EFiled: Jun 20 2024 09:29AM EDT
Transaction ID 73438826
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 |

**MOTION FOR LEAVE TO FILE *AMICI CURIAE* BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, THE NATIONAL ASSOCIATION OF MANUFACTURERS, BIOTECHNOLOGY INNOVATION ORGANIZATION, DELAWARE BIOSCIENCE ASSOCIATION, AND PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF THE DEFENDANTS' APPLICATION FOR INTERLOCUTORY REVIEW**

The Chamber of Commerce of the United States of America (the "Chamber"), the National Association of Manufacturers ("NAM"), the Biotechnology Innovation Organization ("BIO"), Delaware BioScience Association ("Delaware Bio"), and Pharmaceutical Research and Manufacturers of America ("PhRMA"), respectfully move for leave to participate in this action as amici curiae in support of the Defendants' Application for Interlocutory Review of the Court's Denial of Defendants' Motion to Exclude Plaintiffs' General-Causation Experts ("Application for Interlocutory Review") and file the proposed amici brief attached as **Exhibit A**.

## BACKGROUND

1. This case involves over 73,000 individual personal injury claims alleging that pharmaceuticals containing ranitidine caused various forms of cancer. On May 31, 2024, this Court denied Defendants' motion to exclude Plaintiffs'

general causation experts, reaching the opposite conclusion than the Southern District of Florida did in federal multidistrict litigation. Because of the scale of this litigation and the importance of the standard that Delaware courts apply to evaluate expert testimony, the Defendants filed their Application for Interlocutory Review on June 10, 2024. Amici, which include both national and local industry organizations, seek leave to file the attached amici brief because of their members' interest in the important legal issues at stake.

## I. Identity of Amici and Their Interest in the Litigation

2. The Chamber is the world's largest business federation. The Chamber represents approximately 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the state and federal courts.

3. To that end, the Chamber regularly files amicus curiae briefs in cases, like this one, that raise issues of concern to the nation's business community, including cases addressing expert testimony. The Chamber has participated as amicus curiae in cases around the United States addressing legal standards in tort

law. The Supreme Court of Delaware has granted the Chamber leave to file amicus briefs on at least 13 prior occasions.[1]

4. The National Association of Manufacturers ("NAM") is the largest manufacturing association in the United States, representing small and large manufacturers in all 50 states and in every industrial sector. Manufacturing employs nearly 13 million men and women, contributes approximately $2.89 trillion to the United States economy annually, has the largest economic impact of any major sector, and accounts for over half of private-sector research and development. The NAM is the voice for the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States. The NAM frequently files amicus briefs in defense of

---

[1] *See Kellner v. AIM Immunotech, Inc.*, Docket No. 3,2024 (Del. Mar. 18, 2024); *Cantor Fitzgerald LP v. Braid Ainslie, et al.*, Docket No. 162,2023 (Del. May 10, 2023); *Employers Insurance Company of Wausau, et al. v. First State Orthopaedics, P.A.*, Docket No. 27,2023 (Del. Jan. 25, 2023); *State of Delaware, ex rel. Kathleen Jennings, Attorney General of the State of Delaware v. Monsanto Company, et al.*, Docket No. 279,2022 (Del. Aug. 09, 2022); *In Re Versum Materials, Inc. Stockholder Litigation*, Docket No. 266,2020 (Del. Aug. 14, 2020); *Matthew B. Salzberg, et al. v. Matthew Sciabacucchi*, Docket No. 346,2019 (Del. Aug. 05, 2019); *California State Teachers' Retirement System v. Alvarez, Aida M.*, Docket No. 295,2016 (Del. June 10, 2016); *International Paper Co v. Mary Anne Hudson*, Docket No. 508,2015 (Del. Sept. 17, 2015); *Genuine Parts Company v. Ralph Allan Cepec and Sandra Faye Cepec*, Docket No. 528,2015 (Del. Sept. 30, 2015); *Stayton v. Delaware Health Corporation et al.*, Docket No. 601,2014 (Del. Oct. 23, 2014); *Pyott, David v. Louisiana Municipal Police Employees Retirement System*, Docket No. 380,2012 (Del. July 10, 2012); *Riedel, Lillian vs ICI Americas Inc.*, Docket No. 156,2008 (Del. Mar. 25, 2008); *Pfeffer, Beverly et al vs Redstone et al.*, Docket No. 115,2008 (Del. Feb. 28, 2008).

legal rules that ensure a level playing field for manufacturers. *See* NAM, *NAM Legal Center*.[2]

5. BIO is the world's largest life sciences trade association, representing nearly 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and abroad. BIO's members are involved in the research and development of innovative biotechnology products that will help to solve some of society's most pressing challenges, such as sustainably growing nutritious food, improving animal health and welfare, enabling manufacturing processes that reduce waste and minimize water use, and advancing the health and well-being of our families. In particular, BIO advocates for innovation in biotechnology in the healthcare space, based on sound science and peer-reviewed research, to bring treatments and cures to patient populations in the U.S. and throughout the world.

6. The Delaware BioScience Association (Delaware Bio) is a catalyst for bioscience innovation in Delaware. It serves pharmaceutical and biotechnology firms, medical device manufacturers, agricultural biotech and chemical companies, research and testing companies, hospitals and medical institutions, academic partners and other organizations and companies that support them, with the goal of expanding our state's vibrant science economy. Delaware Bio's more than 170

[2] Available at https://www.nam.org/legal-expertise/legal-center.

member companies and organizations are of every size, from global leaders to small start-ups, representing 11,000+ innovation-based jobs vital to Delaware's economic future. Delaware Bio's members' continued investment in the development of innovative medicines, vaccines, and other life-changing technologies is rooted in sound science, and maintaining the *Daubert* standard is vital to that public and national security interest.

7. The Pharmaceutical Research and Manufacturers of America ("PhRMA") represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. Over the last decade, PhRMA member companies have more than doubled their annual investment in the search for new treatments and cures, including nearly $101 billion in 2022 alone. PhRMA's mission is to advocate public policies that encourage the discovery of life-saving and life-enhancing medicines. PhRMA closely monitors legal issues that affect the pharmaceutical industry and frequently participates in such cases as an amicus curiae.

## II. The Amici Brief Will Assist the Court in a Case of Public Interest

8. Amicus briefs may "assist the Court by 'supplementing the efforts of counsel . . . in a case of general public interest'" and "draw attention to 'broader legal or policy implications that might otherwise escape its consideration in the

narrow context of a specific case.'" *La. Mun. Police Emps. Ret. Sys. v. Hershey Co.*, 2013 WL 1776668, at *1 (Del. Ch. Apr. 16, 2013) (quoting *Giammalvo v. Sunshine Min. Co.*, 644 A.2d 407, 409 (Del. 1994)) (ellipsis in original); *see also, e.g., Jimenez v. Palacios,* 250 A.3d 814, 826 (Del. Ch. 2019), as revised (Aug. 12, 2019); *In re Trulia, Inc. Stockholder Litig.,* 129 A.3d 884, 890 (Del. Ch. 2016).

9. The standard for admission of expert testimony has sweeping consequences in cases including mass torts and products liability litigation, significantly affecting amici's members and consumers. Amici do not duplicate the parties' arguments by addressing the specific expert opinions at issue. Instead, their brief discusses, from a policy perspective, the congruence of Delaware and federal law with respect to the admission of expert testimony and the effect of the Court's decision on litigants and the Delaware court system.

## III. Positions of the Parties

10. Defendants consent to the filing of the attached amicus brief. Plaintiffs' counsel were contacted by email for their position on June 12, 2024 and June 17, 2024, but have not responded.

## CONCLUSION

For the foregoing reasons, amici respectfully request that the Court grant them leave to file the attached amici curiae brief.

Dated: June 17, 2024

*Of Counsel*:

Robert M. Palumbos
Andrew R. Sperl
**DUANE MORRIS LLP**
30 South 17th Street
Philadelphia, PA 19103
Telephone: (215) 979-1000
rmpalumbos@duanemorris.com
arsperl@duanemorris.com

**DUANE MORRIS LLP**

*/s/ Richard L. Renck*

Richard L. Renck (#3893)
Tracey E. Timlin (#6469)
1201 North Market St., Suite 501
Wilmington, DE 19801
Telephone: (302) 657-4906
rlrenck@duanemorris.com
ttimlin@duanemorris.com

*Counsel for Amici Curiae Chamber of Commerce of the United States of America, National Association of Manufacturers, Biotechnology Innovation Organization, Delaware BioScience Association, and Pharmaceutical Research and Manufacturers of America*

**IN THE SUPERIOR COURT OF THE STATE OF DELAWARE**

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

**NOTICE OF MOTION**

PLEASE TAKE NOTICE that the Motion for Leave to File *Amici Curiae* Brief of the Chamber of Commerce of the United States of America, The National Association of Manufacturers, Biotechnology Innovation Organization, Delaware Bioscience Association, and Pharmaceutical Research and Manufacturers of America in Support of the Defendants' Application for Interlocutory Review will be presented at the convenience of the Court.

*[Remainder of page intentionally left blank]*

Dated: June 17, 2024

*Of Counsel*:

Robert M. Palumbos
Andrew R. Sperl
**DUANE MORRIS LLP**
30 South 17th Street
Philadelphia, PA 19103
Telephone: (215) 979-1000
rmpalumbos@duanemorris.com
arsperl@duanemorris.com

**DUANE MORRIS LLP**

*/s/ Richard L. Renck*

Richard L. Renck (#3893)
Tracey E. Timlin (#6469)
1201 North Market St., Suite 501
Wilmington, DE 19801
Telephone: (302) 657-4906
rlrenck@duanemorris.com
ttimlin@duanemorris.com

*Counsel for Amici Curiae Chamber of Commerce of the United States of America, National Association of Manufacturers, Biotechnology Innovation Organization, Delaware BioScience Association, and Pharmaceutical Research and Manufacturers of America*

**IN THE SUPERIOR COURT OF THE STATE OF DELAWARE**

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

**[PROPOSED] ORDER**

WHEREAS, upon review and consideration of the Motion for Leave to File *Amici Curiae* Brief of the Chamber of Commerce of the United States of America, The National Association of Manufacturers, Biotechnology Innovation Organization, Delaware Bioscience Association, and Pharmaceutical Research and Manufacturers of America in Support of the Defendants' Application for Interlocutory Review (the "Motion"), and any opposition thereto,

IT IS HEREBY ORDERED, this ___ day of _____, 2024, as follows:

1. The Motion is GRANTED.

2. The *Amici Curiae* Brief of the Chamber of Commerce of the United States of America, The National Association of Manufacturers, Biotechnology Innovation Organization, Delaware Bioscience Association, and Pharmaceutical Research and Manufacturers of America in Support of the Defendants' Application for Interlocutory Review, attached as Exhibit A to the Motion, shall be filed as soon as practicable.

The Honorable Vivian L. Medinilla

# EXHIBIT A

**IN THE SUPERIOR COURT OF THE STATE OF DELAWARE**

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

***AMICI CURIAE* BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, THE NATIONAL ASSOCIATION OF MANUFACTURERS, BIOTECHNOLOGY INNOVATION ORGANIZATION, DELAWARE BIOSCIENCE ASSOCIATION, AND PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF THE DEFENDANTS' APPLICATION FOR INTERLOCUTORY REVIEW**

Dated: June 17, 2024


*Of Counsel*:

Robert M. Palumbos
Andrew R. Sperl
**DUANE MORRIS LLP**
30 South 17th Street
Philadelphia, PA 19103
Telephone: (215) 979-1000
rmpalumbos@duanemorris.com
arsperl@duanemorris.com

**DUANE MORRIS LLP**

Richard L. Renck (#3893)
Tracey E. Timlin (#6469)
1201 North Market St., Suite 501
Wilmington, DE 19801
Telephone: (302) 657-4906
rlrenck@duanemorris.com
ttimlin@duanemorris.com

*Counsel for Amici Curiae Chamber of Commerce of the United States of America, National Association of Manufacturers, Biotechnology Innovation Organization, Delaware BioScience Association, and Pharmaceutical Research and Manufacturers of America*

## TABLE OF CONTENTS

**Page**

## TABLE OF AUTHORITIES

**Cases**

**Statutes**



**Other Authorities**

Amici Curiae the Chamber of Commerce of the United States of America (the "Chamber"), the National Association of Manufacturers ("NAM"), the Biotechnology Innovation Organization ("BIO"), the Delaware BioScience Association ("Delaware Bio"), and Pharmaceutical Research and Manufacturers of America ("PhRMA") file this brief in support of the Defendants' Application for Interlocutory Review of the Court's Denial of Defendants' Motion to Exclude Plaintiffs' General-Causation Experts. The Court's May 31, 2024 Omnibus Order raises significant issues about the standard that applies in Delaware to evaluate expert testimony, and both litigants and Delaware courts will benefit from the Supreme Court's prompt review.

## STATEMENT OF INTEREST

The Chamber is the world's largest business federation. The Chamber represents approximately 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. A significant number of the Chamber's members are incorporated in Delaware. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the state and federal courts.

To that end, the Chamber regularly files amicus curiae briefs in cases, like this one, that raise issues of concern to the nation's business community, including cases

addressing expert testimony. The Chamber has participated as amicus curiae in cases around the United States addressing legal standards in tort law. *See, e.g., Drammeh v. Uber Techs., Inc.*, Ninth Cir. No. 22-36038; *Kuciemba v. Victory Woodworks, Inc.*, 531 P.3d 924 (Cal. 2023); *Helena Chem. Co. v. Cox*, 664 S.W.3d 66 (Tex. 2023) (expert); *Nemeth v. Brenntag N. Am.*, 194 N.E.3d 266 (N.Y. 2022) (expert).

The NAM is the largest manufacturing association in the United States, representing small and large manufacturers in all 50 states and in every industrial sector. Manufacturing employs nearly 13 million men and women, contributes $2.89 trillion to the United States economy annually, has the largest economic impact of any major sector, and accounts for over half of private sector research and development in the nation. The NAM is the voice for the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States. The NAM frequently files amicus briefs in defense of legal rules that ensure a level playing field for manufacturers. *See* NAM, *NAM Legal Center*.[1] A substantial number of the NAM's members are incorporated in Delaware.

BIO is the world's largest life sciences trade association, representing nearly 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and abroad. BIO's members are

[1] Available at https://www.nam.org/legal-expertise/legal-center.

involved in the research and development of innovative biotechnology products that will help to solve some of society's most pressing challenges, such as sustainably growing nutritious food, improving animal health and welfare, enabling manufacturing processes that reduce waste and minimize water use, and advancing the health and well-being of our families. In particular, BIO advocates for innovation in biotechnology in the healthcare space, based on sound science and peer-reviewed research, to bring treatments and cures to patient populations in the U.S. and throughout the world.

Delaware Bio is a catalyst for bioscience innovation in Delaware. It serves pharmaceutical and biotechnology firms, medical device manufacturers, agricultural biotech and chemical companies, research and testing companies, hospitals and medical institutions, academic partners and other organizations and companies that support them, with the goal of expanding our state's vibrant science economy. Delaware Bio's more than 170 member companies and organizations are of every size, from global leaders to small start-ups, representing 11,000+ innovation-based jobs vital to Delaware's economic future. Delaware Bio's members' continued investment in the development of innovative medicines, vaccines, and other life-changing technologies is rooted in sound science, and maintaining the *Daubert* standard is vital to that public and national security interest.

PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. Over the last decade, PhRMA member companies have more than doubled their annual investment in the search for new treatments and cures, including nearly $101 billion in 2022 alone. PhRMA's mission is to advocate public policies that encourage the discovery of life-saving and life-enhancing medicines. PhRMA closely monitors legal issues that affect the pharmaceutical industry and frequently participates in such cases as an amicus curiae.

## SUMMARY OF THE ARGUMENT

This Court's Omnibus Order allowing the Plaintiffs' general causation experts to offer their opinions at trial should be certified for interlocutory review. It raises a "substantial issue of material importance" that is "exceptional," particularly in the context of mass-tort litigations like this one. *See* Supr. Ct. R. 42(b)(i), (ii) (describing standards for granting interlocutory review). Further, as described below, the Court's opinion raises a potential conflict with other Delaware precedent. *See* Supr. Ct. R. 42(b)(iii)(B).

Interlocutory review will also "serve considerations of justice" including fairness and judicial administration. *See* Supr. Ct. R. 42(b)(iii)(H). Defendants here are involved in nationwide litigation concerning Zantac, and may be subject to increased

litigation costs and immense liability if Delaware adopts a more lenient application of *Daubert* and D.R.E. 702. Prompt Supreme Court review will serve important considerations of justice by resolving the issues raised in the Court's opinion before further litigation proceeds. Prompt review is also appropriate and desirable to prevent forum shopping against other businesses.

Amici, including both national and Delaware industry associations, write separately to emphasize the importance of the Supreme Court's prompt review to the Delaware and national business communities. Not only is consistency in the law important to deter forum shopping, but the decision to admit expert testimony in products liability cases has significant impacts on businesses, industry, and even consumers. This significant litigation, involving tens of thousands of litigants, exemplifies those concerns. Indeed, for most of the claimants, this case represents a second bite at the apple, and a second liability exposure for Defendants on those same claims. Because so many businesses make Delaware their corporate home and are amenable to jurisdiction in the State, Delaware's approach to the admission of expert testimony is particularly significant to them. For the reasons described below, amici and their membership are concerned about the ramifications of this case proceeding without the opportunity for Supreme Court review of this Court's opinion on expert testimony, and they respectfully ask the Court to grant the Defendants' Application for Interlocutory Review.

## ARGUMENT

### I. The Court's opinion raises substantial issues of material importance to its gatekeeping role.

Under both federal and Delaware law, "[i]n order for expert testimony to be admissible, the trial judge must act as a gatekeeper and determine that the evidence is both (1) reliable and (2) relevant." *Tumlinson v. Advanced Micro Devices, Inc.*, 106 A.3d 983, 990 (Del. 2013).

Before *Daubert* and the Delaware Supreme Court decisions adopting it, many courts determining the admissibility of expert testimony focused on "general acceptance" of the potential expert's methods in the relevant field. *Daubert v. Merrell Down Pharms., Inc.*, 509 U.S. 579, 585-86 (1993). That standard, however, was displaced by Federal Rule of Evidence 702, which requires a rigorous gatekeeper role for trial courts to ensure that juries are not unduly swayed by unreliable, unscientific opinions cloaked in the false authority of expertise. *See id.* at 589 ("[U]nder the Rules the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable."). D.R.E. 702 imposes the same requirements. *Tumlinson*, 106 A.3d at 990. Moreover, as described below, recent amendments to Federal Rule of Evidence 702 confirm that its purpose is to keep unreliable science from the jury.

Application of the careful standard laid out in the federal and Delaware rules and explained in *Daubert* enables lower courts to resolve cases "finally and quickly"

and to prevent "[c]onjectures that are probably wrong" and "are of little use . . . in the project of reaching a quick, final, and binding legal judgment—often of great consequence—about a particular set of events in the past." *Daubert*, 509 U.S. at 597.[2] Consistent and correct application of D.R.E. 702 is particularly important in cases like this one, where similar litigation has been filed across the country and in both state and federal courts. Delaware and federal precedent both recognize the importance of the court as a gatekeeper to make sure that unreliable science does not go to the jury. *See, e.g., Tumlinson*, 81 A.3d at 1269 ("For proffered expert testimony to be admissible, the trial court must act as a gatekeeper to determine whether the expert opinion testimony is both (i) relevant and (ii) reliable.") (citing *Kumho Tire Co. v. Carmichael,* 526 U.S. 137, 141 (1999)).

Exercising their gatekeeping role, courts routinely exclude unreliable expert evidence of general causation in products liability cases, including where experts utilize unreliable, results-oriented methodologies, including by cherry-picking data, treating research inconsistently, and not applying the same rigor that they do in their

[2] An object of *Daubert* is to "make sure that when scientists testify in court they adhere to the same standards of intellectual rigor that are demanded in their professional work" – in other words, "[l]aw lags science; it does not lead it." *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 318-19 (7th Cir. 1996) (Posner, J.) That reasoning is particularly salient in cases like this one, where, as noted below, there is established epidemiology and it shows no link between ranitidine and the cancers at issue. (*See below* at 16).

own work outside the courtroom.[3] *See, e.g., In re Onglyza (Saxagliptin) and Kombiglyze Prods. Liab. Litig.*, 93 F.4th 339, 347-48 (6th Cir. 2024); *In re Zoloft (Sertraline Hydrocloride) Prods. Liab. Litig.*, 2015 WL 7776911, at *16 (E.D. Pa. Dec. 2, 2015); *In re Lipitor (Atorvasttin Calcium) Marketing, Sales Practices and Prods. Liab. Litig.*, 174 F. Supp. 3d 911, 931 (D.S.C. 2016); *In re Mirena IUS Levo-norgestrel-Related Prods. Liab. Litig. (No. II)*, 341 F. Supp. 3d 213, 296 (S.D.N.Y. 2018); *In re Viagra (Sildenafil Citrate) and Cialis (Tadalafil) Prods. Liab. Litig.*, 424 F. Supp. 3d 781, 796-97 (N.D. Cal. 2020); *In re Incretin-Based Therapies Prods. Liab. Litig.*, 524 F. Supp. 3d 1007, 1036-40 (S.D. Cal. 2021); *In re Acetaminophen—ASD-ADHD Prods. Liab. Litig.*, __ F. Supp. 3d __, 2023 WL 8711617, at *18, 20, 36, 39-40 (S.D.N.Y. Dec. 18, 2023). Of course, federal decisions like these are not binding on Delaware courts, but the fact that Delaware courts have traditionally been aligned with federal law has provided valuable predictability to litigants.

Amici include both national and Delaware industry organizations. The business community they represent, including their members, is greatly impacted by decisions on admissibility of expert testimony, particularly in the context of products-liability actions that have the potential to affect significant numbers of other litigants. As this Court recognized, "[i]n the products liability context, an incorrect decision

[3] For an example of similar testimony in this case, see Defendants' Application for Interlocutory Review. (*See* App. for Interlocutory Review at 29 n.10).

can . . . deprive a plaintiff of warranted compensation while discouraging other similarly situated individuals from trying to obtain compensation"; but, on the other hand, just as importantly, "it can improperly impose liability in a manner that will cause abandonment of an important product or technology." (Op. at 14 (quoting *In re Asbestos Litig.*, 911 A.2d 1176, 1200 (Del. Super. 2006))).

Corporations nationwide, including many members of amici, have long chosen to make Delaware their corporate home. *See* Delaware Division of Corporations, *About the Division of Corporations* ("More than 66% of the Fortune 500 have chosen Delaware as their legal home.").[4] They have had good reason to do so given reputation of the State's judiciary for fairness and predictability. "Delaware has traditionally been popular for incorporation because of its knowledgeable and responsive court system." Francisco V. Aguilar and Benjamin P. Edwards, *Why Public Companies Are Leaving Delaware for Nevada*, Wall Street Journal (June 9, 2024). Indeed, Delaware ranked first in the Chamber's most recent legal climate survey, which considers the State's approach to "[s]cientific and technical evidence" in addition to "[t]reatment of class action suits and mass consolidation suits"; "treatment of tort and contract litigation"; "[e]nforcing meaningful venue requirements"; and "[d]amages"; among other issues. U.S. Chamber Institute for Legal Reform, *2019*

[4] Available at https://corp.delaware.gov/aboutagency/.

*Lawsuit Climate Survey: Ranking the States: A Survey of the Fairness and Reasonableness of State Liability Systems* at 2, 5 (Sept. 2019)[5]; *see also* Delaware Courts: Judicial Branch, *State Liability Systems Ranking Study* (recognizing top spot in survey results).[6]

To the extent the Court has suggested that Delaware in fact applies a different, more lenient standard (*see* Section II below), litigants in this case and others would benefit from the Supreme Court's review and clarification. Such review will ensure the predictability and consistency that have been hallmarks of the Delaware judiciary, which will "serve" important "considerations of justice." Supr. Ct. R. 42(b)(iii)(H).

## II. This Court's opinion creates a conflict with other Delaware precedent that follows *Daubert* and its progeny.

The expert testimony at issue in this case involves similar claims and the same product as in the federal multidistrict litigation ("MDL"). *See In re Zantac (Ranitidine) Prods. Liab. Litig.*, 644 F. Supp. 3d 1075 (S.D. Fla. 2022). As this Court correctly observed, the federal MDL's decision is not binding on it, and this Court exercises its own discretion in evaluating particular expert testimony. However, this Court emphasized its view that "the jurisprudence reflected in the Floridian *Zantac*

[5] Available at https://instituteforlegalreform.com/wp-content/uploads/2020/10/2019-Lawsuit-Climate-Survey-Ranking-the-States.pdf.

[6] Available at https://courts.delaware.gov/superior/top_court.aspx.

[MDL] differs from Delaware's." (Op. at 17). Of course, federal case law is not controlling in Delaware courts (except where it has been adopted by Delaware's Supreme Court, like *Daubert* itself). However, the Court's explication of Delaware law stands in conflict with other Delaware precedent that is consistent with the *Daubert* standard articulated in federal and other state courts.

Delaware courts have looked to federal law for guidance in interpreting D.R.E. 702 since the Delaware Supreme Court adopted the *Daubert* standard 25 years ago. The Delaware Supreme Court has held that *Daubert* and its progeny are the "correct interpretation of Delaware Rule of Evidence 702." *M.G. Bancorporation, Inc. v. Le Beau*, 737 A.2d 513, 522 (Del. 1999); *see also Hudson v. State*, 312 A.3d 615, 625 (Del. 2024); *Tumlinson*, 81 A.3d at 1269; *Perry v. Berkley*, 996 A.2d 1262, 1267 (Del. 2010). Delaware "Rule 702 substantially mirrors the corresponding federal rule of evidence[,] and Delaware courts find federal precedent of assistance when making expert admissibility determinations." *Henlopen Hotel, Inc. v. United Nat'l Ins. Co.*, 2020 WL 233333, at *2 (Del. Super. Jan. 10, 2020); *accord Guy v. Andreas Stihl AG & Co. KG*, 2011 WL 601328, at *2 (Del. Super. Jan. 19, 2011); *see also M.G. Bancorporation*, 737 A.2d at 521; *O'Connell v. LeBloch*, 2000 WL 703712, at *2 (Del. Super. April 19, 2000); *Perry*, 996 A.2d at 1267; *Crowhorn v. Boyle*, 793 A.2d 422, 427-28 (Del Super. March 14, 2002).

Moreover, in applying D.R.E. 702, Delaware courts look not only to federal law but to law in other jurisdictions whose evidentiary standards parallel Federal Rule of Evidence 702. *See Perry*, 996 A.2d at 1269-70 (citing sources including *The New Wigmore*, *Moore's Federal Rules Pamphlet*, *Weinstein's Federal Evidence*, and Virginia common law). That is, Delaware's interpretation of D.R.E 702 is congruent with *Daubert* jurisdictions nationwide, and amici and their members have long relied on the predictability that follows.

The factors that Delaware courts consider in applying D.R.E. 702 are consistent with *Daubert*. As this Court has previously recognized, federal and Delaware courts consider "several factors that may be useful" in their role as "gatekeeper[.]" *Guy*, 2011 WL 601328, at *2 (identifying *Daubert* four-factor test). Delaware courts employ an additional "five-step test to determine the admissibility of scientific or technical expert testimony." *Id.* at *3. That test, however, is "[c]onsistent with *Daubert*." *Id.*; *see also Sturgis v. Bayside Health Ass'n Chartered*, 942 A.2d 579, 584 (Del. 2007) ("We, based on the D.R.E., require, in addition to *Daubert*, a five-step test to determine the admissibility of scientific or technical expert testimony."); *Crowhorn*, 793 A.2d at 430 (describing five-part test as "similar" to *Daubert* factors); *Scaife v. Astrazeneca LP*, 2009 WL 1610575, at *14 (Del. Super. June 9, 2009) (same).

Recent amendments to Federal Rule of Evidence 702 did not change the law. Instead, they clarified the federal rule in response to some courts' incorrect, more lenient application of it. As such, following the amendments, federal law remains instructive to interpret D.R.E. 702. Indeed, the Delaware Supreme Court recently confirmed that "[D.R.E.] 702 is substantively similar to its federal counterpart, Federal Rule of Evidence 702, and we follow the United States Supreme Court's interpretation of F.R.E. 702 in *Daubert*." *Hudson*, 312 A.3d at 625. The 2023 amendments made two clarifying changes to the rule. First, they added language expressly providing that it is the burden of the testimony's proponent to "demonstrate[] to the court that it is more likely than not that" the requirements of the rule are satisfied. *See* Fed. R. Evid. 702 Advisory Committee's Note to 2023 Amendment. That follows "the preponderance of the evidence standard that applies to most of the admissibility requirements set forth in the evidence rules" and was included simply to correct errors by "many courts [holding] that the critical questions of the sufficiency of an expert's basis, and the application of the expert's methodology, are questions of weight and not admissibility." *Id.*

Second, the wording of the fourth factor of the test was changed to make it clear that the "expert's opinion reflects a reliable application of" reliable principles and methods "to the facts of the case." Fed. R. Evid. 702(d). That amendment was intended "to emphasize that each expert opinion must stay within the bounds of what

can be concluded from a reliable application of the expert's basis and methodology." Fed. R. Evid. 702 Advisory Committee's Note to 2023 Amendment. In other words, the amendment was *not* intended to be a substantive change, but rather to clarify how Rule 702, last amended in 2000, was intended to be applied. *See* Fed. R. Evid. 702 Advisory Committee's Note to 2000 Amendment (stating that "the proponent has the burden of establishing that the pertinent admissibility requirements are met by a preponderance of the evidence."); *see also* U.S. Chamber Institute for Legal Reform, *Comments to the Advisory Committee on Evidence Rules and its Rule 702 Subcommittee* ("2020 ILR Comment") at 2-3 (Nov. 9, 2020).[7]

Although the Court's opinion recognizes the applicability of *Daubert* to the application of D.R.E. 702 (Op. at 8-9), its reasoning suggests that the Delaware standard may be more lenient than the federal standard in important respects. For instance, relying on non-Delaware law, this Court held that issues with expert testimony "go to [its] weight, not the admissibility." (Op. at 14 (quoting *Kennedy v. Collagen Corp.*, 161 F.3d 1226, 1230-31 (9th Cir. 1998)). That view, based on Ninth Circuit precedent, is inconsistent with the federal Advisory Committee's clarification that it is an "incorrect application of Rules 702 and 104(a)" to hold that "the critical questions of the sufficiency of an expert's basis, and the application of the

[7] Available at https://instituteforlegalreform.com/letters-comments-petitions/ilr-comments-to-the-advisory-committee-on-evidence-rules/

expert's methodology, are questions of weight and not admissibility." Fed. R. Evid. 702 Advisory Committee's Note to 2023 Amendment. Given the similarities between Federal and Delaware Rule of Evidence 702, the Supreme Court should consider whether the Advisory Committee's clarifying guidance is equally applicable in Delaware, or whether Delaware's standard now departs from the federal standard.

The Court's opinion also suggests that Delaware case law diverges from federal law in several respects that are particularly important to litigants, including the Delaware-incorporated members of amici, in the mass-tort and products-liability context. (Op. at 15-16). Those include key issues such as the use of animal studies, the role of statistical significance, and the importance of threshold dose. In so doing, the Court relied largely on the Superior Court's earlier decision in *Barrera v. Monsanto Co.*, 2019 WL 2331090 (Del. Super. May 31, 2019).

However, it does not follow from *Barrera* that Delaware's standard for the admissibility of expert testimony is more lenient than the federal standard. In fact, the court in *Barrera* explained that it was "guided by the MDL Court [in that litigation] and the conclusions reached by that Court" and "defer[red] to the MDL Court's assessment of the science and underlying studies." *Id.* at *2. Nevertheless, this Court's reasoning makes it substantially easier for plaintiffs in mass-tort and products-liability cases to reach a jury in Delaware than in the federal courts, even with questionable science. The Supreme Court should have the opportunity to consider

whether the standard this Court applied departed too significantly from the federal standard it has previously adopted.[8]

The Court also relied upon this Court's earlier decision in *Long v. Weider Nutrition Group, Inc.*, 2004 WL 1543226, at *1 (Del. Super. June 25, 2004) to adopt a position of "judicial restraint" in light of the concern that "[t]he first of several victims of a new toxic tort should not be barred from having their day in court" because the science particular to their condition is not fully developed. (*See* Op. at 14-15 (quoting *Long*)). However, in *Long*, the product at issue was a dietary supplement, so there was an absence of "the type of epidemiological studies that would have been conducted if [the product] were a prescription medication." *Id.* at *5. That concern is absent here, where "no fewer than sixteen published and peer-reviewed epidemiological studies" have considered whether ranitidine causes the limited types of cancer at issue here. (*See* Defs.' App. For Interlocutory Review at 7). The Supreme Court should have the opportunity to consider whether the "judicial restraint"

[8] Epidemiology and peer review have been interpreted to be as relevant in Delaware law as they are in other jurisdictions that apply the *Daubert* standard. For instance, Delaware courts recognize that "non-peer reviewed weight-of-the-evidence opinion[s]" are "most suspect categorically" because they are "an admission that the available epidemiology is weak." *Tumlinson v. Advanced Micro Devices, Inc.*, 2013 WL 7084888, at *9 (Del. Super. Oct. 15, 2013). Moreover, Delaware courts have recognized that "[t]he lack of . . . dosage specificity . . . weakens the reliability of . . . testimony" on cancer risk. *See Wilant v. BNSF Ry. Co.*, 2020 WL 2467076, at *5 n.43 (Del. Super. May 13, 2020).

that was exercised in *Long* should be extended to cases like this one, where the existing science is much more robust.

## III. Prompt Supreme Court review will serve important policy interests.

### A. If Delaware adopts a more lenient standard for evaluating expert testimony, it will significantly influence plaintiffs' choice of fora.

The State's policy interest in deterring forum shopping, both at a general level and with regard to the specific litigation tactics employed in this case, highlights the need for the Supreme Court to review at this stage.

*First*, plaintiffs' success in obtaining a favorable *Daubert* ruling here constitutes a proverbial "second bite at the apple." As the Court is well aware, a federal MDL was established to address numerous claims arising from the recall of ranitidine-containing Zantac. That court issued a *Daubert* opinion on December 6, 2022, that excluded the general-causation opinions of the plaintiffs' experts and granted summary judgment for defendants. (*See* Op. at 5). In explaining its opposite conclusion in this case, the court identified differences between this case and the MDL – including that the plaintiff, plaintiffs' lawyers, experts, and particular cancers were different. (Op. at 6). Among other things, in the MDL the plaintiffs decided not to pursue claims for five of ten cancers that they originally sued on, meaning that "five of the cancer claims here were not before the MDL Court." (*Id.*)

However, these procedural distinctions should not obscure the fact that, from the perspective of the defendants who were named in both fora, this case represents

a second liability exposure for the same product and the same alleged conduct. That is true even with respect to the five cancers that the plaintiffs elected not to pursue in the MDL but that remain at issue here. Indeed, forum shopping concerns are especially true with respect to such claimants. As Defendants note, nearly 80% of the litigants in this case originally registered their claims in the MDL but sought relief from this Court after the Plaintiffs' experts in the MDL 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* App. for Interlocutory Review at 3 (quoting MDL Plaintiffs' expert report)). The claims asserted by those plaintiffs in this Court are nothing more than a re-do.

Delaware has a public policy interest in comity between the state and federal courts, and not promoting relitigation of questions competently adjudicated elsewhere. Plaintiffs' tactics in this case undermine that interest.

*Second*, and more broadly, adopting a more lenient standard for evaluating expert testimony has the potential to bring significantly more litigation to Delaware, especially because at least some defendants in any mass tort case are likely to be Delaware corporations. Under the forum-defendant rule, the presence of only a single Delaware-incorporated defendant generally prevents removal to federal court. *See* 28 U.S.C. § 1441(b)(2). That gives plaintiffs the option to file in Delaware state

court—an option they will likely avail themselves of if Delaware adopts a more lenient standard for evaluating expert testimony, given the significant and often dispositive effect of such a decision. Most problematically, Delaware's departure from the federal evidentiary standards will open the state courthouses' doors to plaintiffs, like those in this case, who *lost* evidentiary rulings in federal courts. It runs against the interests of both the business community and judicial economy for the Delaware courts to offer a second bite at the apple to parties who pressed claims unsuccessfully in other fora.

Delaware courts, like others, are rightly suspicious of plaintiff forum shopping. *See, e.g., Genuine Parts Co. v. Cepec*, 137 A.3d 123, 146 (Del. 2016); *Kurtin v. KRE, LLC*, 2005 WL 1200188, at *7 (Del. Ch. May 16, 2005). There is no doubt that plaintiffs' counsel give significant weight to the law governing expert testimony when deciding whether to file in a particular forum. Following *Daubert*, the senior counsel of the Association of Trial Lawyers of America recommended that "because it's difficult to see light at the end of the *Daubert* tunnel, plaintiffs must take another tunnel[,]" suggesting that expert admissibility standards may be more favorable in state court. Victor E. Schwartz and Cary Silverman, *The Draining of Daubert and the Recidivism of Junk Science in Federal and State Courts*, 35 Hofstra L. Rev 217, 269 (2006) (quoting Ned Miltenberg, *Out of the Fire and Into the Fryeing Pan or Back to the Future*, Trial, Mar. 2001, at 24)). Likewise, Missouri became a hotbed

for national talc lawsuits in part because "Missouri has a relatively 'flexible' standard for admitting expert testimony." Malerie Ma Roddy, *Consumer Protection: Forum Shopping in Talc Cases*, Nat'l L. Rev. Prod. Liab. & Mass Torts Blog (Dec. 7, 2016).[9]

The congruence between Delaware Rule of Evidence 702 and its federal counterpart, and the Delaware Supreme Court's adoption of *Daubert*, should operate to discourage plaintiffs from filing in Delaware solely to increase the chances that shaky expert testimony will be admitted. However, that is exactly what will occur if Delaware adopts a more lenient standard governing expert opinion. No plaintiff litigating against a Delaware-incorporated defendant would rationally prefer litigating in federal court, where their expert evidence will be subject to the more exacting standard of Federal Rule of Evidence 702. Ultimately, it is important that Delaware law be clear and consistent, which is why Supreme Court review is both appropriate and desirable here.

Finally, Plaintiffs' forum-selection decisions have consequences beyond the litigants in any particular case. They also affect judicial administration. If Delaware courts decisively adopt an evidentiary standard more lenient than the federal *Daubert* standard, Delaware is likely to become a hotbed of products-liability and mass-

[9] Available at https://natlawreview.com/article/consumer-protection-forum-shopping-talc-cases.

tort litigation, which has been on the increase nationwide. Mass-tort litigation "has exploded" in the years following *Daubert*. 2020 ILR Comment at 1. MDLs comprise nearly one-half of the entire federal civil docket (excluding most prisoner and social-security cases). *Id.* From 2002 to 2020, the number of pending cases in MDLs has increased by 650%, and about 90% of cases in MDLs are product-liability claims. *Id.* There has also been a significant increase in class-action litigation in federal courts since 2000. *Id.* at 2.

A significant increase in new filings threatens to overburden the State's courts. Last year, the Delaware Superior Court "experienced record increases in its civil filings. An increase of 2,425 civil filings in 2023 resulted in a 31% increase over the civil filings in 2022." Delaware Judiciary Annual Report at 25-26 (2023).[10] Those included "1,527 product liability cases and 683 Mass Tort cases (Zantac, Pelvic Mesh, etc.)." *Id.* at 26. Complex commercial litigation cases also "rose by 20%" because of "the national recognition of [the Court's] judicial officers' experience and expertise" in handling such matters. *Id.* As this Court acknowledged, in this case alone, "[n]early 75,000 Plaintiffs seek to be heard in Delaware." (Op. at 1).

[10] Available at https://courts.delaware.gov/aoc/annualreports/fy23/doc/2023AnnualReport.pdf.

### B. The procedural history of this case exemplifies the importance of timely, interlocutory review.

Timely appellate review is crucial to protect both industry and consumers in the mass torts context. Amici are deeply concerned by the possibility that this matter could proceed to trial on what the Supreme Court later deems to be a flawed evidentiary ruling—after the potential damage to the business community this Court described has already been done. (*See* Op. at 14 (quoting *In re Asbestos Litig.*, 911 A.2d at 1200)). For one thing, the fact that numerous claims are proceeding in one forum can have significant effects on the commencement and settlement of claims across the country involving the same product.

Moreover, decisions in the courtroom about the admissibility of scientific evidence have real-world effects, often to the detriment of businesses and consumers. A "well-known example is the Bendectin litigation." U.S. Chamber Institute for Legal Reform, *Fact or Fiction: Ensuring the Integrity of Expert Testimony* ("Fact or Fiction") at 5 (February 2021).[11] There, multi-million dollar verdicts were awarded in cases alleging a link between the drug and birth defects. The verdicts were eventually reversed on appeal, but not before the "only FDA-approved medication that blunted the symptoms of morning sickness" was taken off the market. *Id.* The med-

[11] Available at https://instituteforlegalreform.com/research/fact-or-fiction-ensuring-the-integrity-of-expert-testimony/.

ication was eventually made available again to the public, but not before public perceptions of it were tainted by unreliable courtroom science. *See, e.g.,* Gina Kolata, *Controversial Drug Makes a Comeback*, N.Y. Times at F1 (Sept. 26, 2000) ("[E]ven if Bendectin was safe, as its defenders argued, few women or their doctors wanted to use it.")[12] Timely, interlocutory appellate review may have prevented those results.

Of course, it is the nature of our federal system that different claims concerning the same products may arise in federal as well as different state courts. Amici do not suggest that preclusive effect should apply to the MDL court's evidentiary ruling. Rather, amici ask this Court to consider the importance to the business community of clarity, consistency and predictability in Delaware jurisprudence on expert testimony, particularly given the inherent disadvantage defendants face when litigating the same claims in many jurisdictions. Defendants must either prevail in each forum, or see all claims against them consolidate in the forum that applies the rules of evidence most leniently. Where one forum issues an evidentiary ruling that departs from the others, it is in the interests of fairness to certify that ruling for appellate review before large-scale litigation can proceed.

[12] Available at https://www.nytimes.com/2000/09/26/science/controversial-drug-makes-a-comeback.html.

## CONCLUSION

For the reasons above, this Court should grant the Defendants' Application for Interlocutory Review of the Court's Denial of Defendants' Motion to Exclude Plaintiffs' General-Causation Experts.

Dated: June 17, 2024

*Of Counsel*:

Robert M. Palumbos
Andrew R. Sperl
**DUANE MORRIS LLP**
30 South 17th Street
Philadelphia, PA 19103
Telephone: (215) 979-1000
rmpalumbos@duanemorris.com
arsperl@duanemorris.com

**DUANE MORRIS LLP**

*/s/ Richard L. Renck*

Richard L. Renck (#3893)
Tracey E. Timlin (#6469)
1201 North Market St., Suite 501
Wilmington, DE 19801
Telephone: (302) 657-4906
rlrenck@duanemorris.com
ttimlin@duanemorris.com

*Counsel for Amici Curiae Chamber of Commerce of the United States of America, National Association of Manufacturers, Biotechnology Innovation Organization, Delaware BioScience Association, and Pharmaceutical Research and Manufacturers of America*

**IN THE SUPERIOR COURT OF THE STATE OF DELAWARE**

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

## CERTIFICATE OF COMPLIANCE

1. This document complies with the typeface requirements of Superior Court Rule 107(b) because it has been prepared in Times New Roman 14-point typeface using Microsoft Word 2016.

2. This document complies with the type-volume limitation of Superior Court Rule 107(h)(1) because it contains 5,323 words, which were counted by Microsoft Word 2016.

*[Remainder of page intentionally left blank]*

Dated: June 17, 2024

**DUANE MORRIS LLP**

*/s/ Richard L. Renck*
Richard L. Renck (#3893)
Tracey E. Timlin (#6469)
1201 North Market St., Suite 501
Wilmington, DE 19801
Telephone: (302) 657-4906
rlrenck@duanemorris.com
ttimlin@duanemorris.com

*Counsel for Amici Curiae Chamber of Commerce of the United States of America, National Association of Manufacturers, Biotechnology Innovation Organization, Delaware BioScience Association, and Pharmaceutical Research and Manufacturers of America*

*Of Counsel*:

Robert M. Palumbos
Andrew R. Sperl
**DUANE MORRIS LLP**
30 South 17th Street
Philadelphia, PA 19103
Telephone: (215) 979-1000
rmpalumbos@duanemorris.com
arsperl@duanemorris.com

EFiled: Jun 20 2024 09:29AM EDT
Transaction ID 73438826
Case No. N22C-09-101 ZAN

# CERTIFICATE OF SERVICE

I, Richard L. Renck, Esquire, do hereby certify that on the 17th day of June 2024, I caused a true and correct copy of the foregoing *Motion for Leave to File Amici Curiae Brief of the Chamber of Commerce of the United States of America, The National Association of Manufacturers, Biotechnology Innovation Organization, Delaware Bioscience Association, and Pharmaceutical Research and Manufacturers of America in Support of the Defendants' Application for Interlocutory Review* to be served via File&ServeXpress, upon the following counsel of record:

Raeann Warner (#4931)
**COLLINS PRICE & WARNER**
8 East 13th Street
Wilmington, DE 19801

*Counsel for various Plaintiffs*

Joseph J. Rhoades, Esquire (#2064)
Stephen T. Morrow, Esquire (#4891)
**RHOADES & MORROW LLC**
1225 King Street, 12th Floor
Wilmington, DE 19801

*Counsel for various Plaintiffs*

Colleen D. Shields (#3138)
Patrick M. Brannigan (#4778)
Jessica L. Reno (#5950)
**ECKERT SEAMANS CHERIN & MELLOTT, LLC**
222 Delaware Avenue, Suite 700
Wilmington, DE 19801

*Counsel for Defendant GlaxoSmithKline, LLC*

Daniel J. Brown (#4688)
Hayley J. Reese (#6194)
Chelsea A. Botsch (#6715)
**McCARTER & ENGLISH, LLP**
Renaissance Centre
405 North King Street, 8th Floor
Wilmington, DE 19801

*Counsel for Defendant Pfizer, Inc.*

Bernard George Conaway (#2856)
**CONWAY-LEGAL LLC**
1007 North Orange Street, Suite 400
Wilmington, DE 19801

*Counsel for Plaintiffs Represented by Wisner Baum, LLP*

Joseph S. Naylor (#3886)
**SWARTZ CAMPBELL, LLC**
300 Delaware Avenue, Suite 1410
Wilmington, DE 19801

*Counsel for Defendants Boehringer Ingelheim Pharmaceuticals, Inc. and Boehringer Ingelheim USA Corporation*

Nancy Shane Rappaport (#3428)
Stephen H. Barrett (#5865)
**DLA PIPER LLP (US)**
1201 North Market Street, Suite 2100
Wilmington, DE 19801

*Counsel for Defendants Sanofi US Services Inc., Sanofi-Aventis U.S. LLC, and Chattem Inc.*

Sean T. O'Kelly (#4349)
Gerard M. O'Rourke (#3265)
**O'KELLY & O'ROURKE, LLC**
824 North Market Street, Suite 1001A
Wilmington, DE 19801

*Counsel for Defendant Patheon Manufacturing Services, LLC*

Dated: June 17, 2024

**DUANE MORRIS LLP**

*/s/ Richard L. Renck*
Richard L. Renck (#3893)

*Counsel for Amici Curiae United States Chamber of Commerce, National Association of Manufacturers, Biotechnology Innovation Organization, and Pharmaceutical Research and Manufacturers of America*