

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

IN RE ZANTAC (RANITIDINE)
LITIGATION

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C.A. NO. N22C-09-101 ZAN

Submitted: June 20, 2024
Decided: July 1, 2024

**ORDER REFUSING TO CERTIFY DEFENDANTS’
APPLICATION FOR CERTIFICATION OF
INTERLOCUTORY APPEAL OF
OMNIBUS ORDER ON MOTIONS TO EXCLUDE EXPERT OPINIONS**

This 1st day of July 2024, upon consideration of Defendants’ Application for Certification of an Interlocutory Appeal (the “Application”); a Motion for Leave to File *Amici Curiae* Brief (the “Motion”); Plaintiffs’ Opposition to Defendants’ Application for Certification of an Interlocutory Review (the “Response”); this Court’s Omnibus Order on Motions to Exclude Expert Opinions Order dated May 31, 2024 (and corrected without substantive change on June 3, 2024) (the “Order”); Supreme Court Rule 42 (“Rule 42”); and this civil action’s entire record, the Court finds its Order denying exclusion of expert opinion under D.R.E. 702 and *Daubert* does not determine a substantial issue of material importance that merits appellate review before final judgment, and the Application is refused for the following reasons:

BACKGROUND

1. The mass tort claims in these actions involve a molecule known as ranitidine. Ranitidine is marketed under the label name of Zantac. N-Nitrosodimethylamine (“NDMA”) is found in ranitidine. NDMA causes cancer.

2. In September of 2022, nearly 75,000 plaintiffs chose this forum to be heard on allegations that Defendants collectively bear responsibility for their cancer diagnoses, and the related injuries or deaths caused from their exposure to NDMA from the ingestion of Zantac.

3. The claims are against Defendants, the five manufacturers of prescription and over-the-counter ranitidine products—GlaxoSmithKline LLC (“GSK”), Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Ingelheim U.S.A. Corporation (collectively, B.I.), Sanofi US Services Inc., Sanofi-Aventis U.S. LLC, and Chattem, Inc. (collectively, “Sanofi), Pfizer Inc. (“Pfizer”) (together with all those just mentioned are referred to as the “Brand Defendants”) and Patheon, (all collectively “Defendants”). All five manufacturers are incorporated in Delaware.

4. Plaintiffs allege the development of one of ten cancers—bladder, esophageal, gastric, liver, pancreatic, breast, colorectal, kidney, lung and prostate. Consistent with the norm in such cases, the first phase of these proceedings has addressed “general causation”—which involves the question of whether the

ingestion of this product is capable of causing cancer as alleged, not whether the specific plaintiff has established that the product in question caused his or her cancer.¹

5. To carry their burden at this stage, Plaintiffs retained ten experts to offer opinions on general causation for the ten mentioned cancers. Defendants moved to exclude them all.² Plaintiffs also moved to exclude certain opinions proffered by Defendants' sole general causation expert.

6. This Court considered, the parties' competing motions to exclude expert testimony pursuant to Rule 702 of the Delaware Rules of Evidence and *Daubert v. Merrell Dow Pharm. Inc.*³ These motions were the subject of discovery, a three-day "*Daubert*" hearing, multiple layers of briefing, and post-hearing submissions all supported by more than forty volumes of exhibits, including thousands of pages of scientific and legal materials.

7. On June 3, 2024 (correcting May 31st filing), the Court issued its 102-

¹ The agreement between the parties was that both sides would be allowed to raise general causation challenges under D.R.E 702 and *Daubert*. If the *Daubert* challenges were denied, the experts would be permitted to testify and the litigation would proceed with the scheduling of ten bellwether trials representing the ten different cancers alleged.

² Defendants moved to exclude all of Plaintiffs' General Causation Experts: Drs. Charles William Jameson, PhD; William Sawyer, PhD; Alfred I. Neugut, M.D., PhD; Vinod K. Rustgi M.D., MBA; Ioannis Hatzaras, M.D. MPH, PhD, F.A.C.S.; Dan J. Raz, M.D.; Bruce J. Trock, MPH, PhD; George Miller, M.D.; Pablo Leone, M.D.; and Vitaly Margulis, M.D. (collectively "Plaintiffs' General Causation Experts").

³ 509 U.S. 579 (1993).

page Order finding that each side carried its required burden of demonstrating the reliability of its proffered Rule 702 evidence.⁴ It further determined that any remaining challenges would be made at trial via cross-examination and introduction of counter evidence.⁵ The parties' *Daubert* challenges failed, and their motions were denied.

8. Defendants did not move for reargument under Civil Rule 59.⁶ Nor are there any pending dispositive motions before this Court. Instead, Defendants filed this application to certify its *Daubert* rulings for interlocutory appellate review. The Plaintiffs timely filed their Response in opposition.

9. By letter dated June 18, 2024 (the "Letter"), a group of manufacturing and business associations ("Movants")⁷ informed the Court of technical issues through File&Serve in their efforts to file a Motion for Leave to File an Amici Curiae Brief in Support of the Defendants' Application. Exhibits to the Letter include, *inter alia*, the Motion, a Proposed Order, and the Amici Curiae Brief. Movants ground

⁴ Order at 102.

⁵ *Id.*

⁶ That might have allowed this Court to reconsider its findings of fact, conclusions of law, or judgment, if needed. *See Ramon v. Ramon*, 963 A.2d 128, 136 (Del. 2008) ("A motion for reargument is the proper device for seeking reconsideration by the Trial Court of its findings of fact, conclusion of law, or judgment.") (internal citations omitted).

⁷ Those Movants are the Chamber of Commerce of the United States, the National Association of Manufacturers, the Biotechnology Innovation Organization, the Delaware Bioscience Organization, and the Pharmaceutical Research and Manufacturers Association.

the Motion on their “interest in the important legal issues at stake[.]”⁸ Unable to file through File&Serve, this Court permitted the docketing of the Motion with the Prothonotary via traditional means and that has since been accomplished.

APPLICABLE STANDARD

10. Pursuant to Supreme Court Rule 42, “[n]o interlocutory appeal will be certified by the trial court or accepted by this Court unless the order of the trial court decides a substantial issue of material importance that merits appellate review before a final judgment.”⁹

Interlocutory appeals should be exceptional, not routine, because they disrupt the normal procession of litigation, cause delay, and can threaten to exhaust scarce party and judicial resources. Therefore, parties should only ask for the right to seek interlocutory review if they believe in good faith that there are substantial benefits that will outweigh the certain costs that accompany an interlocutory appeal.¹⁰

11. In deciding whether to certify an interlocutory appeal, the trial court must consider: (1) the eight factors listed in Rule 42(b)(iii);¹¹ (2) the most efficient

⁸ Motion, at 2.

⁹ Del. Supr. Ct. R. 42(b)(i).

¹⁰ Del. Supr. Ct. R. 42(b)(ii).

¹¹ Delaware Supreme Court Rule 42(b)(iii) provides that the trial court should consider whether:

- (A) The interlocutory order involves a question of law resolved for the first time in this State;
- (B) The decisions of the trial courts are conflicting upon the question of law;
- (C) The question of law relates to the constitutionality, construction, or application of a statute of this State, which has not been, but should be, settled by this Court in advance of an appeal from a final order;

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.¹² “If the balance [of these considerations] is uncertain, the trial court should refuse to certify the interlocutory appeal.”¹³

DISCUSSION

12. Before going any further, the Court first must determine if the Order Defendants seek certification of “decides a substantial issue of material importance that merits appellate review before a final judgment.”¹⁴

13. Here, this Court was asked to consider only whether the parties carried their respective evidentiary burdens to establish that their first-phase general causation opinions were sufficiently reliable to allow them to be presented to the jury. The experts’ qualifications were not disputed. The Court considered lengthy

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- (D) The interlocutory order has sustained the controverted jurisdiction of the trial court;
 - (E) The interlocutory order has reversed or set aside a prior decision of the trial court, a jury, or an administrative agency from which an appeal was taken to the trial court which had decided a significant issue and a review of the interlocutory order may terminate the litigation, substantially reduce further litigation, or otherwise serve considerations of justice;
 - (F) The interlocutory order has vacated or opened a judgment of the trial court;
 - (G) Review of the interlocutory order may terminate the litigation; or
 - (H) Review of the interlocutory order may serve considerations of justice. *See* Del. Supr. Ct. R. 42(b)(iii).

¹² *Id.*

¹³ *Id.*

¹⁴ Del. Supr. Ct. R. 42(b)(i); *Traditions, L.P. v. Harmon*, 2020 WL 1646784, at *1 (Del. Apr. 2, 2020).

evidentiary presentations in support of the parties' respective positions, which covered all aspects of D.R.E. 702 and *Daubert*. The *Daubert* hearing lasted three days, and the *Daubert* proceedings, in whole, included extensive briefing, oral arguments, and post-hearing submissions.

14. The Court here considers the holding of *In re Asbestos*, where then-Judge Slights rejected a similar request and refused interlocutory relief.¹⁵ Similar to this case, the Court denied motions to exclude expert testimony under *Daubert* and held that a “*Daubert* analysis, at its core, leads the Court to a routine evidentiary determination performed by trial courts every day—whether expert testimony should be presented to a jury.”¹⁶ Such a determination “committed to the discretion of the trial court . . . does not satisfy the criteria set forth in Delaware Supreme Court Rule 42” because it was simply “a pre-trial evidentiary ruling[.]”¹⁷ The Court in *In re Asbestos* concluded its analysis there.¹⁸

15. On a similar record, the Court made a similar evidentiary ruling and issued its Order based upon settled principles of Delaware law; it found as gatekeeper that both sides carried the necessary reliability burden to present their

¹⁵ See *In re Asbestos Litig.*, 2006 WL 1579782 (Del. Super. Ct. June 7, 2006), *app. refused*, 906 A.2d 806 (Del. 2006).

¹⁶ *Id.* at *1.

¹⁷ *Id.*

¹⁸ *Id.* (“In light of this conclusion, the Court need not address the criteria set forth in Supreme Court Rule 42[.]”).

expert evidence under D.R.E. 702 and *Daubert*. The ten bellwether cases can now be scheduled, and any resolution of the remaining scientific debates and challenges to the experts' opinions and conclusions should be addressed either through future dispositive motion practice or by a jury at trial.

16. The questions presented here asked this Court to apply settled law to these claims in the first phase of this litigation. *Daubert* analyses are not uncommon. Whether an expert will be permitted to present an opinion to a jury is a routine evidentiary determination made by the Court. And such a determination is always committed to a trial court's discretion and subject later to an abuse of discretion standard of review.¹⁹

17. Defendants' damning refrain returns to the MDL's ruling and portends that were the Order permitted to stand, it will result in a high volume of cases that "could require dozen of trials, empanelment of dozens of juries and extensive pre- and post-trial litigation all before the Supreme Court has a chance to consider whether the [Order]'s standard is truly more lenient than the consensus federal standard."²⁰

18. To suggest that this Court's lengthy opinion created a different or more

¹⁹ *M.G. Bancorporation, Inc. v. Le Beau*, 737 A.2d 513, 522 (Del. 1999) ("[T]he law grants the trial judge broad latitude to determine whether *Daubert's* specific factors are, or are not, reasonable measures of reliability in a particular case," and the determination of whether to admit or exclude expert testimony is subject to an abuse of discretion standard of review).

²⁰ Defendants' Application at 18.

lenient *Daubert* standard is incorrect and inaccurate as a matter of law. Where the Court spoke about leniency, it was quoting *Daubert*, not expanding it.²¹

19. Furthermore, that this Court opted not follow the MDL should not be misconstrued to suggest that this Court made some declaration of independence from its federal sister. It did not. As discussed in the Order, this Court merely found it could not follow the same course “from what was presented here.”²² This is far from extraordinary. That judges disagree is not remarkable. As observed in the Order, other state courts too have disagreed with the MDL, elected not to follow it, and instead allowed the jury to weigh the strength of the experts’ opinions.²³

20. Notably, this Court considered that the Florida MDL relied heavily on *McClain v. Metabolife International, Inc.*²⁴ The *McClain* plaintiff alleged that a

²¹ See Order at 12-13:

The gatekeeper must apply these particular “factors in a flexible manner that takes into account the particular specialty of the expert under review and the particular facts of the underlying case.” . . . Restated, “[t]he reliability requirement is not a tool for the Court to use to exclude questionably reliable evidence.” This Court’s refusal to establish a bright line rule for proving causality has previously been considered. And no doubt, “the requisite proof necessary to establish causation will vary greatly case by case.”

The Supreme Court in *Daubert* was more direct: ‘Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.’ Thus guided, courts confronted by “shaky but admissible evidence” conduct their *Daubert* analyses “with a ‘liberal thrust’ favoring admission.” (internal citations omitted).

²² Order at 17.

²³ Order at 5-6.

²⁴ 401 F.3d 1233, 1240 (11th Cir. 2005).

dietary supplement containing caffeine caused cardiac injury. The trial court did not conduct a *Daubert* analysis and held “it lacked the knowledge” to make the call and denied the challenges. Rather than remand, the Eleventh Circuit reversed and conducted its own *Daubert* analysis, questioned the credibility of the experts, and determined the scientific evidence was unreliable²⁵ after having engaged internet searches of online toxicological databases to support its interpretations.²⁶ Of note, in *Long v. Weider Nutrition Grp. Inc.*, this Court had earlier been faced with the same *Daubert* challenge of the same scientific issues—but with a different experts; this Court allowed the presentation of the cardiac injury opinions to a jury.²⁷

21. To accept Defendants’ position that interlocutory review is warranted merely because the issue decided might “determine Plaintiffs’ ability to prove the essential element of causation” and thus, must be important,²⁸ would mean every dispositive motion ruling would clear the first hurdle to interlocutory review. This is contrary to Rule 42’s provisions that call for review only in exceptional circumstances.

22. This evidentiary ruling applying *Daubert* does not present a

²⁵ *Id.* at 1238.

²⁶ *Id.* at 1242.

²⁷ See *Long v. Weider Nutrition Grp., Inc.*, 2004 WL 1543226, at *4-6 (Del. Super. Ct. June 25, 2004).

²⁸ Application at 17–18.

substantial issue of material importance meriting appellate review before a final judgment. In turn, as posited here, Defendants' request for certification does not satisfy Rule 42's "substantial issue of material importance" prong.²⁹ Thus, the Application does not satisfy the criteria set forth in Delaware Supreme Court Rule 42(a).

23. No further consideration of the remaining factors is warranted. But an examination of the delineated Rule 42 factors further suggests that certifying Defendants' application would be inappropriate.

24. Defendants seek certification by incanting three of the eight Rule 42(b)(iii) criteria, namely: (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. For completeness, the Court considers these three factors.

25. Under Rule 42(b)(iii)(B), Defendants argue that the *Daubert* ruling stands in conflict with Judge Slights' *In re Asbestos* decisions because, to them, "the focus of any general-causation inquiry must be on the product at issue, not the

²⁹ See *Pfizer, Inc. v. Advanced Monobloc, Corp.*, 1999 Del. Super. LEXIS 509, at ** 17, 19 (Judge Quillen refused to certify an interlocutory appeal in a case where the trial court's potentially dispositive interlocutory orders, *inter alia*, struck a plaintiff's damages expert under the well-settled criteria set forth in *Daubert*); *Wilmington Medical Center, Inc. v. Coleman*, 298 A.2d 320, 322 (Del. 1972)(finding that because the trial court's interlocutory order did not "decide the underlying issue in the case at bar," it likewise did not address a "substantial legal right" as required for certification under Rule 42(a)).

allegedly harmful component.”³⁰ There is no conflict. The Court considered, cited, and was guided by: the holdings of *In re Asbestos*, other similar cases, Delaware law interpreting D.R.E. 702, as well as, *Daubert* and its progeny.³¹

26. Under Rule 42(b)(iii)(G), the Court agrees with Plaintiffs that interlocutory review of the Order would not terminate the litigation. Defendants argue that if review is granted, it may terminate the litigation because without general causation experts, they will undoubtedly attain summary judgment.

27. The Court agrees with Plaintiffs that forcing the issue now, without the benefit of a trial record—as no expert has actually provided testimony—is not prudent. This pre-trial issue, as mentioned earlier, is in infant stages. Defendants will undoubtedly appeal any adverse jury verdict on general causation. Interlocutory review would allow for two bites of the appellate apple. Again, this is not the intended purpose of Rule 42.

28. Under Rule 42(b)(iii)(H), review of the Order would not serve considerations of justice. Defendants argue that it would be unfair to force them to go to trial because of the implications it has on Delaware’s corporate image. This is

³⁰ Application at 19.

³¹ Order at 47. Defendants also suggest there is conflict among the Delaware trial courts about whether a threshold dose is required to prove general causation. There is no conflict in the Delaware law, and this was also considered by this Court in its ruling as one factor for consideration under *Daubert*.

not an appropriate basis for relief. This also assumes no dispositive motions will be filed at all and that Delaware, because of its status in the corporate world, should allow interlocutory review where no other court—federal or state—has been asked for such certification.

29. This request to protect corporations is blithely presented in the Application and supplemented by Movants—a group of manufacturing and business associations who sought leave to file an *Amici* brief. Aside from the timing of Movants’ request, filed only days prior to this Court’s deadline, the proposed arguments by Movants simply re-style Defendants’ arguments that this Court’s failure to follow the MDL may result in dire consequences to Delaware’s reputation in the corporate community. This factor has no bearing of this Court’s evidentiary ruling under Rule 42. Any consideration of the Motion would not change this Court’s ruling under Rule 42.³²

30. Interlocutory review here will not facilitate resolution. Nor do the benefits outweigh certain costs. Cases resolve, one way or the other, when they proceed to trial. These cases are no different. Efficiency is best achieved by

³² Movants emphasize that the Amici Brief discusses “from a policy perspective, the congruence of Delaware and federal law with respect to the admission of expert testimony.”³² That is, more specifically in this context, the *Daubert* standard: a topic developed and addressed in formal discovery, a three-day long *Daubert* hearing, hundreds of pages of post-hearing briefing that concluded on March 7, 2024, and the now challenged 102-page Order resolving the parties’ various *Daubert* challenges.

allowing the traditional judicial process here to move forward toward trial. Interlocutory appellate review of the Order will not terminate this litigation and are more likely instead to further prolong these proceedings.

31. Counsel for both sides are professional, well-versed in this area of law, and have established the required agreements to address the logistics normally involved in mass tort litigation. In fact, on June 21, 2024, after Defendants filed this request for interlocutory review, they filed a Motion to Enforce Severance Agreement, seeking that this Court enter an order requiring the regular filing of Plaintiffs' individual complaints to comply with the severance agreement and deadline established in the parties' Case Management Order (CMO 1). Thus, the Defendant applicants themselves have asked the Court to keep the cases moving here. This Court, too, is no stranger, to the process and trusts it. Interlocutory review is not a necessary or usual part of the process. The case will move forward.

CONCLUSION

IT IS HEREBY ORDERED that certification to the Supreme Court of the State of Delaware for disposition in accordance with Rule 42 is **REFUSED**.

/s/ Vivian L. Medinilla
J. Vivian L. Medinilla