan's testimony.

18 MS. BUENO: Your Honor, we have
19 Dr. Longo's motion, and then a motion on tissue
20 testing and that would be it.

21 THE COURT: All right. Longo.

22 MR. COWAN: I will be very brief. The
23 papers -- may I approach?

24 THE COURT: Yeah.

25 MR. COWAN: The paper that we filed has

1 CERTIFICATE

2 STATE OF NORTH CAROLINA)

3 COUNTY OF GUILFORD)

4

5 I, Corinne J. Blair, Certified Real-Time

6 Reporter, Certified Court Reporter, Registered

7 Professional Reporter, and Certified LiveNote

8 Reporter, certify that the foregoing transcript of the

9 proceedings taken at the July 29th, 2024 session of

10 Richmond County Superior Court is a true and accurate

11 transcript of said proceedings recorded by me, is

12 contained in one volume, and was transcribed by me.

13 I further certify that I am not a relative,

14 employee, attorney or counsel of any of the parties;

15 nor financially interested in the outcome of this

16 action.

17

18 This 31st day of July, 2024.

19

20

21 

22

23 Corinne J. Blair, CRR, CCR, RPR, CLR

24 Certified Real-Time Reporter

25 Certified Court Reporter

Registered Professional Reporter

Certified LiveNote Reporter

RoA_09867

Exhibit C

STATE OF SOUTH CAROLINA
COUNTY OF RICHLAND

IN THE COURT OF
COMMON PLEAS
FOR THE FIFTH
JUDICIAL CIRCUIT

- - -

MICHAEL L. PERRY AND LONNIE	)	
L. LONG,	)	
	)	
Plaintiffs,	)	
	)	Case No.
vs.	)	2023-CP-40-04072
	)	
AMERICAN INTERNATIONAL	)	
INDUSTRIES, ET AL.,	)	
	)	
Defendants.	)	

TRIAL BEFORE: THE HONORABLE JEAN H. TOAL
DAY 1

DATE TAKEN: Monday, August 5, 2024

TIME BEGAN: 9:00 a.m.

TIME ENDED: 5:39 p.m.

LOCATION: Richland County Judicial Center
1701 Main Street
Courtroom 3B
Columbia, South Carolina

REPORTED BY: Cynthia First, RPR, CRR
EveryWord, Inc.
P.O. Box 1459
Columbia, South Carolina 29202
803-212-0012

1 MS. BUENO: On Tuesday, during pretrial
2 argument, plaintiffs filed a motion in limine
3 to apply the McBrayer order here. You granted
4 that motion. Plaintiffs have given you what
5 they intend to be the J&J spoliation
6 instruction you will give. That's before Your
7 Honor right now.

8 We have reviewed this and we see no
9 problem with it, but there is a catch. I want
10 to let the Court know that Johnson & Johnson
11 has made a strategic decision, in light of the
12 evidentiary ruling that you've offered in this
13 case, we are not going to be offering any
14 evidence in this trial in front of this jury
15 that would trigger a spoliation instruction.

16 So here is what I ask Your Honor to do. I
17 ask Your Honor not to charge this, to wait for
18 the evidence. And to the extent Your Honor
19 thinks that we've done something to trigger it,
20 then we can have that discussion and argument.
21 But I'm telling you right now that we do not
22 intend to offer any evidence that would trigger
23 this for the jury.

24 And that, again, is a decision we've made
25 only because of Your Honor's adverse ruling in

1 before, but send it up to me and we'll revisit
2 it sometime later today.

3 MS. MCVEY: And, Your Honor, Dr. Longo has
4 concluded the tissue digestion and is in the
5 process, I think, today. And we'll be able to
6 put him up for a, you know, short deposition.

7 THE COURT: Well, Longo is not going
8 today, is he?

9 MS. MCVEY: No.

10 THE COURT: Well, then we can figure this
11 out before that.

12 MS. BUENO: Yes, but, Your Honor, we
13 cannot have an opening statement before we know
14 what Dr. Longo says he found in this tissue.
15 This is unbelievable that we now have tissue
16 testing coming in after we're going to start
17 trial, where Dr. Longo is going to say he found
18 something that we haven't even been able to
19 discover yet. This has to be excluded, Your
20 Honor.

21 THE COURT: I hear.

22 MS. MCVEY: Your Honor, we discussed this
23 at length, of course, and I'll let Mr. Adams
24 speak to the digestion.

25 THE COURT: I'm not going to talk about

1 issue to me. The issue is whether it's
2 admissible. I find it is admissible.

3 MS. BUENO: Your Honor, we cannot start
4 this trial and provide an opening statement
5 without understanding what testimony Dr. Longo
6 is going to come into this courtroom and talk
7 to the jury about.

8 THE COURT: Well, I disagree with that.
9 You can certainly say what you want to say
10 about tissue digestion, but I'm not going to
11 stop the trial and say they can't mention it
12 simply because they were able to perform it and
13 you were not.

14 In terms of knowing what Dr. Longo says,
15 my bet is, just a bet, that as experienced as
16 you lawyers are in this little particular slice
17 of evidence, that what Dr. Longo says is going
18 to come as no surprise to you.

19 MS. BUENO: It will come as a surprise to
20 me, Your Honor, because he said less than three
21 weeks ago that he was not able to get this
22 done.

23 THE COURT: That has no bearing on the
24 admissibility of it. Able to get done is not
25 something. What he found is the something.

1 And you're going to, I think, pretty well be
2 able to guess what he found.

3 MS. BUENO: I am not able to guess.

4 THE COURT: Well, then, I'm sorry for
5 that, but I am not going to do anything about
6 not admitting this evidence and I'm not doing
7 anything about excluding the mention of this
8 evidence in opening statement.

9 MS. BUENO: When can we get this evidence,
10 Your Honor?

11 THE COURT: I don't know, but I'm not
12 debating that with you right now. I'm going to
13 rule on these things and bring this jury in.
14 And it's past time to bring them in as it
15 stands. I've made my ruling.

16 MS. MCVEY: Your Honor, just to be
17 clear --

18 THE COURT: I have made my ruling.

19 MS. MCVEY: I was going to agree with you.

20 THE COURT: There's a rule that says when
21 the judge makes a ruling, you move on. I have
22 ruled.

23 MS. BUENO: Final issue, Your Honor.

24 THE COURT: Yes, ma'am.

25 MS. BUENO: Dr. Barlow, we mentioned her

CERTIFICATE OF REPORTER

I, Cynthia First, Registered Professional Reporter and Notary Public for the State of South Carolina at Large, do hereby certify: That the proceedings and evidence are contained fully and accurately in the notes taken by me in the above cause and that it is a correct transcript of the same.

I further certify that I am neither related to nor counsel for any party to the cause pending or interested in the events thereof. Witness my hand, I have hereunto affixed my official seal this 5th day of August 2024, at Chapin, Lexington County, South Carolina.

Cynthia First,
Registered Professional Reporter
Notary Public
State of South Carolina at Large
My Commission expires:
October 16, 2028

Exhibit D

STATE OF SOUTH CAROLINA
COUNTY OF RICHLAND

IN THE COURT OF
COMMON PLEAS
FOR THE FIFTH
JUDICIAL CIRCUIT

- - -

MICHAEL L. PERRY AND
LONNIE L. LONG,

Plaintiffs,

vs.

AMERICAN INTERNATIONAL
INDUSTRIES, ET AL.,

Defendants.

)
)
)
) Case No.
) 2023-CP-40-04072
)
)
)
)

TRIAL BEFORE: THE HONORABLE JEAN H. TOAL
DAY 4

DATE TAKEN: Friday, August 9, 2024
TIME BEGAN: 8:48 a.m.
TIME ENDED: 5:27 p.m.
LOCATION: Richland County Judicial Center
1701 Main Street
Courtroom 3B
Columbia, South Carolina
REPORTED BY: Cindy A. Hayden, RMR, CRR
EveryWord, Inc.
P.O. Box 1459
Columbia, South Carolina 29202
803-212-0012

1 cured by trying to figure out something
2 this weekend that takes the sting out of
3 that. That's not professional, in my view.

4 And, again, I have to tell clients
5 plenty of times "no." The way we operate
6 and our lawyers' relationship that we love
7 doesn't permit me to act like a -- getting
8 obstructionist about things. And that's
9 what they're doing.

10 So I cannot imagine that there is any
11 deep mystery about these economic damages.
12 So they are proceeding at their peril, and
13 you let them know that.

14 MS. FLYNN: I understand, Your Honor.

15 THE COURT: All right.

16 MS. FLYNN: Our position would just be
17 that AII is entitled to have the plaintiff
18 demonstrate the damages --

19 THE COURT: AII's position is not
20 dissimilar from J&J's position. Very same
21 position. That has nothing to do with AII,
22 and I don't want to hear their names
23 brought into it one moment that has to do
24 with what Perry's economic damages are.
25 So, ponder that.

1 demonstrate that we surpassed and exceeded
2 the Industry Standard J-41?

3 Your Honor, there is nothing in this
4 transcript and nothing I asked of Dr. Haber
5 about any test results or negative results
6 of Johnson & Johnson testing. This did not
7 trigger the spoliation order.

8 THE COURT: Well, here's my reaction
9 to that: There has already been
10 information that's been put in front of the
11 jury about Johnson & Johnson testing,
12 including no detection or no asbestos.
13 They've already heard in other testimony
14 that's already been offered to them.

15 MS. BUENO: Nothing about Johnson &
16 Johnson. Just FDA, Your Honor.

17 THE COURT: All right. Well, I
18 disagree. That's not my memory of it. But
19 the issue of them projecting no detect to
20 the FDA has already been touched upon in
21 front of this jury. No motion to strike it
22 or anything else.

23 I think I said at some point yesterday
24 that the door was opening on this. And I
25 think the door has been opened, not just on

1 Haber, but on other things that have been
2 done that's put before the jury.

3 I know your whole mantra is bottle,
4 air and dose. That is an attempt to avoid
5 focusing on this whole issue of testing and
6 whether J&J concealed its knowledge of
7 asbestos in its product.

8 The stage has already been set for
9 that here. And so if that -- that's not
10 going to influence me at all about
11 spoliation. The concept of my spoliation
12 order exempted from any projection to the
13 jury by anybody of the claim that Johnson &
14 Johnson concealed information in that
15 internally about its product is not
16 something that I intended by that order at
17 all.

18 So to the extent that is something you
19 think is intended by it, I did not intend
20 that, and that is not what I will do.

21 This issue has already been outlined
22 for the jury in opening statements. It's
23 already been alluded to many different
24 times in bits and pieces of evidence about
25 what Johnson & Johnson knew, what its

1 MS. McVEY: Correct.

2 THE COURT: It's not -- and things
3 that you said should not be considered in
4 deciding whether the door is opened include
5 the Hopkins' deposition. So I get that.

6 MS. McVEY: Okay. So we believe it's
7 open anyway, but I did want to say we don't
8 believe it's open because of this Hopkins
9 deposition.

10 THE COURT: All right. I understand
11 that.

12 All right. What else?

13 MS. BUENO: Your Honor, I have to
14 state that during the break, when we had a
15 brief moment to work on the video that
16 we've already discussed with Your Honor,
17 there were some statements made that I
18 think I need to make Your Honor aware of
19 and I definitely want on the record.

20 Mr. Adams said to me that I am
21 unethical and that he was going to report
22 me to the state bar if it's the last thing
23 he did. He called us criminals. He called
24 my partner Mr. Cowan a criminal who works
25 for a criminal organization hiring criminal

1 lawyers.

2 My partner, Tara Blake, who is in the
3 courtroom who Your Honor hasn't even heard
4 from, who is here to assist with documents
5 today, he said to her, "You are a criminal,
6 unethical, and we will do to you worse than
7 what we did in Lee." And as Your Honor
8 knows, Lee was the last trial with
9 Johnson & Johnson.

10 I want to make Your Honor aware of
11 this because I take this very seriously to
12 have officers of the court making these
13 kind of comments and allegations when this
14 team has done nothing but be professional
15 at this trial.

16 THE COURT: Well, now, wait a minute.
17 I'm not going to -- I'm not going to get
18 into that. I will not get into that. I'm
19 not going to do it on the basis of "Hey,
20 have you been unprofessional?" and we have
21 to go tit for tat. I don't want either
22 side to do that.

23 Now, I've fussed awfully hard about
24 some of the unprofessional information that
25 was already admitted or said to me, and I

1 A. When you -- you use the word
2 "vehemently," I don't think that's a word that I
3 would use. I would say, I don't believe Johnson's
4 Baby Powder caused his mesothelioma based upon all
5 the review of the company documents that I've
6 done, exposure assessments that have been done and
7 my understanding of the scientific data.

8 So I would say, based upon scientific
9 grounds, that is why I would say I don't believe
10 Johnson's Baby Powder caused his mesothelioma.

11 Q. And because of that, Johnson & Johnson
12 hires experts in these cases to come defend the
13 company, correct?

14 A. Yes. My understanding is plaintiffs
15 hire experts, and company [sic] hires experts,
16 and that's my understanding of how these cases go.

17 Q. Do you know who these people are?

18 A. I -- I've met -- I've met some of
19 these people. I don't -- I don't know all of the
20 people, no.

21 Q. You know that -- did you know that
22 these are the experts that Johnson & Johnson hired
23 in this case?

24 A. I -- I haven't asked or reviewed who
25 were the experts in the case.

1 Q. Before you came and told the jury that
2 Johnson & Johnson had nothing to do with Michael
3 Perry's cancer, did you even check and see which
4 experts they hired in the case?

5 A. I -- I didn't check to see. As a
6 medical toxicologist, I've looked at the company
7 data, I've looked at the scientific data, but I
8 didn't ask our counsel about who was coming,
9 potentially, or involved in this case, no.

10 Q. Did you review any of the reports each
11 of the six experts hired by Johnson & Johnson have
12 prepared in this case?

13 A. I -- I didn't specifically -- I know
14 I've seen a few reports. I didn't review all the
15 reports, no.

16 Q. Did you review any of the depositions
17 each of the six experts hired by Johnson & Johnson
18 gave in this case?

19 A. I -- I did not review the depositions,
20 no.

21 Q. But you understand that within this
22 case, experts were hired, paid; they prepared
23 reports, and they gave depositions. Fair?

24 A. Again, I don't know who gave specific
25 depositions, but --

1 THE COURT: Just answer the question,
2 Dr. Kuffner.

3 THE WITNESS: I would generally agree.
4 People -- experts gave depositions. I
5 don't know who did.

6 BY MR. ADAMS:

7 Q. And then there was a tissue digestion
8 done, and we looked inside Michael Perry's lungs,
9 right?

10 A. Yes. I believe it was Dr. Longo who
11 did the tissue digestion.

12 Q. Do you know if any of the six experts
13 are still going to come defend Johnson & Johnson?

14 A. That's not something that I
15 specifically know.

16 Q. Do you know if even one of them is
17 going to come?

18 A. I've concerned myself with myself
19 being here. I don't know when it comes to other
20 people who would be coming.

21 Q. One of the things I think we can agree
22 on probably is that Johnson & Johnson tested its
23 baby powder thousands of times for asbestos,
24 right?

25 A. I would agree about that, yes.

1 Q. And as part of that assessment, did
2 you do what's called a health hazard evaluation to
3 see if that bottle from 2019, that lot that
4 had .00002 percent, did you do an evaluation to
5 see if that would be a health hazard?

6 A. Yes.

7 MS. BUENO: I'm marking as
8 Exhibit 23 -- DX23 that evaluation. And
9 I'll seek to offer this into evidence.

10 MR. ADAMS: Your Honor, this looks
11 like some kind of expert report from
12 Dr. Kuffner, but he was never designated as
13 an expert in this case. So we would object
14 on that basis.

15 MS. BUENO: Your Honor, this is a J&J
16 document that was done as part of the
17 voluntary recall, and his signature is
18 affixed to the last page. He was part --

19 THE COURT: All right. Just let me
20 look at it for a sec. You're saying this
21 is part of a voluntary recall?

22 MS. BUENO: This is what we were just
23 talking about, Your Honor.

24 THE COURT: Yeah, but you told -- you
25 said it wasn't a recall; it was just a

1 decision that you spent a -- a lot of time
2 spent; it wasn't a recall at all; it was a
3 commercial decision to not sell it in the
4 United States. Now you're calling it a
5 recall?

6 MS. BUENO: I'm sorry. I backtracked.
7 This is from the 2019 voluntary recall, the
8 one lot we discussed --

9 THE COURT: Right.

10 MS. BUENO: -- not --

11 THE COURT: I mean, what --

12 MS. BUENO: -- not the decision to --

13 THE COURT: -- what you -- she just
14 finished asking you a bunch of questions
15 about this. And the projection was: It
16 didn't come out of the medical department.
17 It came out of the commercial department.
18 It was a commercial decision to quit
19 selling it in the United States. That's
20 not a recall. You said that.

21 MS. BUENO: Oh, yes, Your Honor.
22 And -- and I'm sorry I -- I messed up the
23 timeline here. If -- if I confused you, I
24 probably confused the jury.

25 THE COURT: I'm not talking about the

1 timeline --

2 MS. BUENO: No, this is --

3 THE COURT: I'm talking about --

4 MS. BUENO: This was months before the
5 decision to stop selling Johnson's Baby
6 Powder. This is a document, October 18th
7 of 2019, which is the day that
8 Dr. Kuffner's team decided to do a
9 voluntary recall of that one lot.

10 MS. McVEY: Your Honor, can we
11 approach just briefly? This is the subject
12 of a motion in limine that I think we need
13 to discuss just for a moment.

14 THE COURT: That -- that's what's got
15 me confused a little bit.

16 You can rest a minute, ladies and
17 gentleman. Just relax.

18 (Bench conference.)

19 MS. McVEY: Your Honor, this is
20 essentially an expert report that he's
21 going to come in and testify this is a
22 report --

23 THE COURT: Uh-huh.

24 MS. McVEY: -- that he has signed. We
25 had a whole conversation about he's not to

1 give expert opinions.

2 THE COURT: Yeah. That's why I'm
3 trying to sort this out.

4 MS. McVEY: This would be inadmissible
5 under any scenario, but certainly if he's
6 going to testify --

7 THE COURT: And they've got their case
8 coming on where they may have some expert
9 that they can present it.

10 MS. MCVEY: That's right.

11 THE COURT: But it's not going to be
12 through him.

13 MS. McVEY: That's right.

14 THE COURT: Do you get what I'm
15 saying?

16 MS. BUENO: Yeah, but, Your Honor,
17 this is the --

18 THE COURT: I don't care whether he
19 authored it or not. He -- this thing is an
20 expert opinion. Y'all have already agreed
21 he isn't going to give expert opinions.

22 MS. BUENO: This is -- we are not
23 offering it for an expert opinion.

24 THE COURT: Well --

25 MS. BUENO: We're offering it for what

1 Johnson & Johnson stated --

2 THE COURT: Well, you've already got
3 into evidence that it was recalled. You've
4 got a document in there about that. That's
5 plenty to establish that fact. This is an
6 attempt to go into more than that and put a
7 report in evidence.

8 He's not to testify about expert
9 witness things; therefore, I'm going to
10 deny allowing this exhibit in through
11 Kuffner at this time, and instruct -- don't
12 ask him anything about expert testimony.
13 I'll put it on the record right now.

14 MS. McVEY: Okay. Thank you.

15 (End of bench conference.)

16 THE COURT: Ladies and gentlemen, let
17 me put on the record this: The exhibit
18 that Ms. Bueno had asked Dr. Kuffner about
19 is an expert opinion. You may recall that
20 experts get qualified in a particular
21 subject. If they're qualified, then they
22 can express an opinion.

23 Dr. Kuffner is the corporate
24 representative. He can't express some
25 expert opinion. You can tell you what

1 happened. All right. He's already told
2 you that they withdrew from the market or
3 recalled -- I don't know exactly how they
4 determined it -- one lot consisting of many
5 cases of a particular talc that had been
6 tested. They withdrew it from the market
7 on October the 19th, 1994, I believe it
8 was.

9 This is an expert report about that.
10 It has already been agreed that he will not
11 testify about expert matters. They're
12 going into their case at some point next
13 week, and they're going to present experts,
14 and if there's any expert opinion about
15 this thing, it's just -- they'll choose to
16 ask for admission, we'll address that at
17 this time. So I have denied the admission
18 of this report -- expert opinion, whatever
19 it is at this time. And instruct Ms. Bueno
20 not to ask him about the opinion or his
21 opinion about this memo.

22 BY MS. BUENO:

23 Q. We're going to move on, and,
24 Dr. Kuffner, next week if -- since we're running
25 out of time --

1 finding of a winchite fiber or particle in any
2 bottle of Johnson's Baby Powder?

3 A. No.

4 Q. Are you familiar with where winchite
5 comes from?

6 A. Yes.

7 Q. Where is that?

8 A. It certainly doesn't come from the
9 Italian mine that we used. It certainly doesn't
10 come from the Vermont mine that we used. It does
11 not come from the Chinese mine that we used. But
12 it can come from other sources.

13 Q. And the jury has heard that there was
14 an expert named Dr. Sanchez who counsel --

15 THE COURT: That's why -- what I'm
16 going to do is strike any testimony by him
17 about the geological arguments, winchite,
18 or whether it -- whether it occurs in
19 various mines. He's not being offered for
20 this. You got an expert, Mr. Sanchez --
21 Dr. Sanchez that's what he -- he is a
22 geologist and he will talk about these
23 matters.

24 But I direct you to move on, not ask
25 him any further questions about the

1 presence of winchite or anything. And
2 looking at documents in the records of J&J
3 is not going to be enough to express some
4 expert opinion about the presence or
5 absence of a particular mineral in a
6 particular mine. That will come up when
7 you have your geologist. So move on.

8 MS. BUENO: Understood, Your Honor.
9 And I'm not asking an expert opinion. As a
10 corporate representative --

11 THE COURT: I'm not going to allow you
12 to get around a ruling by saying, "As a
13 corporate representative are you aware of
14 anything in the records that pertains it
15 winchite." That's an attempt to discuss
16 the presence of that mineral in these
17 mines. I have ruled that he can't testify
18 about that. So please move on to the next
19 subject.

20 BY MS. BUENO:

21 Q. You were shown some documents earlier
22 and there was a discussion about something called
23 "industrial talc." Can you briefly tell us
24 whether or not Windsor Mines in Vermont used both
25 industrial and cosmetic talc or manufactured both

1 CERTIFICATE OF REPORTER

2 I, Cindy A. Hayden, Registered Merit
3 Reporter and Notary Public for the State of South
4 Carolina at Large, do hereby certify:

5 That the foregoing proceeding was taken
6 before me on the date and at the time and location
7 stated on Page 1 of this transcript; that the
8 testimony and all objections made at the time of
9 the examination were recorded stenographically by
me and were thereafter transcribed; that the
foregoing proceedings as typed is a true, accurate
and complete record of the testimony and of all
objections made at the time of the examination to
the best of my ability.

10 I further certify that I am neither
11 related to nor counsel for any party to the cause
12 pending or interested in the events thereof.
13 Witness my hand, this 10th of August, 2024.

14
15 _____
16 Cindy A. Hayden,
17 Registered Merit Reporter
18 Notary Public
19 State of South Carolina at Large
20 My Commission expires:
21 July 27, 2030
22
23
24
25

Exhibit E

HHE _ FDA Notification of aberrant test results for Johnsons Baby Powder 22oz, Lot 22318R

**Office of Consumer Medical Safety
Johnson & Johnson Family of Consumer Companies**

Medical Safety Evaluation of a Significant Quality Issue

FDA Reports Chrysotile Detected in Johnson's Baby Powder

This document is a:

- ☒ Health Hazard Evaluation (HHE) of Product Released for Use in Market or Research
☐ Health Risk Assessment (HRA) of Product Not Released and within Company Control

Version: v1.0
Date: 18 October 2019
Prepared by: Office of Consumer Medical Safety
Document Name: **FDA Reports Chrysotile Detected in Johnson's Baby Powder**
Location: United States

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TV-eFRM-03815v2.0

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**DEFENDANT'S
EXHIBIT
DX-8929**

JNJ TALC001282155

DX-8929 Page 1 of 12

RoA_09895

DX23.1

Product Name	Johnson & Johnson Baby Powder
Panel Code	NA
Product Code	381370030140
Model	FORMULA 9883-052
Lot/Serial Numbers	Lot #22318RB
Marketing Status	In market

1. PROBLEM, DEFINITION AND ANALYSIS

1.1. Summary of the Problem

On October 16, 2019 the company was notified by the US Food and Drug Administration (FDA) that testing of what they believe to be Johnson's Baby Powder (JBP) revealed the presence of chrysotile by weight no greater than 0.00002%.

For the last 16 years Johnson & Johnson (J&J) has sourced the cosmetic talc used in US-based products from the same mine. This talc has been rigorously tested by independent testing labs and has not tested positive for asbestos. Johnson & Johnson has put in place a rigorous testing standard to help ensure its cosmetic talc is safe. Years of testing, including testing by the US FDA in 2009-2010 and as recently as last month, have confirmed the safety of the current talc source.

J&J has commenced an investigation to better understand the accuracy and implications of the FDA's findings.

On October 17, 2019, J&J received a 55-page report detailing the findings of chrysotile by AMA Analytical Services, Inc (AMA). Based on an initial review of the report, the company verbally communicated to FDA that three main areas need to be investigated before the validity of AMA's test results can be confirmed. Those include information about:

- The source of the sample (As yet, we do not have any information from FDA about the source of the product / seller of the product. We cannot, at this time, confirm the authenticity of the product as Johnson's Baby Powder until we have more information);
- Sample preparation at multiple stages of the process, including steps taken to ensure product integrity both before and after the sample was sent to AMA; and
- AMA's process /handling, including details about how the controls were prepared

It is important to note that due to the widespread use of chrysotile for industrial purposes in the US for decades such as in building materials, insulation, and brake shoes for cars, a finding

of chrysotile in a test sample raises serious concerns of a false positive result due to environmental contamination. Any open-air or uncontrolled exposure could result in contamination. For example, the transfer of talc from the original container to lab sample bottles could result in a contaminated sample. Based on a preliminary review of the report, the company has questions about how the samples were prepared before being sent to AMA.

The company's investigation will involve testing and analyzing retain samples for the lot at issue. The company is also seeking, from FDA, access to the samples tested by AMA on behalf of FDA to conduct testing at another independent, qualified laboratory with expertise in testing talc.

Based upon the company's preliminary review of the report numerous questions have been raised which are critical to an understanding of the situation and require further information and investigation.

The company is seeking answers from FDA to many questions including, but not limited to:

- (1) How and where the product tested was acquired, including the vendor that sold the product and if the product was purchased on-line;
- (2) Where the bottles and closures used to hold the test samples were sourced, whether the sample was taken from a bottle that was sealed and whether the sample was taken under a controlled environment;
- (3) The chain of custody once the product was acquired, including control of the environment during opening of the manufacturer's original packaging, extracting the sample and transferring the sample in the sample bottle sent to AMA;
- (4) How the sample was divided and prepared at AMA;
- (5) Why FDA initially requested an additional sample (a 4th sample) be tested and then cancelled the request; and
- (6) Information about the sample itself, including how the Agency assured its authenticity as Johnson's Baby Powder.

There could have been contamination at AMA during the testing. There are several potential sources for chrysotile contamination in a talc analysis in a commercial lab including ones specific to the AMA analysis that have not been ruled out. Specifically, AMA's report indicates that the analysts prepared a reference sample, a talc powder intentionally spiked with 10%

HHE _ FDA Notification of aberrant test results for Johnsons Baby Powder 22oz, Lot 22318R

chrysotile, alongside the samples of the products at issue. Moreover, the lab that conducted this analysis holds itself out as a specialty laboratory for asbestos analysis where routine asbestos analysis of products can occur on any given day also on the same instruments and equipment. Thus, it is to be expected that trace amounts of chrysotile, the most widely used type of asbestos in asbestos-containing materials, can be present in the background of the lab at any given time. For example, the talc sample can come into contact with a contamination when weighing the samples on a scale, treating with assorted reagents, filtering, and preparing slides. The shared instruments used for analysis can be sources of contamination as well.

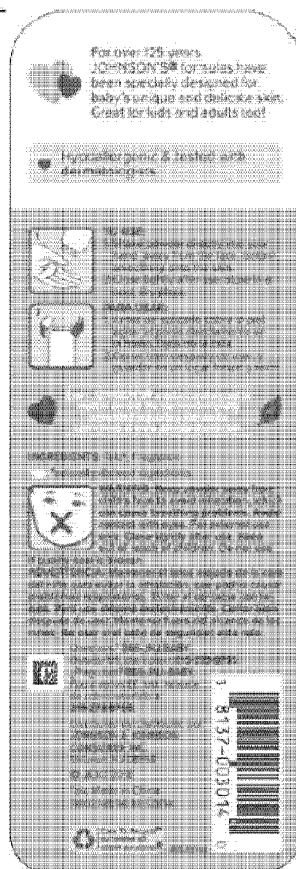
The company is in active discussions with FDA regarding the testing and to gather additional information and is also conducting its own investigation.

1.2. Product Information

Johnson's Baby Powder contains talc and fragrance. JBP adsorbs moisture to keep the skin dry and fresh, and provides anti-chaffing effects. In the US JBP is classified as a cosmetic. It is intended to be use by babies and adults. Product label including instructions for use and warning and precautions is presented in figure 1.

HHE _ FDA Notification of aberrant test results for Johnsons Baby Powder 22oz, Lot 22318R

Figure 1: Johnson's Baby Powder label



1.3. Investigation (INV) / Escalation (ESC)

All raw material, incoming inspection and finished good inspection data met specifications.^{1 2}
An investigation was opened (INV # 106924)

Root cause of the problem (if known)

The company's investigation is ongoing.

¹ Raw Material Talc Analytical testing 29 May 2018

² Talc Powder material report Part 1 and 2 May and June 2018

Company's estimate of number of units affected**Table 1. Number of bottles of JBP from Lot #22318RB in distribution and under J&J control**

Region/Country	in distribution (units)	under J&J control (units)	Total
USA	37,998	0	37,998

- *How many units will reach the consumer level, and will the likelihood of harm increase with time? Consider the risk vs. exposure link and if progressive degradation occurs.*

The numbers of units distributed to market are presented in the tables above.

It is not expected that appropriate use of this lot of JBP will result in adverse health consequences.

(see Section 2. Health Risks and Medical Safety Assessment).

If product failure occurs, does the user easily recognize it?

If the product did contain chrysotile the user would likely not be able to recognize it.

Factors that may contribute to product risk (i.e., product design, manufacturing problems, or user error).

None identified. (see Section 2. Health Risks and Medical Safety Assessment).

Factors that might mitigate risk (i.e., product labeling).

Johnson's Baby Powder is intended to be used externally. Product label advice to not use on broken skin. Avoid contact with eyes as well as to keep the powder away from child's face to avoid inhalation. In addition, the label instructs users to keep the product out of reach of children and avoid use if quality seal is broken.

Does the health consequence have significant public health impact beyond users?

No, it is not anticipated that appropriate use of the product would result in adverse health consequences for either users or others.

2. MEDICAL SAFETY ASSESSMENT

Product Quality Complaints

A search was conducted in PQMS for complaints received from August 1, 2018 through October 17, 2019 for all product quality complaints for the product J&J BABY POWDER 22OZ USA 381370030140 8137003014USA 8137003014USA with following results:

- No product quality complaints (other than the one documented due to FDA contact) for lot number 22318RB / UPC 381370030140 were identified.
- 6 product quality complaints were identified where no lot number was provided (see attachment for detailed complaint information). A review of the complaint content for these 6 complaints found no similarities to the issue reported against lot # 2231RB.

The shelf life expiration date of this lot is July 10, 2021.

Adverse Event Review

A search³ was conducted on Company global safety database from 01-August-2018 through 17-Oct-2019 for closed cases reporting J&J BABY POWDER 22OZ USA 381370030140 8137003014USA as suspect, interacting or concomitant product.

No cases were identified reporting lot 22318R B.

Seven (n=7) cases (1 serious and 6 non serious) out of a total of 17 cases did not provide lot number. These cases were selected for further review in a conservative approach.

Serious case #150013703948 is a spontaneous non medically confirm report received on 30-Jul-2019 referring to a woman of unspecified age who died of ovarian cancer on unspecified date. No further information was provided.

Remaining non serious cases (n=6) referred to mild and transient application site reactions (n=4) and 2 off label uses (used to shave and fix makeup) without AEs.

Post marketing search strategy was focused on Johnson's BABY POWDER 22OZ USA 381370030140 for the time period since this batch was manufactured as is the one in scope of this assessment This review did not include Johnsons Baby powder (not further specified)

³ OCMS SSP search ticket: 2019-1240

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reports. Within the reports of unspecified Johnson's Baby powder there are a numerous cases, mostly from legal sources, referring to ovarian cancer and mesothelioma.

Table 1. Distribution of Events by SOC-PT and Seriousness for Johnson's Baby Powder 22oz USA with Blank/Unknown Lot number (n=15)

System Organ Class / Preferred Term	Event Count ^(a)		
	Serious	Non-serious	Total
General Disorders and Administration Site Conditions	0	12	12
Application site discomfort	0	1	1
Application site erythema	0	1	1
Application site exfoliation	0	1	1
Application site odour	0	1	1
Application site pain	0	3	3
Application site papules	0	1	1
Application site rash	0	2	2
Application site reaction	0	1	1
Therapeutic response unexpected	0	1	1
Injury, Poisoning and Procedural Complications	0	2	2
Off label use	0	2	2
Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)	1	0	1
Ovarian cancer	1	0	1
Total	1	14	15

Coverage period: 01AUG2018 - 17OCT2019

(a) Event Count = count of unique combination of AER, Product, PT.

3. HEALTH RISKS AND MEDICAL SAFETY EVALUATION

The following assessment is based on currently available information. Conclusions may change if additional information becomes available in the future.

Post-marketing Safety Review

Review of post-marketing safety data and quality data did not identify any case reported in relation to lot 22318R B.

No trend of safety concern has been identified through the review of cases of unspecified lot. Only one serious non medically confirmed case was received referring to a consumer who died from ovarian cancer on an unknown date and who have used the product. Lack of essential information regarding consumer's medical history, date of diagnosis and usage period prevents a meaningful assessment. It is unlikely though that the referred case pertains to the lot under investigation.

Segment of the Population that is Most at Risk?

Product is intended to be used by babies and adults. Adverse health consequences are unlikely with appropriate use of the product. No specifically susceptible population has been identified.

Assessment of the Likelihood and Consequences (Immediate and Long-Range) of Occurrence of the Hazard**Exposure Assessment**

The FDA report states that the levels of chrysotile by weight are no greater than 0.00002%. The Environmental Protection Agency (EPA) and Occupational Safety and Health Administration (OSHA) define “asbestos-containing materials” as material containing 1% asbestos or higher. The FDA said in 1986 that a hypothetical worst-case scenario of 0.1% asbestos content in talc based body powders would be lower than the risk from asbestos exposure from background and would not present a health hazard.⁴

J’s Baby inhalation estimates

Johnson & Johnson (Russell et al., 1979⁵) published an airborne exposure modeling study for talc by consumers (adults and caregivers on mannequin babies) to determine the airborne exposure from the use of talc verse occupational exposure limits. Using the TEM values from FDA, Toxicology has generated calculations of the hypothetical exposure to the consumer from the reported 0.00002% asbestos in a consumer use of talc (adult and baby) vs the allowable occupational exposure to asbestos from talc. Both the Time Weighted Average (8 hr) work day and a thirty-minute Excursion (spike, acute exposure) were compared to the consumer use estimations.

In each case, the allowable occupational exposures were *at least* 2 million times higher than the potential consumer exposure to the reported 0.00002% asbestos fiber (TEM; FDA).

Therefore, the consumer exposure to the reported asbestos, if actually present, results in a *de minimus* risk to the consumer.

⁴ FDA response to Citizen’s petition Re: Docket lb. 83P-0404 July 11th, 1986

⁵ RS Russell *et al.* The determination of respirable particles in talcum powder. *Fd. Cosmet. Toxicol.* vol 17, pp 117-122 (1979)

Post marketing and quality data review:

Post marketing and quality data review did not identify any complaint received with the referred lot. No cases of accidental inhalation or respiratory disorders were identified with the unspecified lots reviewed in a conservative approach.

SHIPMENT DATA AND REPORTING RATE (RR)

A total of 35,346. units of Lot #22318RB were shipped in US.

No cases were identified with for lot #22318RB. In a conservative approach retrieved cases within retrieved period were considered potentially in scope. Reporting rate of Adverse events was RARE as per CIOMS Working Group.

Product	Case Count	Shipment units	Reporting Rate ^(a)
Johnsons Baby Powder 22oz USA - Blank/Unknown Lot Number	7*	35,346	198.042

Coverage period: 01AUG2018 - 30SEP2019

* Cases received during the period with unknown lot number – No cases were identified for Lot #22318RB

(a) Reporting Rate = (Case Count/Positive Sales)*1,000,000.

Reporting frequencies are classified according to the CIOMS Working Group⁶.

Very common	$\geq 1/10$	($\geq 100,000$ per million units sold)
Common	$\geq 1/100$ and $< 1/10$	(>10,000 and $< 100,000$ per million units)
Uncommon	$\geq 1/1000$ and $< 1/100$	($\geq 1,000$ and $< 10,000$ per million units)
Rare	$\geq 1/10000$ and $< 1/1000$	(≥ 100 and $< 1,000$ per million units sold)
Very Rare	$< 1/10000$	(< 100 per million units sold)

4. CONCLUSION

At this time it is unclear if JBP Lot #22318RB contains chrysotile.

Given the consistent sourcing and rigorous testing that has been performed on the talc used within JBP, the many unknowns related to the FDA investigation and report, J&J's current belief that the finding of chrysotile is likely the result of contamination and the levels of chrysotile by weight are

⁶ Guidelines for Preparing Core Clinical Safety Information on Drugs - Report of CIOMS Working Group III. Geneva, WHO, 1995 (Chapter 5, Good Safety Information Practices).

HHE _ FDA Notification of aberrant test results for Johnsons Baby Powder 22oz, Lot 22318R

no greater than 0.00002%, it is unlikely that use of the product would result in adverse health consequences.

SIGNATURES

AUTHOR

I have reviewed this report and confirm that, to the best of my knowledge, it accurately describes the data available to date:

ADRIANA POTOCKI

Digitally signed by ADRIANA POTOCKI
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0.9.2342.19200300.100.1.1=1040209, cn=ADRIANA POTOCKI
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Date: 2019.10.18 20:17:24 -04'00'

Adriana Potocki, MD
Global Medical Safety Officer Skin Health
Office of Consumer Medical Safety

Date

APPROVER

I have read this report and, based on the data as presented, agree with the conclusions drawn:

**Kenneth
Henderson**

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0.9.2342.19200300.100.1.1=172724, cn=Kenneth Henderson
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Edwin KUFFNER JR

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Edwin Kuffner, MD
Chief Medical Officer Consumer Inc
Office of Consumer Medical Safety

Date

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Annex 1: Framework for Assessment of Severity and Probability of the Adverse Health Consequences

Assess the Probability that Use of, or Exposure to, Product under Recall evaluation will Cause Adverse Health Consequences				
	<u>Serious Adverse Health Consequences</u>		<u>Medically Reversible or Transient Adverse Health Consequences</u>	
	Overall Population Using Device	Population at Greatest Risk	Overall Population Using Device	Population at Greatest Risk
Very Common ¹ (Every Time ²)	☐	☐	☐	☐
Common ¹ (Frequent)	☐	☐	☐	☐
Uncommon ¹ (Infrequent)	☐	☐	☐	☐
Rare ¹ (Reasonable Probability that Use will Cause ²)	☐	☐	☐	☐
Very Rare ¹	☐	☐	☐	☐
Remote (Remote Probability that Use will Cause ²)	☐	☐	☐	☐
Improbable (Not Likely that Use will Cause Any Adverse Events ²)	☒	☒	☒	☒
¹ CIOMS Working Group III ² FDA CDRH HHE/HRA Form				