## IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

	)	General Zantac Litigation
In re: Zantac (Ranitidine) Litigation	)	
	)	C.A. No.: N22C-09-101 ZAN

Submitted: October 23, 2025 Decided: December 1, 2025

## OPINION AND ORDER ON PLAINTIFFS' MOTION TO MODIFY CASE MANAGEMENT ORDER NO.7 TO ALL SUPPLEMENTAL EXPERT DISCLOSURES

## DENIED.

John J. Snidow, Esquire, Keller Postman, (Argued) Washington, D.C., pro hac vice Attorneys for Plaintiff

Andrew T. Bayman, Esquire, King & Spaulding (Argued) Atlanta, GA., Attorney for Defendants

Raeann Warner, Esquire, Collins, Price, Warner Woloshin, Wilmington, Delaware, Attorney for Interested Parties.

Bernard G. Conaway, Esquire, Conaway Legal, LLC, Wilmington, Delaware, Attorney for Interest Parties.

*Patrick C. Gallagher, Esquire*, Jacobs and Crumplar, PA, Wilmington, Delaware, Attorney for Interested Parties.

*Nancy Shane Rappaport, Esquire*, DLA Piper US LLP, Wilmington, Delaware, Attorney for Attorneys for Defendants Sanofi US Services Inc., Sanofi-Aventis U.S. LLC, and Chattem, Inc.

Joseph Naylor, Esquire, Swartz Campbell, Wilmington, Delaware, Attorneys for Boehringer Ingelheim Pharmaceuticals, Inc. and Boehringer Ingelheim USA Corporation.

Sean T. O'Kelly, Esquire and Gerard M. O'Rourke, Esquire, O'Kelly & O'Rourke, LLC, Wilmington, Delaware, Attorneys for Patheon Manufacturing Services LLC.

Daniel J. Brown, Esquire, McCarter & English, Wilmington, Delaware, Attorneys for Pfizer, Inc.

Colleen Shields, Esquire and Patrick M. Brannigan, Esquire, Eckert, Seamans, Cherin & Mellott, LLC, Attorneys for GlaxoSmithKline, LLC.

## Jones, J.

On July 10, 2025, the Delaware Supreme Court issued a decision reversing this Court's May 31, 2024, decision which denied Defendants' *Daubert* challenges to Plaintiffs' proposed general causation experts.<sup>1</sup> The Supreme Court ruled that the trial court had "erred in adopting a standard that favored or presumed the admissibility of expert testimony." The Supreme Court also ruled that for a general causation opinion to be admissible, a general causation expert's conclusion must reliably bridge the gap by scientifically linking the disease-causing agent to the product at issue. In other words, "ultimately an expert offering an opinion regarding general causation for a product must opine as to the product itself."

Defendants have moved for summary judgment maintaining that the Supreme Court decision in this case mandates that all of Plaintiffs' claims must be dismissed.<sup>5</sup> Plaintiffs have filed a separate motion asking the Court to Modify Case Management Order Number 7 to allow Plaintiffs to supplement their expert disclosures.<sup>6</sup> The

<sup>&</sup>lt;sup>1</sup> In re Zantac (Ranitidine) Litig., 342 A.3d 1131 (Del. 2025).

<sup>&</sup>lt;sup>2</sup> *Id.* at 1134.

<sup>&</sup>lt;sup>3</sup> *Id.* at 1153 (citing *In re Asbestos Litig.*, 911 A.2d 1176, 1202 (Del. Super. Ct. 2006)).

<sup>&</sup>lt;sup>4</sup> *Id.* at 1154.

<sup>&</sup>lt;sup>5</sup> Docket Item ("D.I.") 527.

<sup>&</sup>lt;sup>6</sup> D.I. 534.

outcome of Defendants' Motion depends heavily on the outcome of Plaintiffs' Motion. Therefore, the Court previously advised the parties that Defendants' Motion would not be considered until Plaintiffs' Motion is resolved.<sup>7</sup> I turn to Plaintiffs' motion.

Each side has spent a fair amount of time trying to convince the Court as to what the Supreme Court wanted the next step to be in this litigation. I am not a mind reader, but what is clear is that the Supreme Court left the determination of the next step in this case to the trial court's discretion.

While the case law is not crystal clear, the parties agree that the standard I must apply to the issue of whether to allow Plaintiffs to open discovery is good cause. Each side points me to the well settled Delaware law that cases are to be decided on the merits whenever possible and argues that either has or has not occurred, depending on one's point of view. Both sides point me to the test outlined in *Coleman v. PricewaterhouseCoopers, LLC* and maintain the application of that test favors their side.<sup>8</sup> In *Coleman*, the Delaware Supreme Court articulated a test addressing an application to modify scheduling orders that requires "a balancing of factors including considering the original scheduling order, whether there is good cause to allow the supplement, the prejudice to the opposing party and the possible

<sup>&</sup>lt;sup>7</sup> Defendants have moved for summary judgment maintaining that the Supreme Court decision in this case mandates that all 85,000 plus Zantac cases must be dismissed.

<sup>&</sup>lt;sup>8</sup> Coleman v. PricewaterhouseCoopers, LLC, 902 A.2d 1102 (Del. 2006).

trial delay." I start with *Coleman* even though, as the Defendants point out, *Coleman* addressed a modification of a scheduling order, not a request for a redo a/k/a, a mulligan.

Plaintiffs argue that good cause exists to modify the scheduling order because Plaintiffs diligently prepared and disclosed expert testimony and, according to Plaintiffs, the Supreme Court's decision altered the playing field and changed the rules of the game. Defendants maintain that the Supreme Court's decision did not change the law on either point. I agree with the Defendants.

The Supreme Court opined that the Superior Court misapplied well settled Delaware *Daubert* law.<sup>10</sup> The Court held that the Superior Court's "liberal thrust" standard was the incorrect standard to be applied.<sup>11</sup> The Court reaffirmed well settled existing Delaware law that the Plaintiff has the burden, by a preponderance of the evidence, to meet the *Daubert* threshold.<sup>12</sup> There is nothing new or novel about this statement of Delaware *Daubert* law. This standard was articulated as early as 2006 by then Judge Slights in his seminal decision in *In re Asbestos Litigation*.<sup>13</sup> While the Supreme Court took notice of the 2023 amendments to FRE 702, the Court

-

<sup>&</sup>lt;sup>9</sup> Coleman, 902 A.2d at 1106, n. 6.

<sup>&</sup>lt;sup>10</sup> In re Zantac (Ranitidine) Litig., 342 A.3d at 1134-35, 1151; see also Daubert v. Merrell Dow Pharmaceuticals Inc., 509 U.S. 579 (1993)

<sup>&</sup>lt;sup>11</sup> In re Zantac (Ranitidine) Litig., 342 A.3d at 1146-47, 1151.

<sup>&</sup>lt;sup>12</sup> *Id.* at 1147, 1151.

<sup>&</sup>lt;sup>13</sup> *In re Asbestos Litig.*, 911 A.2d 1176, 1200-01 (Del. Super. Ct. 2006).

held that the amendments were "not substantive," "only clarified the existing federal standard," and were consistent with existing Delaware Law. 14

Nor was the Court's conclusion that the Plaintiffs' experts had to focus their general causation on ranitidine rather than NDMA a new precept of Delaware law. When discussing this issue, the Supreme Court cited to Judge Slight's opinion in *In re Asbestos Litigation*: "a general causation expert's conclusion must reliably bridge the gap by scientifically linking the disease-causing agent to the product at issue." The Supreme Court was relying on well settled Delaware precedent when it held that the trial court's ruling permitting experts to draw conclusions from NDMA studies was "inconsistent with this precedent."

In short, the Supreme Court did not adopt new *Daubert* standards or general causation standards in its opinion. It applied well settled *Daubert* principles and well settled general causation standards. The Plaintiffs argument that expert discovery should start again because of new requirements and standards is simply not the case.

I agree that the Plaintiffs were diligent in the prosecution of the case and the production of expert reports. However, what was produced did not meet the well

<sup>&</sup>lt;sup>14</sup> In re Zantac (Ranitidine) Litig., 342 A.3d at 1146.

<sup>&</sup>lt;sup>15</sup> *Id.* at 1153 (citing *In re Asbestos Litig.*, 911 A.2d 1176, 1202)).

<sup>&</sup>lt;sup>16</sup> *Id.* (citing *In re Asbestos Litig.*, 911 A.2d 1176, 1202)). The court also references the pair of *Grenier* decisions, *Gen. Motors Corp. v. Grenier*, 981 A.2d 524, 530 (Del. 2009) and *Gen. Motors Corp. v. Grenier*, 981 A.2d 531, 538 (Del. 2009), to illustrate how a non-product can be "reliably linked to the exposures caused by the product at issue." *In re Zantac (Ranitidine) Litig.*, 342 A.3d at 1152-54.

settled standards of Delaware law as to what was required of the Plaintiffs' experts to meet their burden of proof. This should not have come as a surprise to the Plaintiffs given the history of this litigation.

In September 2022, nearly 75,000 Ranitidine related personal injury cases were filed in Delaware. At the time of that filing, there was multidistrict litigation pending in Florida. Almost 80% of the Delaware Plaintiffs originally registered their claims in the MDL, and almost 90% of the Delaware Plaintiffs allegedly suffered from one of the five types of cancer for which the MDL Plaintiffs acknowledge there was insufficient evidence of causation.

Prior to the Delaware filings, *Daubert* challenges were made in the federal multidistrict litigation. All the *Daubert* hearings, and every brief except one, were completed before the Delaware filings. On December 6, 2022, the federal MDL court issued its opinion on the pending *Daubert* and summary judgment motions. In its 200-page opinion the MDL court excluded the Plaintiffs' experts' general causation opinions and granted summary judgment.<sup>17</sup> The MDL court found Plaintiffs' experts improperly supported their general causation opinions by extrapolating data "not on the conclusions of any ranitidine-based study author, but instead (for the most part) upon the raw data found in studies that analyzed NDMA-rich food and NDMA-rich air." In short, as in the Delaware litigation, the MDL

<sup>&</sup>lt;sup>17</sup> In re Zantac (Ranitidine) Prods. Liab. Litig., 644 F. Supp. 3d 1075, 1094, 1286 (S.D. Fla. 2022).

<sup>&</sup>lt;sup>18</sup> *Id*. at 1093.

experts did not bridge the required scientific gap. Additionally, as the Defendants point out, the Plaintiffs in this Delaware litigation not only failed to present expert evidence which relied on Ranitidine based studies, but the Plaintiffs doubled down by focusing only on NDMA based studies. This was done with the full knowledge of existing Delaware law on the topic and the MDL conclusion on the issue.

Given this history, the good cause factor of the *Coleman* test favors Defendants.

The second factor that must be considered under the Coleman test is prejudice.<sup>19</sup> There is no doubt that there will be prejudice to the Plaintiffs if the scheduling order is not opened. But there will also be prejudice to the Defendants as well. This case is similar to the *In Re: Onglyza* litigation.<sup>20</sup> In that litigation, which involved only one expert on general causation, the Court spoke to the prejudice the Defendants would experience:

As to prejudice, the parties spent significant resources conducting discovery, litigating multiple discovery disputes, briefing *Daubert* issues, and preparing for and attending consecutive days of hearings in Covington, Kentucky. The parties then spent more time and money on the summary judgment briefing. Plaintiffs now ask the Court to stay a ruling on the defendants' summary judgment motion and reopen expert discovery. They ask for an additional three months just to identify another expert. If the past history of this case is any indication, the additional expert discovery would likely involve significant additional time for multiple disputes with extensive

<sup>&</sup>lt;sup>19</sup> Coleman, 902 A.2d at 1106, n. 6.

<sup>&</sup>lt;sup>20</sup> In re Onglyza (Saxagliptin) & Kombiglyze XR (Saxagliptin & Metformin) Prods. Liab. Litig., 2022 WL 3050665 (E.D. Ky. Aug. 2, 2022), aff'd 93 F.4th 339 (6th Cir. 2024).

briefing, which would be followed by another round of *Daubert* briefing and hearings and dispositive motions. This is unduly prejudicial to the defendants. There is nothing that distinguishes this case from any other where a party produces only one expert witness on a crucial issue who is later excluded. If reopening discovery to permit the party a second chance to identify an admissible expert were the appropriate relief here, then it would be appropriate in every such case.<sup>21</sup>

Judge Caldwell's reasoning is applicable to the instant case. As in *Onglyza*, the instant Defendants have also "spent significant resources conducting discovery, litigating multiple discovery disputes, briefing *Daubert* issues, and preparing for and attending consecutive days of hearings" in Delaware.<sup>22</sup> In fact, the prejudice is greater to the instant Defendants than the Defendants in *Onglyza* because the Plaintiffs seek to disclose three new experts to correct the deficiencies of not one excluded expert, but ten. The prejudice factor of the *Coleman* test favors the Defendants' position.<sup>23</sup>

The final factor, trial delay, favors the Defendants because trial will now be years away if the Court grants the Plaintiffs' request. When the *Coleman* factors are weighed, the balancing clearly favors the Defendants.

The Court is well aware of the ramifications of a decision denying Plaintiffs' motion on the thousands of Plaintiffs. However, this is not the first time that this

<sup>&</sup>lt;sup>21</sup> *Id.* at \*5.

 $<sup>^{22}</sup>$  Id

<sup>&</sup>lt;sup>23</sup> I <u>REJECT</u> Plaintiffs' argument that requiring Defendants to relitigate the general causation issue does not constitute prejudice as a legal matter. My disagreement clearly aligns with those courts that have dismissed cases where there has been a successful *Daubert* challenge.

Court has refused to open the record at the request of Plaintiffs where an expert was excluded. In *Wilant v. BNSF Railway Co.*, Judge Butler excluded a general causation expert.<sup>24</sup> Following the decision, the Plaintiff asked the Court to reconsider its ruling and permit a live hearing so that the general causation expert could respond to the flaws identified in the Court's *Daubert* opinion.<sup>25</sup> Judge Butler rejected this request, holding that the mere fact that the outcome did not go the way Plaintiff hoped is not a basis for giving Plaintiff a mulligan and staring over.<sup>26</sup>

Judge Butler's approach is consistent with that of the U.S. Supreme Court, as well as the majority of federal courts around the country. The U.S. Supreme Court explained in *Weisgram v. Marly Co.*, "[s]ince *Daubert*, ... parties relying on expert evidence have had notice of the exacting standards of reliability such evidence must meet," making it unreasonable for a party to "initially present less than their best expert evidence in the expectation of a second chance should their first try fail." As in *Weisgram*, Plaintiffs here "w[ere] on notice every step of the way that [Defendants were] challenging [their] experts," yet they "made no attempt to add or substitute other evidence." Plaintiffs are not entitled to "shore[] up their cases" now by disclosing new experts that they failed to disclose in the first place. 29

<sup>-</sup>

<sup>&</sup>lt;sup>24</sup> Wilant v. BNSF Ry. Co., 2020 WL 2467076, at \*1 (Del. Super. Ct. May 13, 2020), order vacated in part on denial of reconsideration, 2020 WL 3887881 (Del. Super. Ct. July 9, 2020).

<sup>&</sup>lt;sup>25</sup> Wilant v. BNSF Ry. Co., 2020 WL 3887881, at \*1 (Del. Super. Ct. July 9, 2020).

 $<sup>^{26}</sup>$  *Id* 

<sup>&</sup>lt;sup>27</sup> Weisgram v. Marley Co., 528 U.S. 440, 455 (2000).

<sup>&</sup>lt;sup>28</sup> *Id.* at 456.

<sup>&</sup>lt;sup>29</sup> *Id*.

Similarly, the Seventh Circuit has held that Rule 702 "does not include 'a dress rehearsal or practice run' for the parties."<sup>30</sup> Plaintiffs "had ample time to develop [their] case... during the discovery period," and their "inability to produce admissible expert testimony is due to [their] own actions," namely their failure to meet the long-established standard of reliability under DRE 702.<sup>31</sup> "[F]airness does not require that a Plaintiff, whose expert witness[es] ... ha[ve] been found inadmissible under *Daubert*, be afforded a second chance to marshal other expert opinions and shore up [their] case before the court may consider a Defendant's motion for summary judgment."<sup>32</sup>

The Court understands it is the public policy of Delaware that cases be decided on the merits. The Delaware Supreme Court has made it clear that this policy requires the Court to fashion remedies short of dismissal when expert deadlines have not been met.<sup>33</sup> However, this is not a situation where an expert deadline was not met. The deadline was met with inadequate evidence. This is also not a situation where the Plaintiff was not given a full and fair opportunity to present its case. Plaintiffs were given a full and fair opportunity to present their evidence. Plaintiffs

<sup>&</sup>lt;sup>30</sup> Winters v. Fru-Con Inc., 498 F.3d 734, 743 (7th Cir. 2007) (citing Steen v. Myers, 486 F.3d 1017, 1022 (7th Cir. 2007)) (quoting Hammel v. Eau Galle Cheese Factory, 407 F.3d 852, 859 (7th Cir. 2005)).

<sup>&</sup>lt;sup>32</sup> Nelson v. Tennessee Gas Pipeline Co., 243 F.3d 244, 250 (6th Cir. 2001).

<sup>&</sup>lt;sup>33</sup> Hill v. DuShuttle et. al., 58 A.3d 403, 406 (Del. 2013); see also Christian v. Counseling Resource Associates, Inc., 60 A.3d 1083, 1087 (Del. 2013); see also Drejka v. Hitchens Tire Service, Inc., 15 A.3d 1221, 1224 (Del. 2010). In Drejka, the Court identified the following 6 factors that must be balanced to determine whether the sanction of dismissal is warranted: (1) the party's personal responsibility; (2) the prejudice to the opposing party; (3) the history of the delay; (4) whether the party's conduct was willful or in bad faith; (5) the effectiveness of lesser sanctions; and (6) the meritoriousness of the claim. This test does not apply to the instant situation. Even if it did, the application of the test would still favor the Defendants.)

decided what evidence to present with a well settled body of Delaware law on the topic, as well as a Federal MDL decision that pointed out the flaws of Plaintiffs experts. They chose to proceed ahead as they did and cannot now be heard to complain that they should get a mulligan.

Plaintiffs, first in the MDL and now in this Court, have been given adequate opportunity to muster what evidence they could gather to satisfy the general causation standard and show that various cancers result from the ingestion of Zantac.<sup>34</sup> Unfortunately, the evidence Plaintiffs choose to present did not meet the standard required under Delaware law. To afford Plaintiffs the relief requested would essentially allow Plaintiffs to start over. That would be fundamentally unfair to Defendants.

Plaintiffs point the Court to the decision in *Rimbert v. Eli Lilly & Co.* to argue that it is an abuse of discretion for a trial court to fail to grant a request to open the evidence to add experts where a higher court reversed the lower court decision on a *Daubert* challenge.<sup>35</sup> I do not read *Rimbert* as broadly as the Plaintiffs. As set forth in the *Rimbert* opinion, that case involved a unique set of facts. In *Rimbert*, the first trial court judge denied Defendant's *Daubert* challenge.<sup>36</sup> After the first judge stepped aside due to some unspecified conflict of interest, a second trial court

<sup>&</sup>lt;sup>34</sup> In their moving papers, Plaintiffs suggest that there is "new science" which they contend satisfies the *Daubert* requirements under the Zantac decision. Even at this late date, Plaintiffs have failed to identify this new evidence. The lack of identification suggests to the Court that the evidence mustered, whatever it is, remains lacking.

<sup>&</sup>lt;sup>36</sup> Rimbert v. Eli Lilly & Co., 647 F.3d 1247, 1250 (10th Cir. 2011).

reconsidered the *Daubert* decision, reached an opposite conclusion from the first judge, and granted Defendant's motion.<sup>37</sup> A close reading of *Rimbert* leads to a conclusion that it is not as broad as Plaintiffs suggest. In explaining its decision, the *Rimbert* Court wrote the following:

In the normal course of events, district courts are well within permissible discretion to deny the opportunity to name a new expert after discovery has closed and a party receives an unfavorable *Daubert* ruling. Here, however, the district court was not faced with a case that had proceeded normally, and the unique circumstances presented called for flexibility in the discovery schedule. In light of the procedural oddities of the case, including an initial favorable *Daubert* ruling, and the district court's unorthodox consideration of the motion for a new scheduling order as if it had been made at a prior date when the case was in a vastly different posture, this court is left with the "definite and firm conviction" that disallowing Rimbert's request for additional time to name a substitute expert was an abuse of discretion.<sup>38</sup>

The instant case does not involve the unique facts that were present in *Rimbert*. In fact, if there are unique facts in the present case it would be that the Plaintiffs choose a similar litigation path in Delaware as they had taken in the Federal MDL, which resulted in a successful *Daubert* challenge by the Defendants. To the extent these facts are unique, they compel denial of Plaintiffs' motion.

-

<sup>&</sup>lt;sup>37</sup> *Id.* at 1250-1251.

<sup>&</sup>lt;sup>38</sup> Rimbert, 647 F.3d at 1256 (citation omitted).

The question now becomes: what Plaintiffs are bound by this decision. This

issue has not been addressed by the parties in any of the papers filed. It must be

addressed.

Plaintiffs' Reply to the Defendants' Motion for Summary Judgment did not

address the merits but simply stated that the substance of the reply would need to

await the Court's decision on the Plaintiffs' motion. On or before January 9, 2026,

all parties should file a brief addressing the question of which Plaintiffs should be

bound by this order. At the same time Plaintiffs file their brief on this point, they

should file a supplemental answering brief addressing Defendants' Motion for

Summary Judgment in light of this opinion. On or before January 30, 2026, both

parties should file a reply to the other side's brief addressing the question of which

Plaintiffs should be bound by this decision and the Defendant at the same time

should file its reply brief in support of its motion for summary judgment.

IT IS SO ORDERED.

/s/ Francis J. Jones, Jr.

Francis J. Jones, Jr., Judge

cc:

Counsel of Record via File & Serve Xpress

13