EFiled: Jun 10 2024 03:11PM EDT
Transaction ID 73354083
Case No. N22C-09-101 ZAN

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

In re: Zantac (Ranitidine) Litigation	)	GENERAL ZANTAC LITIGATION
	)	CIVIL ACTION NO.:
	)	N22C-09-101 ZAN

APPLICATION FOR INTERLOCUTORY REVIEW OF THE COURT'S DENIAL OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' GENERAL-CAUSATION EXPERTS

INTRODUCTION

This case raises substantial issues of material importance warranting an interlocutory appeal, before the parties and Delaware courts expend their resources adjudicating what is likely the single largest litigation in Delaware history, with over 73,000 individual claims, 99.6% of which are brought by non-Delaware plaintiffs. In denying Defendants' motion to exclude Plaintiffs' experts' opinions that ranitidine—the active ingredient in the antacid medication Zantac—can cause ten cancers because it contains the probable human carcinogen *N*-nitrosodimethylamine (NDMA), the Court ruled contrary to the federal court overseeing the *Zantac* multi-district litigation (MDL), which excluded nearly identical opinions under the same legal standard. The Court held that the Delaware *Daubert* standard differs, in three critical respects, from the federal standard applied by the MDL court.

- *First*, the Court held that Plaintiffs' experts' general-causation analysis need not concentrate on epidemiological studies regarding the product at issue (which consists of sixteen studies, none of which conclude the product causes cancer), but could instead extrapolate from non-product studies of the probable carcinogen that Plaintiffs allege the product contains. Op. at 18–23.

- *Second*, the Court held that Plaintiffs' experts need not identify a "threshold dose" at which the product or the alleged carcinogen can cause cancer. *Id*. at 29–32.

- *Third*, adopting as Delaware law a Ninth Circuit admonition that *Daubert* should be applied with "a liberal thrust favoring admission," the Court held that critiques of the experts' methodologies went to weight, not admissibility. *Id*. at 13.

The Court's ruling conflicts with prior Delaware *Daubert* decisions, which are consistent with the federal consensus on these issues. The Opinion would mark a major shift in Delaware's *Daubert* jurisprudence, permitting general-causation experts to reach a jury so long as they can claim a product contains a toxic substance in some undefined amount, even when the experts' methods are at odds with those generally accepted by scientists and regulators. *See, e.g.*, *Scottoline v. Women First, LLC*, 2023 WL 2325701, at *5 (Del. Super. Ct. March 1, 2023) (LeGrow, J.) (excluding opinion that could not "point to any published medical studies or literature stating that [the injury suffered by the plaintiff] causes [autism].").

If the Court is correct that Delaware courts should apply a more permissive version of *Daubert*, then Delaware could quickly become one of the country's go-to destinations for mass-tort litigation, especially given the number of companies that are incorporated in Delaware and thus subject to general jurisdiction here. The national legal press has already raised the prospect that the Opinion will "make Delaware a mass torts magnet."[1] The resulting influx of cases could have significant consequences for the efficient administration of justice in Delaware, for both

[1] Alison Frankel, "Will Zantac Ruling Make Delaware a Mass Torts Magnet?" *Reuters* (June 3, 2024). Plaintiffs' counsel stated on the record that the ruling would influence their choice of forum going forward: "'It's absolutely something that plaintiffs' lawyers must consider,' Wisner said. 'Forum selection is the most important thing I have to do at the beginning of a case.'" *Id*.

Delaware-domiciled companies and Delaware residents. Given the legal and practical implications of the Opinion, the Supreme Court should have the opportunity to clarify the Delaware *Daubert* standard now, giving certainty and predictability to the parties in likely the largest litigation in Delaware history and to companies deciding where to locate, rather than waiting for piecemeal appeals at the conclusion of a lengthy, multi-year bellwether process.

The procedural history of this case illustrates the dramatic consequences of adopting a more lenient version of Rule 702 and *Daubert* in Delaware. The overwhelming majority of Plaintiffs—over 58,000, or about 79%, of the 73,474 in the litigation—originally registered their claims with the MDL court, but fled to Delaware when the ***MDL plaintiffs' own experts*** concluded that the "evidence was not sufficient to support an opinion that use of ranitidine can cause breast, prostate, kidney, lung, or colorectal cancer."[2] Taking advantage of the fact that seven of the nine Defendants in this litigation are incorporated in Delaware, those Plaintiffs sought to avoid certain dismissal in the MDL because of the plaintiffs' experts' concessions and consolidated their claims here by filing dozens of complaints, each naming hundreds of plaintiffs. If the Court's ruling stands, tens of thousands of cases

[2] Expert Report of Anne McTiernan, No. 20-md-2924, *In re Zantac (Ranitidine) Prods. Liab. Litig.* (S.D. Fla. Dec. 30, 2022), ECF 6171-9, at 16.

will move forward with general-causation evidence that even the plaintiffs' experts in the MDL opined did not support a claim of causation.

Immediate appeal is particularly appropriate because it offers the most efficient path, by far, to resolving this massive litigation, however the Supreme Court rules. The principal reasons courts are generally skeptical of interlocutory appeals—the desire to avoid unnecessary delay and to preserve judicial and party resources—counsel in *favor* of immediate review here. An interlocutory appeal of the *Daubert* ruling will hasten, not delay, resolution of the litigation. Interlocutory review will allow the Supreme Court to resolve potentially dispositive issues now, across all cases, instead of waiting years for piecemeal appeals after individual trials. If the Supreme Court reverses, then its opinion could resolve Plaintiffs' claims, whether on appeal or after remand, saving the parties and Delaware courts the enormous costs associated with managing and trying such a large number of cases. And if the Supreme Court affirms, no time will be lost and the ordinary procession of the litigation will not be disrupted, because the parties will continue case-specific discovery in the bellwether cases while the appeal is pending.

There is no benefit to postponing review of the *Daubert* ruling. Delaying review would not bring the bellwether cases to conclusion any faster, and it would deprive the parties of the legal certainty necessary for bellwether proceedings to be informative. The Court should certify its order for an immediate appeal, rather than

requiring the parties to wait until the conclusion of an indeterminate number of bellwether trials taking place in the shadow of a potential reversal.

BACKGROUND

A. History of Zantac

For nearly four decades, ranitidine was approved by the U.S. Food and Drug Administration ("FDA") and widely used in prescription and over-the-counter ("OTC") forms to treat stomach ulcers, gastroesophageal reflux disease, heartburn, indigestion, and other conditions of the stomach and esophagus. A predecessor company of Defendant GlaxoSmithKline LLC ("GSK") developed ranitidine in the early 1980s, and in 1983, the FDA granted the company's "New Drug Application" (NDA) for ranitidine and approved its sale as a prescription drug under the trade name "Zantac." GSK continued to make prescription Zantac for sale in the United States until 2018. The FDA first approved an OTC version of Zantac in 1995. Four of the Defendants—GSK, Pfizer, Boehringer Ingelheim, and Sanofi—sold OTC Zantac at different points in time. In 1997, after GSK's patent for ranitidine expired, manufacturers of generic drugs began to sell their own ranitidine products.

In 2019, a private online pharmacy called Valisure submitted a citizen petition to the FDA with test results purporting to show that some ranitidine products contained *N*-nitrosodimethylamine (NDMA), which is classified as a "probable" human carcinogen by the EPA and International Agency for Research on Cancer. *In*

re Zantac (Ranitidine) Prods. Liab. Litig., 644 F. Supp. 3d 1075, 1095 (S.D. Fla. 2022). That headline-grabbing result stemmed, however, from badly flawed testing. Valisure's testing conditions *generated* NDMA and did not determine the actual levels of NDMA in real-world ranitidine. *See id*. Valisure found over 3 million nanograms of NDMA in some samples of ranitidine after heating them to ***266 degrees*** Fahrenheit, far beyond the temperature to which ranitidine could ever be exposed outside a laboratory. When Valisure tested ranitidine at 98 degrees, it found no NDMA. In a separate test, Valisure detected 300,000 nanograms of NDMA after allowing samples of ranitidine to react with salt in artificial stomach acid, but Valisure used a near-lethal amount of salt. When Valisure used a more realistic salt concentration, it detected no NDMA. *See id*.

The FDA, noting the obvious flaws in Valisure's testing, conducted its own testing of ranitidine products in response to the citizen petition. The FDA testing found far lower levels of NDMA in ranitidine samples, with many results below its conservative, recommended daily intake of 96 nanograms. *Id*. at 1093. Indeed, if one were to consume that amount of NDMA every day for 70 years, the FDA estimates the risk of cancer would be 1 in 100,000, or 0.001%. *Id*. Even for the ranitidine samples that exceeded the daily limit, the FDA compared the level of NDMA detected to what "you would expect to be exposed to if you ate common foods like grilled or smoked meats" and stated that these "low levels" of NDMA

"would not be expected to lead to an increase in the risk of cancer." *Id*. at 1191. Nonetheless, because the FDA did detect NDMA above its daily limit in some ranitidine samples, out of an abundance of caution, it requested manufacturers voluntarily withdraw ranitidine products from the market in April 2020. *Id*.

After the withdrawal, independent scientists sought to determine whether ranitidine use is associated with an increased risk of cancer. No fewer than ***sixteen*** published and peer-reviewed epidemiological studies have now investigated the question,[3] and ***not one*** has found that ranitidine use causes cancer. That is not just Defendants' interpretation of the studies. The FDA and its equivalent in the European Union have reviewed the epidemiological literature and concluded that it reveals no evidence of a causal relationship between ranitidine use and cancer.

Independent Epidemiology	**Sixteen studies, <u>none</u> of which conclude ranitidine causes cancer**
FDA	**"[N]o consistent signals emerged across studies, and studies with comparison to active controls found <u>no association between ranitidine and overall or specific cancer risk</u>."**
EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH	**"Based on a comprehensive review of epidemiological and post marketing data, it can be concluded that <u>there is no evidence of a causal association between ranitidine therapy and the development of cancer in patients</u>."**

[3] When the parties submitted their *Daubert* briefs to the Court, fifteen studies had concluded there was no evidence ranitidine causes cancer. Since the close of briefing, a sixteenth study has reached the same conclusion.

Id. at 1107, 1191. The FDA also commissioned a controlled human trial that compared the NDMA levels in the urine of participants who had ingested ranitidine with the urine of those who ingested a placebo. That study, later published in the *Journal of the American Medical Association*, concluded that "oral ranitidine (300 mg), compared with placebo, did not significantly increase 24-hour urinary excretion of NDMA when participants consumed noncured-meats or cured-meats diets."[4]

B. The Federal MDL Court Excludes Plaintiffs' Experts' General-Causation Opinions and Enters Summary Judgment for Defendants.

The flawed Valisure test results prompted the filing of tens of thousands of personal-injury lawsuits, ***before*** any epidemiological studies designed to analyze the potential impact of NDMA in ranitidine were published. Cases that were filed in or removed to federal court were eventually consolidated in an MDL before Judge Robin Rosenberg in the United States District Court for the Southern District of Florida in February 2020.

The parties engaged in extensive discovery for two years, while the epidemiological consensus that ranitidine does not cause cancer built. The MDL plaintiffs' lead counsel hired experts to provide general-causation opinions, but the

[4] Florian, et al., *Effect of Oral Ranitidine on Urinary Excretion of N-Nitrosodimethylamine (NDMA): A Randomized Clinical Trial*, JAMA 326(3):240–49 (2021).

experts would only offer opinions that ranitidine use was associated with five cancers: liver, stomach, esophagus, pancreas, and bladder. 644 F. Supp. 3d at 1099. In their reports, the plaintiffs' experts affirmatively opined that the "evidence was *not* sufficient to support an opinion that use of ranitidine can cause breast, prostate, kidney, lung, or colorectal cancer." *See supra*, at 3 n.2. Without an expert to support a significant percentage of their cases, in mid-2022, plaintiffs' attorneys who had filed claims alleging those five cancers in the MDL registry withdrew them and filed in Delaware, where leadership counsel offered a new slate of causation experts.

The MDL plaintiffs' experts supported the general-causation opinions they did offer by extrapolating from studies that analyzed the potential links between cancer and dietary NDMA exposure, or occupational exposure to rubber dust and fumes containing NDMA, rather than focusing on studies directly investigating ranitidine use, which necessarily account for whatever NDMA ranitidine might contain. *Id*. at 1093. In December 2022, the MDL court issued a 341-page *Daubert* opinion excluding under Rule 702 the plaintiffs' experts' general-causation opinions. Three of the MDL court's legal rulings are especially important here.

First, the MDL court held that the general-causation inquiry must focus on the product that the plaintiffs ingested, ranitidine, and not extrapolations from studies about the allegedly harmful component of that product, NDMA. *See id*. at 1104–1106. The court applied federal *Daubert* precedent, including an Eleventh Circuit

decision concerning zinc exposure from the denture adhesive Fixodent, in which the appellate court held "plaintiffs had to show Fixodent—not zinc, generally—could cause the injury at issue." *Id*. at 1106 (citing *Chapman v. Procter & Gamble*, 766 F.3d 1296, 1303, 1303–04 (11th Cir. 2014)); *see id*. at 1217–18 (citing similar cases concerning benzene in gasoline). A focus on NDMA would be illogical, the court noted, because the plaintiffs could not prevail on their claims just by showing that NDMA can cause cancer, but instead "must show that ranitidine consumption can result in sufficient NDMA ingestion to cause their alleged injuries." *Id*. Indeed, "NDMA is a ubiquitous substance found in trace amounts in air, water, and food," and no one would contend that "air, water, vegetables, and many meats cause cancer." *Id*. Ranitidine must be the focus of the general-causation inquiry, not NDMA, because ranitidine is the product that allegedly injured the plaintiffs.

As the MDL court further observed, "[t]he amount of ranitidine in NDMA is uncertain" and "[a] critical, important benefit of the ranitidine epidemiology is that it removes this question from the estimate of cancer risk." *Id*. at 1218. "***Regardless of how much NDMA was in ranitidine products at the time of manufacture, people consumed them***," and no studies have shown that ranitidine consumption—with whatever NDMA exposure that entails—causes cancer. *Id*. With the non-ranitidine dietary and occupational studies, by contrast, experts can only guess at whether the

NDMA exposures in those studies are comparable to the NDMA exposure associated with ranitidine use.

Second, the MDL court held that the plaintiffs "must identify a threshold dose range at which ranitidine can cause cancer." *Id*. at 1109. Again, the court applied Eleventh Circuit precedent, which held that "a plaintiff must demonstrate *the levels of exposure* that are hazardous to human beings generally as well as the plaintiff's actual level of exposure." *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1241 (11th Cir. 2005) (emphasis added). The MDL court noted that the requirement to identify a threshold dose follows naturally from the fact that "[c]ourts universally reject general causation theories based upon the idea that *any* amount of a carcinogen, no matter how small, is actionable." 644 F. Supp. 3d at 1109. If "an actionable exposure threshold dose cannot, as a matter of law, be merely *anything*, that means it must be *something provable*." *Id*.

Third, the MDL court emphasized its gatekeeping obligation to ensure that "speculative and unreliable opinions do not reach the jury." *Id*. at 1102 (quoting *McClain*, 401 F.3d at 1237). To meet that obligation, a court must examine the expert's methodology and exclude his or her opinion when there is "too great an analytical gap between the data and the opinion proffered" or where the opinion "is connected to existing data only by the *ipse dixit* of the expert." *Gen. Elec. v. Joiner*, 522 U.S. 136, 146 (1997). Applying that required scrutiny, the MDL court concluded

that the plaintiffs' experts had "utilized unreliable methodologies" with "a lack of substantiation for analytical leaps" and "a lack of internally consistent, objective, science-based standards for the evenhanded evaluation of data." *Id*. at 1094. The plaintiffs' experts resorted to such unprincipled methodologies to dismiss the large body of epidemiological and experimental evidence regarding ranitidine use in humans (and any NDMA in that real-world use of ranitidine), all of which indicates that ranitidine does not cause cancer and does not produce significant levels of NDMA in the human body.[5] Indeed, as the MDL court observed, "there is no scientist outside this litigation," despite extensive study of the question after the product's voluntary withdrawal, "who concluded ranitidine causes cancer." *Id*. Accordingly, the MDL court concluded that, while it might seem surprising in light of the voluntary withdrawal, its decision to exclude the plaintiffs' experts was in fact "somewhat unremarkable." *Id*.

C. The Court Declines to Exclude Nearly Identical Opinions and Admits Opinions the MDL Experts Rejected.

As noted above, after the MDL plaintiffs' experts conceded that five cancers lacked sufficient evidence of causation, and before the MDL court's *Daubert* ruling,

[5] *See* Masao Iwagami, et al., "Risk of Cancer in Association with Ranitidine and Nizatidine vs. Other H2 Blockers," *Drug Safety* 44:369 (2021) ("One possible explanation of the lack of association in the current study may be that few people were exposed to a high enough level of NDMA to increase the risk of cancer.").

plaintiffs' attorneys withdrew tens of thousands of claims from the MDL registry and filed them in Delaware. At present, ***79 percent*** of the 73,000-plus Plaintiffs here originally registered their claims in the MDL, and ***88 percent*** of Plaintiffs allege breast, colorectal, kidney, lung, or prostate cancers for which the MDL plaintiffs' experts explicitly found no causation evidence. Of the Plaintiffs alleging such cancers, more than 65 percent are represented by attorneys who served in the MDL leadership—meaning Plaintiffs' own counsel acknowledged in separate proceedings that there was inadequate evidence of general causation to support their claims.

In light of the MDL court's opinion, the parties asked the Court to enter an early Case Management Order to focus their initial efforts on *Daubert*. The parties also identified 300 potential bellwether cases, but, because their work has been geared towards the general-causation question, they have not yet conducted significant plaintiff-specific discovery. The Court oversaw fulsome *Daubert* proceedings that involved extensive expert discovery, briefing focused exclusively on the general-causation issue, a three-day hearing, and the submission of post-hearing briefs.

On May 31, 2024, the Court issued its opinion denying all *Daubert* motions, including all of Defendants' challenges to Plaintiffs' general-causation experts. The Opinion began its analysis by stating that "the evidentiary law governing some of the salient issues differs" between Delaware and federal court, and thus that

"Defendants' praise of the MDL court's rationale breathes not a whisper to the difference in Delaware law." *Id*. at 17.[6] The Court also opined that "Delaware courts are loath to step into the heart of technical debate between opposing scientists" and that, "[i]n that regard, the jurisprudence reflected in the Floridian *Zantac* differs from Delaware's." *Id*. The Court concluded its general discussion of the *Daubert* standard by citing Ninth Circuit caselaw instructing courts to "conduct their *Daubert* analyses 'with a liberal thrust favoring admission.'" Op. at 13 (quoting *Messick v. Novartis Pharms. Corp.*, 747 F.3d 1193, 1196 (9th Cir. 2014)).

The Court next addressed whether its analysis should concentrate on ranitidine or NDMA and concluded that "general causation focuses on NDMA." *Id*. at 18. The Court correctly observed that "[t]his fundamental dispute of whether the science should focus on ranitidine versus NDMA lies at the heart of every challenge mounted in the Motions." Op. at 22. The Court acknowledged Defendants' argument that "studies of ranitidine *necessarily account* for any exposure to NDMA contained in ranitidine products," but countered that "Defendants do not dilate on" why that is true. *Id*. at 19. Ultimately, the Opinion concluded it could not "turn a

[6] The Court noted that no experts in this litigation appeared in the MDL, Op. at 16, but in fact Dr. Ramin Najafi did and was excluded. The Court also observed that five of the cancers at issue here were not analyzed in the MDL opinion, Op. at 6, but as described above that is only because the MDL plaintiffs' experts conceded they could not support a general-causation opinion for those cancers. *See supra*, at 3 n.2.

blind eye to the focus on NDMA, especially where the record suggests that Defendants acknowledged the dangers of it." *Id*. at 21. For the latter point, the Opinion cited a Hazard Assessment Report on NDMA prepared by GSK.

The Opinion began its analysis of Plaintiffs' experts' opinions with "[o]ne challenge [that] merits discussion at the outset: Plaintiffs' alleged failure to offer satisfactory proof of a threshold dose." Op. at 29. The Court read the decision in *Tumlinson v. Advanced Micro Devices, Inc.*, 2013 WL 7084888 (Del. Super. Ct. Oct. 15, 2013), *aff'd*, 81 A.3d 1264 (Del. 2013), as holding that any requirement to identify a threshold dose is "excus[ed]," Op. at 29, when "the substance in question is known to be harmful at some level and the plaintiff suffered the precise harm connected to that exposure." *Id*. (quoting *Tumlinson*, 2013 WL 7084888, at *7). The Opinion dismissed Defendants' argument that the sort of "precise harm" that might excuse the need to identify a threshold dose must be far more specific than ten different types of cancer. The Court "rejected such a precious reading, at least at the general causation phase, especially given the conclusions of GSK's 2019 Hazard Assessment" regarding the carcinogenicity of NDMA. *Id*. at 30.

Having set out the framework guiding its *Daubert* analysis, the Court proceeded to evaluate the opinions of Plaintiffs' experts. For each expert, the Opinion concluded that the flaws Defendants identified in Plaintiffs' experts' methodologies were solely matters for cross-examination, and that a jury should be

permitted to evaluate for itself the analytic gaps in the experts' opinions. The Opinion concluded in each case that Defendants' "criticisms go to weight," *id*. at 42; *see id*. at 40, 91, 94, or that it should not intervene in what it perceived to be merely a "battle of the experts," *id*. at 39, 50, 52. Because the Court did not require the experts to focus their analysis on ranitidine or identify a threshold at which NDMA can be carcinogenic, and reserved judgment on the adequacy of the experts' methodologies, the Court allowed the experts to minimize the importance of the human ranitidine epidemiology, in favor of extrapolating from non-ranitidine animal data and studies about dietary and occupational NDMA exposure. The Opinion reached this conclusion despite the fact that Plaintiffs' experts' approach:

- is at odds with the approach and conclusions of every one of the 16 epidemiologic studies that were designed to assess whether there is a relationship between ranitidine and cancer,
- is inconsistent with the methods and conclusions of the FDA and EMA;
- is not employed by the experts in their professional work and has not been published or peer reviewed.

LEGAL STANDARD

Supreme Court Rule 42(b) provides the standard for certifying an interlocutory appeal: the order appealed from must "decide[ ] a substantial issue of material importance that merits appellate review before a final judgment." Sup. Ct. R. 42(b)(i). The Rule also requires that, in making its certification decision, the trial court consider: "(1) the eight factors listed in Rule 42(b)(iii); (2) the most efficient

and just schedule to resolve the case; and (3) whether and why the likely benefits of interlocutory review outweigh the probable costs, such that interlocutory review is in the interests of justice." *Alcoa World Alumina LLC v. Glencore Ltd.*, 2016 WL 3659424, at *1 (Del. Super. Ct. March 10, 2016). Interlocutory review can be warranted where "at least one" of the Rule 42(b) factors is met. *Green v. GEICO Gen. Ins. Co.*, 2019 WL 4643937, at *3 (Del. Super. Ct. Sept. 23, 2019); *see also Al Jazeera Am. v. AT&T Servs.*, 2013 WL 5738034, at *3 (Del. Ch. Oct. 23, 2013) (certifying interlocutory appeal that involved "a question of law that is of first instance in this State"). Here, multiple criteria are satisfied.

ARGUMENT

I. The Court Should Certify Its *Daubert* Ruling for Interlocutory Appeal.

A. The *Daubert* Ruling Decided a Substantial Issue of Material Importance

"The 'substantial issue' requirement is met when an interlocutory order decides a main question of law which relates to the merits of the case, and not to collateral matters." *Sprint Nextel Corp. v. iPCS, Inc.*, 2008 WL 2861717, at *1 (Del. Ch. July 22, 2008). The holdings at issue—whether the general-causation analysis should focus on ranitidine or NDMA, whether Plaintiffs' experts must identify a threshold dose, and whether Delaware applies a "liberal thrust favoring admission" in *Daubert* analyses—are questions of law in interpreting Rule 702 and *Daubert*, and undoubtedly relate to the merits, because they will determine Plaintiffs' ability

to prove the essential element of causation. *See Barrera v. Monsanto Co.*, 2019 WL 2331090, at *16 (Del. Super. Ct. May 31, 2019) ("If plaintiffs do not provide proof of general causation, then they are unable to establish an essential element of their case and summary judgment should be granted in favor of the defendant.").

The issues are clearly of "material importance" because a ruling reversing the Opinion has the potential to resolve more than 73,000 cases. Whether those cases go forward will have significant practical effect for the parties, the Delaware court system, and other Delaware litigants. To put the size of the litigation in perspective, in all of 2023, just over 5,000 civil complaints were filed in the Superior Court, and 4,154 civil cases were resolved.[7] This litigation includes more than *fourteen times* as many civil cases as the Superior Court typically handles in a year. This volume of cases could require dozens of trials involving multiple judges, the empanelment of dozens of juries, and extensive pre- and post-trial litigation—all before the Supreme Court has a chance to consider whether, as set forth by the Opinion, this state's *Daubert* standard is truly more lenient than the consensus federal standard.

B. Rule 42(b)(iii) Criteria Counsel in Favor of Interlocutory Review.

Rule 42(b)(iii) instructs trial courts, "in deciding whether to certify an interlocutory appeal," to consider eight criteria, including whether:

[7] *See* 2023 Annual Report Statistical Information for the Delaware Judiciary, at 16, *available* at https://courts.delaware.gov/aoc/annualreports/fy23/.

- **(B)** The decisions of the trial courts are conflicting upon the question of law;
- **(G)** Review of the interlocutory order may terminate the litigation; or
- **(H)** Review of the interlocutory order may serve considerations of justice.

Those three criteria are applicable here and counsel strongly in favor of interlocutory review.

1. The Decisions of the Trial Courts Are in Conflict.

In light of the Court's decision, the Delaware trial courts have now issued conflicting rulings on the questions of law presented by the appeal.

First, the *In re Asbestos* decision by Judge Slights makes clear that—contrary to the Court's ruling—the focus of any general-causation inquiry must be on the product at issue, not the allegedly harmful component. The *Asbestos* plaintiffs argued there was adequate evidence of general causation "because we already know that friction products contain chrysotile, chrysotile causes disease and, therefore, friction products cause disease." 911 A.2d at 1201. The court "rejected this approach" and "found that plaintiffs must establish that their experts can reliably conclude that exposure to friction products increases the risk of contracting an asbestos-related disease." *Id*. at 1202. In other words, the object of the general-causation analysis must be the product at issue.

Accordingly, *Asbestos* did not authorize plaintiffs' causation expert to discount product-specific epidemiology in favor of less relevant evidence regarding

the alleged carcinogenic agent, as Plaintiffs' experts did here. On the contrary, the *Asbestos* plaintiffs' expert engaged the product-specific epidemiology in great detail, and even published a peer-reviewed study concluding that the findings of the epidemiology were "equivocal." *Id*. at 1192. Because a valid methodology led the expert to conclude the epidemiology on exposure to friction products was not definitive, plaintiffs could try to demonstrate causation by presenting evidence that the products "release respirable chrysotile fibers that are indistinguishable in size and other characteristics from unrefined chrysotile fibers" and, "with that evidentiary predicate in hand," rely on the "undisputed" evidence that unrefined chrysotile fibers could cause respiratory disease. *Id*. at 1202. Accordingly, the plaintiff's expert established that the friction products released chrysotile fibers in a study that he wrote and published in a peer-reviewed journal. *See id*. The contrast with this case is stark. Here, Plaintiffs' experts used methodologies never published, much less subjected to peer review, to conclude that ranitidine can cause cancer based on extrapolations from studies regarding NDMA exposures in food and rubber fumes, while bypassing the unanimous body of epidemiology showing no evidence of a causal association between ranitidine use and cancer.

The Opinion's conclusion that "general causation focuses on NDMA," Op. at 18, is also irreconcilable with the federal *Daubert* standard. Multiple federal courts have held that the causation inquiry must focus on the product at issue rather than

the toxic component. *See, e.g.*, *Chapman*, 766 F.3d at 1303–04; *Burst v. Shell Oil Co*., 120 F. Supp. 3d 547, 553 (E.D. La. 2015) ("The simple explanation that gasoline contains benzene, and benzene is a known carcinogen cannot be the justification for such extrapolation[.]"), *aff'd*, 650 F. App'x 170 (5th Cir. 2016); *Henricksen v. ConocoPhillips Co.*, 605 F. Supp. 2d 1142, 1156 (E.D. Wash. 2009) ("[T]he court cannot simply presume that the qualitative toxic and carcinogenic effects of benzene from any source are the same."). The need to focus on the product at issue is particularly acute here, where a robust body of epidemiology on the product exists, yet Plaintiffs cannot even offer a threshold dose for the allegedly carcinogenic component.

Second, the Opinion's holding that general-causation experts need not identify a threshold dose is in conflict with the decisions in *Tumlinson* and *Wilant v. BNSF Ry. Co.*, 2020 WL 2467076 (Del. Super. Ct. May 13, 2020), *vacated in part on other grounds on denial of reconsideration*, 2020 WL 3887881 (Del. Super. Ct. July 9, 2020). *Tumlinson* excluded a general-causation expert's opinion that the chemicals encountered by an employee at a computer-chip factory could cause birth defects because the expert "refuse[d] to specify dosages." 2013 WL 7084888, at *7. *Tumlinson* acknowledged that there were some cases (all from non-Delaware courts) where "imprecision ha[d] been excused" and "general causation [was] assumed where neither the specific dose required for human toxicity nor the specific dose

plaintiffs received [was] known." *Id*. at *8 & n.44. But those were situations where the alleged injury was a "signature harm" of the product at issue, *id*. at *8—such as fatigue, confusion, and memory problems after carbon-monoxide exposure, the death of oyster beds after an oil spill, and carpal tunnel syndrome after decades of operating a railroad car.[8] Cancer, by contrast, is hundreds of different diseases that, collectively, are one of the most common medical conditions in the United States. Individual cancers can be caused by a variety of environmental exposures, lifestyle factors, and genetic mutations. That GSK acknowledged in its Hazard Assessment that NDMA is a probable human carcinogen, as the Opinion notes, does not compel a different result. The Hazard Assessment did not identify any signature cancers caused by NDMA and, critically, it did not attempt to quantify a threshold at which NDMA is dangerous to human health. Even if NDMA may be a carcinogen *at some level*, like many substances to which people are exposed, it is Plaintiffs' burden to identify—based on reliable scientific evidence—at what level that is the case.

The Opinion did not address *Wilant*, precedent that is perhaps even stronger than *Tumlinson* on this issue. In *Wilant*, the plaintiff alleged that inhalation of diesel fumes caused him to develop bladder cancer. 2020 WL 2467076, at *1. The

[8] *See Hardyman v. Norfolk & W. Ry. Co.*, 243 F.3d 255 (6th Cir. 2001); *Clausen v. M/V NEW CARISSA*, 339 F.3d 1049 (9th Cir. 2003); *John's Heating Serv. v. Lamb*, 46 P.3d 1024 (Alaska 2002).

plaintiff's expert—doing much more than the experts did here—"suggested that a proposed 'threshold limit value' based on the known risk for lung cancer was a 'reasonable place to start.'" *Id*. at *5 (citations omitted). But the court refused to "presume" that "a 'threshold limit value' to one organ could be toxic to another organ." *Id*. Consequently, the court found the expert's causation opinion must be excluded under *Daubert* because it failed to identify a threshold dose. As the court put it, "the dosage problem here is quite acute: we do not know how much diesel exhaust the Plaintiff inhaled while employed at BNSF, *but even if we did, we do not know how much diesel exhaust one would need to inhale to increase the risk of bladder cancer*." *Id*. at *5 (emphasis added). The approach of the *Wilant* court to the threshold-dose issue is irreconcilable with the Opinion's approach.

Federal courts also consistently apply a threshold-dose requirement to general-causation opinions. *See, e.g.*, *McClain*, 401 F.3d at 1241 ("[A] plaintiff must demonstrate the levels of exposure that are hazardous to human beings generally…."); *Mitchell v. Gencorp*, 165 F.3d 778, 781 (10th Cir. 1999) (same); *Wright v. Willamette Indus.*, 91 F.3d 1105, 1106 (8th Cir. 1996) (same); *Allen v. Pennsylvania Eng'g Corp.*, 102 F.3d 194, 199 (5th Cir. 1996) ("Scientific knowledge of the harmful level of exposure to a chemical, plus knowledge that the plaintiff was exposed to such quantities, are minimal facts necessary to sustain the plaintiffs' burden in a toxic tort case."); *Krik v. Exxon Mobil Corp.*, 870 F.3d 669, 677 (7th Cir.

2017) ("[M]ore than thirty other federal courts and state courts have held that this cumulative/'any exposure' theory is not reliable[.]").[9] The Opinion diverges from this federal requirement. Indeed, although the Opinion held that "Delaware does not recognize a 'threshold dose' requirement" in attempting to distinguish Delaware law from the federal *Daubert* standard applied by the MDL court, Op. at 16, the Supreme Court has expressly instructed that Delaware's Rule 702 "is substantially similar to Federal Rule of Evidence 702." *Bowen v. E.I. DuPont de Nemours & Co*., 906 A.2d 787, 794-95, 797 (Del. 2006).

The requirement to identify a threshold dose is not an arbitrary box-checking exercise. An expert need not provide a specific number; an estimated range supported by science and based upon a reliable expert opinion will suffice. *See In re Zantac*, 644 F. Supp. 3d at 1109. But it is vital that a general-causation expert identify *some* minimum level at which a toxic substance begins to present a risk of the harm in question. Otherwise, plaintiffs could advance the untenable theory that "*any* amount of a carcinogen, no matter how small, is actionable." *Id*. If that were the case, experts could reach juries with opinions that all variety of medications,

[9] The Opinion cited the Ninth Circuit's decision in *Kennedy v. Collagen Corp.*, 161 F.3d 1226, 1229–31 (9th Cir. 1998), as support for its threshold-dose ruling, Op. at 23, but the decision has no bearing on the issue at hand. *Kennedy* permitted the causation expert to focus on collagen, but collagen was the active ingredient in the product in question, not an alleged degradant like NDMA. 161 F.3d at 1228.

foods, and household products cause cancer because they contain trace amounts of substances that are potentially carcinogenic at some dose. The problem is especially acute for NDMA, which is ubiquitous in our air, food, and elsewhere in the environment, *see id*. at 1106, as Plaintiffs' experts acknowledge. Without the need to identify a threshold level (or to rebut contrary epidemiology), an expert opining that air, water, and common foods are carcinogenic would pass muster under *Daubert* simply because those substances contain some amount of NDMA.

Third, the Opinion's adoption of an admonition that often appears in Ninth Circuit *Daubert* opinions—that courts should "conduct their *Daubert* analyses 'with a liberal thrust favoring admission'"—confuses the level of scrutiny Delaware courts should apply to experts' methodologies. Op. at 13 (quoting *Messick*, 747 F.3d at 1196). The "liberal thrust favoring admission" is an outlier approach to *Daubert*, applied almost exclusively in the Ninth Circuit. The "liberal thrust" phrase comes from *Daubert*, but the U.S. Supreme Court used it only to explain that "a rigid 'general acceptance' requirement," which would be more onerous than the *Daubert* standard, "would be at odds with the 'liberal thrust' of the Federal Rules." 509 U.S. 579, 588 (1993). The U.S. Supreme Court never suggested that the *Daubert* standard *itself* should be approached with a "thrust" one way or the other. Instead, the U.S. Supreme Court has made clear that a trial judge must determine for herself whether "there is simply too great an analytical gap between the data and the opinion

proffered" and, if so, exclude the expert's opinion. *Joiner*, 522 U.S. at 146; *see* Fed. R. Evid. 702, advisory committee's note to 2000 amendment ("[T]he trial court must scrutinize not only the principles and methods used by the expert, but also whether those principles and methods have been properly applied to the facts of the case.").

The Opinion also relied on a Second Circuit case that it believed approached *Daubert* with a "liberal thrust," but did not address the Second Circuit's subsequent clarification that such lenient *Daubert* review is not acceptable. The Opinion repeatedly cited *McCullock v. H.B. Fuller Co.*, 61 F.3d 1038 (2d Cir. 1998), which held that "fault in [an expert's] use of differential etiology as a methodology, or lack of textual authority for his opinion, go to the weight, not the admissibility, of his testimony." *Id*. at 1044; *see* Op. at 14, 39, 40, 42, 46, 47. But the Second Circuit restricted *McCullock* to its facts in *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249 (2d Cir. 2005), emphasizing that it only addressed the opinion "*in that case*." *Id*. at 255. *Ruggiero* made clear that a liberal application of *McCullock* was untenable after the U.S. Supreme Court's subsequent decision in *Joiner* and held that "when an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, *Daubert* and Rule 702 ***mandate*** the exclusion of the unreliable opinion testimony." *Id*. (quoting *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 266 (2d Cir. 2002)) (emphasis added). Even the Ninth Circuit, in a case that declined to invoke the "liberal thrust favoring

admission," held that dismissing an argument as "'going to the weight, not admissibility, of [the expert's] testimony' is *not* a reliability determination." *United States v. Valencia-Lopez*, 971 F.3d 891, 899 (9th Cir. 2020) (quoting *Nease v. Ford Motor Co.*, 848 F.3d 219, 230 (4th Cir. 2017)).

The 2023 amendments to Federal Rule of Evidence 702 confirmed that *Daubert* should not be applied with a presumption in favor of admissibility. The Rule now states that the proponent of an expert opinion must "demonstrate[ ] to the court that it is more likely than not" that the opinion satisfies *Daubert*. Fed. R. Evid. 702 (emphasis added). The advisory committee expressly rejected the position of "certain courts," and which the Court took here, "that arguments about the sufficiency of an expert's basis always go to weight and not admissibility." *Id*. This is the same approach that Delaware courts have consistently taken. *See, e.g.*, *Zayas v. State*, 273 A.3d 776, 788 (Del. 2022) (affirming exclusion of opinion that "was based upon an incomplete factual predicate"); *Scottoline*, 2023 WL 2325701, at *5 ("Studies showing an association between two conditions are not, standing alone, sufficient evidence to support an opinion as to causation."); *Scaife v. Astrazeneca LP*, 2009 WL 1610575, at *18 (Del. Super. Ct. June 9, 2009) (excluding opinion because "the expert cannot accept some but reject other data from the medical literature without explaining the bases for her acceptance or rejection").

The Opinion's embrace of the "liberal thrust favoring admission" short-circuited its substantive evaluation of the methodological shortcomings of Plaintiffs' experts' opinions. It led the Court to bless opinions that have significant hallmarks of unreliability: they fail to describe objective methodologies, are internally inconsistent in their treatment of the data, and make impermissible analytical leaps. It also caused the Court to minimize the fact that "general acceptance" remains an important factor for the *Daubert* gatekeeper to consider. While *Daubert* rejected a rigid general-acceptance requirement, general acceptance is nonetheless an "important factor," and a methodology that attracts "only minimal support" will "properly be viewed with skepticism." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 594 (1993). But the Opinion seemed to dismiss the significance of general acceptance altogether, declaring that "***[n]one*** of the *Daubert* factors, specific or otherwise, is binding on the trial court." Op. at 9–10 (emphasis added).

Rather than requiring Plaintiff's experts to justify their departure from the standard methodology for assessing causation in these circumstances—looking to the unanimous finding of sixteen epidemiological studies about the product at issue—the Opinion instead found it was reliable for the experts to extrapolate from less relevant studies involving distinct NDMA exposures, even though the experts would not employ such an approach in their non-litigation work and no scientist or regulatory body outside this litigation endorses their opinions. *See, e.g.*, *In re Mirena*

Ius Levonorgestrel-Related Prods. Liab. Litig., 341 F. Supp. 3d 213, 268 (S.D.N.Y. 2018) (excluding opinion whose "conclusion lack[ed] any acceptance, let alone general acceptance, in the scientific community outside this litigation."). As an example, the Opinion found reliable the opinion of an expert who—despite proffering a litigation opinion that ranitidine causes kidney cancer—went on (after his deposition) to publish in peer-reviewed literature that ***the available scientific evidence is insufficient to conclude that ranitidine causes kidney cancer***.[10]

The Supreme Court should have the opportunity to clarify whether the more exacting federal *Daubert* standard that does not lean in favor of admissibility, but rather conducts the rigorous Rule 702 analysis without preconception, applies in Delaware, or whether the state has adopted a "liberal thrust" toward admission.

2. Interlocutory Review May Terminate the Litigation.

The issues presented in the interlocutory appeal have the potential to resolve the entire 73,000-plaintiff litigation. If the Supreme Court holds that Plaintiffs' causation experts were required to identify a threshold carcinogenic dose of NDMA or ranitidine, their causation opinions will fail, and Plaintiffs' claims along with

[10] *Compare* Expert Report of Vitaly Margulis (June 29, 2023), at 22 ("In my opinion, stated to a reasonable degree of medical and scientific certainty, the NDMA in ranitidine is capable of causing renal cancer."), *with* Gold & Margulis, Reply by Authors, JU OPEN PLUS (2023) ("We believe preclinical data and limited population data demonstrate an association between this now-recalled medication and kidney cancer but not causation.").

them. If the Supreme Court holds that the general-causation inquiry must focus on the product at issue, not the allegedly toxic component, or that the Opinion erred in deferring to the jury for evaluation of the experts' methodologies, then the experts' failure to adequately grapple with the ranitidine epidemiology and their inconsistent use of the data will be fatal to their opinions, whether on appeal or after remand. The substantial possibility that the resolution of the *Daubert* issue could lead to a summary-judgment order that ends this litigation—as it did in the MDL—obviating the need for the parties and Delaware courts to manage and try dozens of bellwether cases, is reason enough to certify the Opinion for appeal. *See Shaev v. Wyly*, 1998 WL 155540, at *1 (Del. Ch. March 26, 1998) (certifying interlocutory review on ground that "review of the interlocutory order may terminate the litigation"); *Maffei v. Palkon*, No. 125, 2024, at 6 (Del. April 16, 2024) (granting interlocutory appeal in part on ground that "interlocutory review may terminate the litigation").

3. Interlocutory Review Will Serve Considerations of Justice.

An interlocutory appeal will also provide justice to Defendants in a way that, due to the size of the litigation, an appeal after final judgment cannot. Delaware law "imposes a special obligation upon a trial judge" to serve as a "gatekeeper" and "ensure that any and all scientific testimony is not only relevant, but reliable." *Bowen*, 906 A.2d at 794. The consequences of the Court's gatekeeping decision here are amplified tens of thousands of times over, given the number of cases governed

by the Opinion. Without immediate review, Defendants will be forced to endure the costs of many bellwether proceedings, including trials, before they can raise the *Daubert* issue in discrete post-judgment appeals, one cancer and plaintiff at a time.[11]

The Court's decision will also set a high-profile precedent for mass-tort plaintiffs, with significant implications for the administration of justice in Delaware courts. The great majority of Plaintiffs originally intended to pursue their cases in the federal MDL, but opted to file suit in Delaware when the MDL plaintiffs' experts opined that ranitidine could not have caused their cancers. The Court has now permitted tens of thousands of cases that could not pass muster in federal court to proceed in Delaware. If the Court's decision stands, plaintiffs with claims predicated on causation theories that federal courts find unsupported by reliable evidence—like the plaintiffs whose claims alleging acetaminophen causes autism were recently rejected in the Southern District of New York—will have every incentive to try their luck in Delaware. *See In re Acetaminophen – ASD-ADHD Prods. Liab. Litig.*, 2023 WL 8711617, at *36 (S.D.N.Y. Dec. 18, 2023) (excluding causation opinions of experts who "repeatedly cherry pick[ed] isolated findings," "ignore[d] inconsistent

[11] The huge number of cases affected by the Court's order distinguishes it from the *Daubert* ruling that the court declined to certify in *In re Asbestos Litigation*, which applied only to "[s]everal plaintiffs" in the larger litigation. 2006 WL 1579782, at *1 (Del. Super. Ct. June 7, 2006). Moreover, the *Asbestos* court concluded that the *Daubert* ruling was not eligible for certification because it had not "established a legal right," which is no longer required by Rule 42. *Id*.

results," and "dismisse[d] the express limitations of study authors."). Such a disparity between the federal and Delaware *Daubert* standards has the potential to turn Delaware into a mass-tort magnet.

The Opinion signals to mass-tort plaintiffs that they should file suit in Delaware state court whenever possible—which, given the number of companies in industries that are frequent targets of mass-tort litigation incorporated in Delaware, it very often will be. Mass-tort plaintiffs would gain the benefit of a more liberal and lenient *Daubert* standard than would apply in federal court, contrary to what the Supreme Court's existing decisions suggest, greatly increasing their chances of reaching a jury. The volume of litigation in Delaware courts would increase substantially, taxing the resources of the state's courts, all to litigate claims by non-Delaware citizens against Delaware-based companies, and defendants would face huge litigation costs simply because they chose to incorporate in Delaware.

C. Interlocutory Review Allows for the Most Just and Efficient Resolution of the Litigation.

Interlocutory review of the Opinion would also enhance the efficiency of these coordinated proceedings. Ordinarily, there are "two highly undesirable problems inherent in" interlocutory appeals that compromise the efficiency of litigation: "fragmentation of a case and a delay in its final disposition." *Levinson v. Conlon*, 385 A.2d 717, 720 (Del. 1978). In the mass-tort context, however, interlocutory

review of a dispositive issue does not raise either concern. On the contrary, *postponing* review would fragment the litigation and delay ultimate resolution.

An interlocutory appeal here would allow for comprehensive review of the Court's ruling, for every case in the litigation. Because competent proof of general causation is required in every plaintiff's case, the parties agreed in an early Case Management Order that the issue should be decided on a global basis. There were obvious efficiency gains in resolving this threshold issue before proceeding to case-specific litigation, and those same efficiency considerations counsel in favor of interlocutory review.

By contrast, if Defendants must await an adverse jury verdict to appeal in an individual case, the Supreme Court's review would be piecemeal. Defendants would be forced to challenge the general-causation testimony in multiple appeals from individual trials, each of which could present the issues in a different light. The Supreme Court's review would be limited to the testimony of specific experts in specific trials, regarding specific cancers. And in each appeal, there undoubtedly would be other case-specific issues warranting the Supreme Court's attention, some of which might obviate the need to address the general-causation issue. Far better for the Supreme Court to resolve the cross-cutting, generally applicable issues raised by the *Daubert* opinion now, and on a complete record.

An interlocutory appeal also would not delay resolution of the litigation. With over 73,000 cases pending before the Court, there is no prospect that final judgment could be entered in every case, or even more than a handful, before an appeal. Resolution of a litigation this size requires expeditious and conclusive review of dispositive legal questions, not a rush to trial. In an interlocutory appeal, the Supreme Court will either reverse the *Daubert* ruling, potentially ending the litigation, or it will affirm, allowing the parties to approach bellwether proceedings with confidence that the applicable legal framework has been settled. *See In re E.I. du Pont de Nemours & Co. C-8 Personal Injury Litig.*, 54 F.4th 912, 938 (6th Cir. 2022) (explaining that "[b]ellwether trials are preliminary trials meant to help the parties gather information, value the cases, [and] test legal theories"). Defendants are not seeking to stay bellwether discovery while the interlocutory appeal is pending. As such, if the Supreme Court affirms, bellwether case-specific motions practice and trials can proceed without undue delay. *See, e.g.*, *In re Cornerstone Therapeutics Inc. Stockholder Litig.*, 2014 WL 4784250, at *1 (Del. Ch. Sept. 26, 2014) (certifying decision for appeal without entering a stay). There will be no sacrifice of time. By contrast, there will be a potentially enormous waste of resources if appellate review is postponed and the Court moves forward with a series of bellwether trials in the shadow of legal uncertainty regarding the viability of Plaintiffs' general-causation evidence.

D. The Benefits of Interlocutory Review Far Outweigh the Costs.

For the foregoing reasons, the benefits of interlocutory review outweigh the costs. The benefits are high because the ruling creates conflicts on important legal questions among the Delaware trial courts, incentivizes mass-tort plaintiffs across the nation to flock to Delaware, and is potentially litigation dispositive. The typical costs of interlocutory review—fragmentation and delay—are not present here. Interlocutory review will *avoid* fragmentation by allowing the Supreme Court to resolve the *Daubert* issue for the whole litigation, and it will hasten resolution by either ending the litigation or providing the certainty the parties need for bellwether proceedings to be informative. Review should not be postponed while the Court presses ahead with bellwether trials that, if they result in verdicts for plaintiffs, may be nullified on appeal and, in any event, cannot facilitate global resolution without the legal certainty that only the Supreme Court can provide. Before Delaware becomes a "magnet" for mass-tort claims with a "liberal thrust favoring admission" under *Daubert*, the Supreme Court should provide much-needed guidance on the split the Court's decision creates with both federal and prior Delaware law.

CONCLUSION

For the foregoing reasons, Defendants respectfully request the Court certify the Opinion for interlocutory review.

DATED: June 10, 2024

By:

Brand Defendants' Lead Delaware Counsel:

/s/ Colleen Shields
Colleen Shields (ID No. 3138)
ECKERT SEAMANS CHERIN & MELLOTT, LLC
222 Delaware Avenue, Suite 700
Wilmington, DE 19801
Tel: (302) 552-2901
cshields@eckertseamans.com

/s/ Joseph S. Naylor
Joseph S. Naylor (ID No. 3886)
SWARTZ CAMPBELL
300 Delaware Ave., Suite 1410
Wilmington, DE 19801
Tel: (302) 656-5935
jnaylor@swartzcampbell.com

/s/ Nancy Shane Rappaport
Nancy Shane Rappaport (ID No. 3428)
DLA PIPER LLP (US)
1201 North Market Street, Ste. 2100
Wilmington, DE 19801
Tel: (302) 468-5631
nancy.rappaport@us.dlapiper.com

/s/ Daniel J. Brown
Daniel J. Brown (ID No. 4688)
MCCARTER & ENGLISH
405 N. King St., 8th Floor
Wilmington, DE 19801
Tel: (302) 984-6309
djbrown@mccarter.com

Brand Defendants' Lead National Counsel:

/s/ Mark S. Cheffo
Mark S. Cheffo
DECHERT LLP
1095 Avenue of the Americas
New York, NY 10036
Tel: (212) 698-3500
mark.cheffo@dechert.com

/s/ Andrew T. Bayman
Andrew T. Bayman
KING & SPALDING LLP
1180 Peachtree Street NE, Ste. 1600
Atlanta, GA 30309-3521
Tel: (404) 572-4600
abayman@kslaw.com

/s/ Loren H. Brown
Loren H. Brown
DLA PIPER LLP (US)
1251 Avenue of the Americas
New York, NY 10020
Tel: (212) 335-4846
loren.brown@us.dlapiper.com

/s/ Joseph G. Petrosinelli
Joseph G. Petrosinelli
WILLIAMS & CONNOLLY LLP
680 Maine Avenue SW
Washington, DC 20024
Tel: (202) 434-5000
jpetrosinelli@wc.com

Patheon Manufacturing Services LLC's Delaware Counsel:

/s/ Sean T. O'Kelly
Sean T. O'Kelly (ID No. 4349)
O'Kelly & O'Rourke, LLC
Sean T. O'Kelly (4349)
Gerard M. O'Rourke (3265)
O'KELLY & O'ROURKE, LLC
824 N. Market Street, Suite 1001A
Wilmington, DE 19801
Telephone: 302-778-4000
sokelly@okorlaw.com
gorourke@okorlaw.com

Patheon Manufacturing Services LLC's National Counsel:

/s/ John D. Garrett
John D. Garrett
BOWMAN & BROOKE LLP
2901 Via Fortuna, Suite 500
Austin, TX 78746
Tel: (512) 874-3832
Fax: (512) 874-3801
John.garrett@bowmanandbrooke.com

CERTIFICATE OF COMPLIANCE WITH RULE 42(B)(III)

Defendants and their counsel hereby certify that they have determined in good faith that the foregoing application for interlocutory review meets the criteria set forth in Supreme Court Rule 42(b)(iii).

DATED: June 10, 2024

By:

Brand Defendants' Lead Delaware Counsel:

/s/ Colleen Shields
Colleen Shields (ID No. 3138)
ECKERT SEAMANS CHERIN & MELLOTT, LLC
222 Delaware Avenue, Suite 700
Wilmington, DE 19801
Tel: (302) 552-2901
cshields@eckertseamans.com

/s/ Joseph S. Naylor
Joseph S. Naylor (ID No. 3886)
SWARTZ CAMPBELL
300 Delaware Ave., Suite 1410
Wilmington, DE 19801
Tel: (302) 656-5935
jnaylor@swartzcampbell.com

/s/ Nancy Shane Rappaport
Nancy Shane Rappaport (ID No. 3428)
DLA PIPER LLP (US)
1201 North Market Street, Ste. 2100
Wilmington, DE 19801
Tel: (302) 468-5631
nancy.rappaport@us.dlapiper.com

Brand Defendants' Lead National Counsel:

/s/ Mark S. Cheffo
Mark S. Cheffo
DECHERT LLP
1095 Avenue of the Americas
New York, NY 10036
Tel: (212) 698-3500
mark.cheffo@dechert.com

/s/ Andrew T. Bayman
Andrew T. Bayman
KING & SPALDING LLP
1180 Peachtree Street NE, Ste. 1600
Atlanta, GA 30309-3521
Tel: (404) 572-4600
abayman@kslaw.com

/s/ Loren H. Brown
Loren H. Brown
DLA PIPER LLP (US)
1251 Avenue of the Americas
New York, NY 10020
Tel: (212) 335-4846
loren.brown@us.dlapiper.com

/s/ Daniel J. Brown
Daniel J. Brown (ID No. 4688)
MCCARTER & ENGLISH
405 N. King St., 8th Floor
Wilmington, DE 19801
Tel: (302) 984-6309
djbrown@mccarter.com

Patheon Manufacturing Services LLC's Delaware Counsel:

/s/ Sean T. O'Kelly
Sean T. O'Kelly (ID No. 4349)
O'Kelly & O'Rourke, LLC
Sean T. O'Kelly (4349)
Gerard M. O'Rourke (3265)
O'KELLY & O'ROURKE, LLC
824 N. Market Street, Suite 1001A
Wilmington, DE 19801
Telephone: 302-778-4000
sokelly@okorlaw.com
gorourke@okorlaw.com

/s/ Joseph G. Petrosinelli
Joseph G. Petrosinelli
WILLIAMS & CONNOLLY LLP
680 Maine Avenue SW
Washington, DC 20024
Tel: (202) 434-5000
jpetrosinelli@wc.com

Patheon Manufacturing Services LLC's National Counsel:

/s/ John D. Garrett
John D. Garrett
BOWMAN & BROOKE LLP
2901 Via Fortuna, Suite 500
Austin, TX 78746
Tel: (512) 874-3832
Fax: (512) 874-3801
John.garrett@bowmanandbrooke.com

CERTIFICATE OF SERVICE

I, Patrick M. Brannigan, hereby certify that on this 10th day of June, 2024, I caused to be served a true and correct copy of the foregoing **APPLICATION FOR INTERLOCUTORY REVIEW OF THE COURT'S DENIAL OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' GENERAL-CAUSATION EXPERTS** upon the following counsel of record via email and File & Serve*Xpress*:

Raeann Warner, Esq.
COLLINS PRICE & WARNER
8 East 13th Street
Wilmington, DE 19801
raeann@jcdelaw.com

Joseph J. Rhoades, Esq.
Stephen T. Morrow, Esq.
RHOADES & MORROW LLC
Legal Arts Building
1225 N. King St., Suite 1200
Wilmington, DE 19801
joe.rhoades@rhoadeslegal.com
stephen.morrow@rhoadeslegal.com

Bernard Conway, Esq.
CONWAY LEGAL LLC
1007 North Orange Street, Suite 400
Wilmington, DE 19801
bgc@conway-legal.com

Jennifer A. Moore, Esq.
MOORE LAW GROUP, PLLC
1473 South 4th Street Louisville,
KY 40208
jennifer@moorelawgroup.com

R. Brent Wisner, Esq.
WISNER BAUM
10940 Wilshire Blvd., 17th Floor
Los Angeles, CA 90024
rbwisner@wisnerbaum.com

Justin Parafinczuk, Esq.
PARAFINCZUK WOLF
Two Town Centre
5550 Glades Rd., Suite 526/527 Boca
Raton, FL 33431
jparafinczuk@parawolf.com

Counsel for Plaintiffs

/s/ Patrick M. Brannigan
Patrick M. Brannigan (ID No. 4778)