APPENDIX

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APPENDIX A

23-877
Bacher v. Boehringer Ingelheim Pharmaceuticals, Inc., et al.

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

August Term 2023

Argued: November 20, 2023
Decided: July 23, 2024

Docket Nos. 23-877(L), 23-878(Con), 23-879(Con), 23-880(Con), 23-881(Con), 23-882(Con), 23-883(Con), 23-884(Con), 23-885(Con)

BETH BACHER, REPRESENTATIVE FOR PAUL BACHER (DECEASED), JEROME JAY BERKOWITZ, MARY CASSIDY, JOHN CORWIN, ARMANDO RAMOS, RAFAEL ROLON, RODERICK SULLIVAN, THOMAS VAZZANO, ANNE YOST, PLAINTIFF REPRESENTATIVE FOR RICHARD YOST (DECEASED), *et al.*,

Plaintiffs – Appellees,

—v.—

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., BOEHRINGER INGELHEIM CORPORATION, BOEHRINGER INGELHEIM USA CORPORATION, GLAXOSMITHKLINE LLC, GLAXOSMITHKLINE HOLDINGS (AMERICAS), INC., PFIZER, INC., SANOFI-AVENTIS U.S. LLC, SANOFI US SERVICES INC.,

Defendants – Appellants.

Before: KEARSE, CALABRESI, and NATHAN, *Circuit Judges*.

Defendants-Appellants appeal from an order of the United States District Court for the District of Connecticut (Meyer, J) remanding these nine actions to state court. Defendants removed these actions from state court to federal court, arguing that a motion to consolidate filed in state court by Plaintiffs proposed a joint trial sufficient to confer federal subject-matter jurisdiction under the Class Action Fairness Act's "mass action" provision. Plaintiffs disagree, asserting that their motion proposes consolidation only for pretrial purposes. We agree with the Plaintiffs, finding the text of their motion ambiguous in isolation but clear in context, and therefore **AFFIRM**.

Judge Kearse dissents in a separate opinion.

DANIEL S. PARISER, Arnold & Porter Kaye Scholer LLP (Anand Agneshwar, Arnold & Porter Kaye Scholer LLP, New York, NY; Joseph W. Martini, Spears Manning & Martini LLC, Southport, CT; Patrick M. Fahey, Jamie A. Welsh, Shipman & Goodwin LLP, Hartford, CT; Lindsey B. Cohan, Dechert LLP, Austin TX; Robert Reginald Simpson, Lauren R. Greenspoon, Shook, Hardy & Bacon LLP, Hartford, CT; James I. Glasser, James O. Craven, Wiggin and Dana LLP, New Haven, CT, *on the brief*), Washington, D.C., *for Defendants-Appellants.*

JOHN A. BRUEGGER, Parafinczuk Wolf, P.A. (Robert A. Izard, Craig A. Raabe, Izard, Kindall & Raabe, LLP, West Hartford, CT, *on the brief*), Boca Raton, FL *for Plaintiffs-Appellees.*

CALABRESI, *Circuit Judge*:

Defendants-Appellants appeal from an order of the United States District Court for the District of Connecticut (Meyer, J.) remanding these nine actions to state court.

The Class Action Fairness Act ("CAFA") is best-known as a landmark expansion of federal subject-matter jurisdiction over class actions. CAFA also conferred federal subject-matter jurisdiction over "mass actions," or civil actions "in which monetary relief claims of 100 or more persons are proposed to be tried jointly." 28 U.S.C. § 1332(d)(11)(B)(i). But CAFA is clear that actions consolidated "solely for pretrial purposes" are not considered "mass actions." *Id.* § 1332(d)(11)(B)(ii)(IV).

"Federal courts are courts of limited jurisdiction." *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994). As a result, the federal statutes controlling our jurisdiction often allow plaintiffs to structure litigation strategically to evade federal subject-matter jurisdiction. Thus, to avoid federal question jurisdiction, plaintiffs can choose not to bring a federal cause of action; or, to escape invocation of CAFA's mass action provision, plaintiffs can structure their complaints to include 99 plaintiffs rather than 100.

In this case, which involves nine virtually identical cases filed in Connecticut state court, Plaintiffs sought to do just this. They went to great lengths to evade various triggers of federal subject-matter jurisdiction. Time and again, Plaintiffs walked the edge of one jurisdictional line or another, and each time they sought to avoid missteps that might allow the cases to be brought into federal court.

Defendants claim that Plaintiffs made one such misstep—Plaintiffs filed a "motion to consolidate"—which Defendants allege triggered federal jurisdiction by

proposing a joint trial, thereby fulfilling a requirement of CAFA's mass action provision. Accordingly, Defendants removed the case to federal court. Plaintiffs sought remand. Conceding that they otherwise met the requirements of CAFA's mass action provision, Plaintiffs argue that they proposed only pretrial consolidation and not a joint trial. They thus assert that they have not run afoul of CAFA's jurisdictional grant.

The district court agreed with the Plaintiffs and ordered remand of these nine actions. It held (a) that Plaintiffs' motion cited authority that could be used to propose consolidation for either pretrial management or for a joint trial and (b) that, read in the context of Plaintiffs' many attempts to avoid CAFA jurisdiction, the best reading of Plaintiffs' motion was that it proposed only pretrial. consolidation. Defendants timely appealed, arguing that the district court erred in two ways: (1) in considering Plaintiffs intent when intent is not contemplated by the statute and, (2) if intent were to be considered, in its evaluation of the evidence of Plaintiffs' intent.

We hold: (1) that the district court correctly understood CAFA as requiring a determination of whether the Plaintiffs *intended* to seek a joint trial—that is, whether a reasonable observer would conclude that Plaintiffs acted with the intention of bringing about a joint trial and (2) that, analyzing the record, the district court correctly concluded that the Plaintiffs sought only pretrial consolidation. We therefore affirm.

I. BACKGROUND

A. Proceedings in State Court

Between July and October 2022, nine lawsuits were filed in the Connecticut Superior Court for the Judicial District of Danbury. Each suit asserts virtually

indistinguishable state-law personal injury claims stemming from usage of a gastrointestinal medication known as Zantac; each suit was brought by the same firm and against the same eight defendants, companies that have held the right to market over-the-counter Zantac; each suit named three defendants and one. Plaintiff domiciled in Connecticut; and each suit contains just fewer than 100 plaintiffs, with seven suits containing 99 plaintiffs and the other two containing 80 plaintiffs. In total, these nine suits include claims filed on behalf of 853 Plaintiffs from thirty-six states.

Each complaint further contained a clause indicating that every Plaintiff sought an individual judgment against Defendants, preserving the individual nature of their respective claims: "Wherefore, *each* Plaintiff requests that the Court enter an order or judgment against the Defendants." J. App'x 106, 345, 605, 730, 862, 986, 1121, 1257 (emphasis added). And each complaint contained a lengthy, express disclaimer of federal jurisdiction.[1]

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[1] Each complaint contained the following provision:

> This lawsuit is not subject to removal based on the existence of a federal question. Plaintiffs assert common law and/or statutory claims under state law. These claims do not arise under the Constitution, laws, or treaties of the United States. 28 U.S.C. § 1447(c). There is no federal jurisdiction over this matter because all Plaintiffs assert claims against a forum defendant, Boehringer Ingelheim. One of the Plaintiffs is a citizen of Connecticut as alleged herein. Defendants are therefore precluded from removing this civil action due to the presence of a forum defendant, Boehringer Ingelheim, with respect to each Plaintiff named herein. 28 U.S.C. § 1441(b)(2) ("A civil action . . . may not be removed if any of the parties properly joined and served as defendants is a citizen of the State in which such action is brought.").

J. App'x 49, 287-288, 423, 547-548, 672-673, 805, 928-929, 1082, 1200.

After these nine actions were filed as separate suits in Connecticut state court, Plaintiffs' counsel corresponded with Defense counsel over the Plaintiffs' desire to file motions consolidating these actions and transferring them to the Connecticut Superior Court's specialized Complex Litigation Docket ("CLD"). Following a phone call between counsel, Defense counsel wrote the following email to Plaintiffs' counsel:

> Before I start making my calls, I want to make sure my notes are accurate. Plaintiffs want all cases consolidated in the same court and as far as CLD designation, would like to designate: 1) Hartford, 2) Stamford. If I have that right, I will start making calls today and hopefully get back to you early next week.

Id. at 143. Five days later, Plaintiff's counsel followed up on the "consolidation motions/CLD application" and asked if there had been "[a]ny progress on your end?" *Id.* Defense counsel expressed that the Defendants consented to CLD transfer and were comfortable with Plaintiffs' recommended CLD venues. *Id.* at 142. Accordingly, Plaintiffs' counsel responded that they would "prepare the consolidation motion and CLD application." *Id.*

After Defense counsel consented to the CLD transfer, Plaintiffs filed a motion to consolidate the nine actions. Plaintiffs' motion requested consolidation "[p]ursuant to Conn. Prac. Book § 9-5." *Id.* at 117. The motion cited no other authority but did contain a few statements "support[ing]" consolidation: Specifically, the motion stated that "[c]consolidating these actions will allow for the court to *manage* all of them in an orderly and efficient manner" and that "[i]t is likely that issues raised in any one of the cases could impact the other cases." *Id.* at 118 (emphasis added).

B. Proceedings in Federal Court

Before the state court could act on Plaintiffs' motion to consolidate, the Defendants filed notices of removal for all nine actions, asserting federal subject-matter jurisdiction under the mass action provision of CAFA. That provision confers on federal courts subject-matter jurisdiction over "any civil action . . . in which monetary relief claims of 100 or more persons are *proposed* to be tried jointly on the ground that the plaintiffs' claims involve common questions of law or fact." 28 U.S.C. § 1332(d)(11)(B)(i) (emphasis added). Plaintiffs do not dispute that the consolidated actions include the claims of 100 or more persons; nor do they dispute that the instant actions are civil actions for monetary relief. Instead, the sole disputed question is whether Plaintiffs' motion to consolidate "proposed" a joint trial.

Defendants argued that the plain text of Plaintiffs' motion proposed a joint trial because of its citation to Section 9-5. That section provides in relevant part: "Whenever there are two or more separate actions which should be tried together, the judicial authority may, upon the motion of any party or upon its own motion, order that the actions be consolidated for trial." Conn. Prac. Book § 9-5(a).

Eight days after Defendants removed these actions, Plaintiffs sought remand. They contended that the federal court lacked subject-matter jurisdiction because their motion proposed consolidation only for pretrial management, and CAFA is clear that actions consolidated "solely for pretrial proceedings" are not "mass actions." 28 U.S.C. § 1332(d)(11)(B)(ii)(IV). Plaintiffs argued that Section 9-5 has been used by Connecticut courts to effectuate transfer both for pretrial management and for trial, and that, as a result, their citation to Section 9-5 did

not necessarily propose a joint trial. Further, Plaintiffs claimed that the context of their motion clearly indicated that the purpose of consolidation was pretrial management in order to avoid paying a transfer fee for each individual action.

The district court agreed with the Plaintiffs. It found that Plaintiffs' citation to Section 9-5 was ambiguous and that the record did not show that Plaintiffs proposed a joint trial:

> The most natural interpretation of their motion and the context in which it was filed is that they sought consolidation only for purposes of pre-trial case management. . . . [T]he plaintiffs sought consolidation as no more than an expedient for an easier and less costly transfer of the cases to the [CLD] for superior case management.

Bacher v. Boehringer Ingelheim Pharms., Inc., No. 3:22-CV-01432 (JAM), 2023 WL196053, at *3 (D. Conn. Jan. 17, 2023). Accordingly, the district court remanded all nine cases to Connecticut state court. The Defendants timely appealed.

II. Standard of Review

The district court had jurisdiction because "a federal court always has jurisdiction to determine its own jurisdiction. "*LeChase Constr. Servs., LLC v. Argonaut Ins. Co.*, 63 F.4th 160, 171 (2d Cir. 2023) (quoting *United States v. Ruiz*, 536 U.S. 622, 628 (2002)).

We also have jurisdiction. Usually, an order remanding a removed case to state court is not reviewable on appeal. *See* 28 U.S.C. § 1447(d). CAFA provides an exception to that rule. CAFA authorizes the courts of appeals to review an appeal from a district court's order deciding a motion to remand pursuant to CAFA's

jurisdictional provisions. 28 U.S.C. § 1453(c)(1). The Defendants timely filed an application to appeal, and we therefore have jurisdiction to consider the order of remand.

On appeal from the grant or denial of a motion to remand for lack of CAFA- conferred jurisdiction, "we review the court's legal conclusions *de novo* and its factual findings for clear error." *Blockbuster, Inc. v. Galeno*, 472 F.3d 53, 56 (2d Cir. 2006) (citing *Briarpatch Ltd. v. Phoenix Pictures, Inc.*, 373 F.3d 296, 302 (2d Cir. 2004)). CAFA, moreover, is no exception to the well-known rule that the party asserting subject-matter jurisdiction has the burden of proving by a preponderance of the evidence that jurisdiction exists. *See Makarova v. United States*, 201 F.3d 110, 113(2d Cir. 2000); *McNutt v. Gen. Motors Acceptance Corp. of Indiana*, 298 U.S. 178, 189 (1936) ("[T]he court may demand that the party alleging jurisdiction justify his allegations by a preponderance of evidence."); *c.f. Blockbuster, Inc.*, 472 F.3d at 59.[2]

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[2] Under CAFA, the burden of demonstrating that remand is warranted "on the basis of one of [CAFA's] enumerated exceptions" shifts to the plaintiffs "once the general requirements of CAFA jurisdiction are established." *Greenwich Fin. Servs. Distressed Mortg. Fund 3 LLC v. Countrywide Fin. Corp.*, 603 F.3d 23, 26 (2d Cir. 2010).

The question in this case, however, is whether the Defendants have met the general requirements of CAFA jurisdiction, not whether the Plaintiffs have proved an exception. The provision of CAFA at hand is not an "exception" to its jurisdiction. Rather, it is a definitional clause. CAFA confers jurisdiction over "mass actions." *See* 28 U.S.C. § 1332(d)(11). The provision in question defines "mass actions" as actions for which a joint trial has been proposed. *Id.* at § 1332(d)(11)(B)(i). Accordingly, an action consolidated only for pretrial purposes does not qualify as a "mass action" that has met CAFA's general requirements. In *Greenwich*, on the other hand, "[plaintiffs] argued . . . that their suit fell within an exception to CAFA jurisdiction

III. Discussion

At every turn, Plaintiffs have gone to great lengths to avoid federal jurisdiction. This is obvious from the structure of their complaints. Each includes one plaintiff from Connecticut, ensuring that complete diversity between the parties does not exist. Each falls just shy of the 100-plaintiff federal removal threshold, with seven just a single plaintiff shy, indicating a particularized intent to avoid CAFA's mass action provision. Each contains a lengthy express disclaimer of federal jurisdiction, and each indicated that the individual plaintiff's claims remained separate.

It is, therefore, clear that Plaintiffs originally sought to keep these actions in state court. Consistent with that desire, there is nonetheless an obvious reason why Plaintiffs might seek consolidation for pretrial management: avoidance of a costly fee. "Pursuant to Connecticut General Statutes Sec. 52-259, there is a $335.00 fee for each case requested" to be transferred to the CLD. State of Connecticut Judicial Branch, *Facts About the Connecticut Judicial Branch Complex Litigation Docket*, https://www.jud.ct.gov/external/super/FACTS_082123.pdf [https://perma.cc/PB9V-QHV6] (last accessed July 21, 2024).[3]

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for actions 'that relate[ ] to the rights, duties (including fiduciary duties), and obligations relating to or created by or pursuant to any security . . . .'" 603 F.3d at 26 (quoting 28 U.S.C. § 1332(d)(9)(C)). The question in this case, however, is whether Plaintiffs' actions constitute a mass action and, thus, whether they constitute an action covered by the terms of CAFA at all. Accordingly, Defendants, as the party invoking federal jurisdiction, bear the burden of demonstrating that jurisdiction is proper by a preponderance of the evidence.

[3] Before the district court, Plaintiffs' counsel explained that they requested consolidation for this very reason. J. App'x 195.

Consolidation before transfer, thus, would presumably have saved Plaintiffs thousands of dollars in filing fees by allowing them to pay one fee rather than nine. Notably, in discussions with Defense counsel, Plaintiffs' counsel always discussed the two motions—consolidation and transfer to the CLD—in tandem. And when it came time to file motions to consolidate and for transfer, Plaintiffs first filed the motions for consolidation. Plaintiffs' actions are thereby consistent with a desire to consolidate to facilitate the economical transfer of these actions to the CLD. Defendants nevertheless make two broad arguments for reversal.

A.

First, Defendants argue that courts seeking to determine whether a joint trial has been proposed can examine only the plain text of a contested proposal and cannot "look[] beyond the words of Plaintiffs' consolidation request." Appellant's Br. 16. Defendants argue that to require courts to look to Plaintiffs' intent would require an unwieldy inquiry. *Id.* at 15.

We disagree and hold that CAFA permits a consideration of Plaintiffs' "intent. The common usage of the word "propose[]," 28 U.S.C. § 1332(d)(11)(B)(i), indicates as much. As the Eleventh Circuit, considering the same argument, explained: "[W]e would hardly say that a mouse 'proposes' to be eaten by a cat when it makes the mistake of being seen by the cat, recognizes the danger, and then quickly scurries away." *Scimone v. Carnival Corp.*, 720 F.3d 876, 884 (11th Cir. 2013). Instead, our common understanding is that for one to "propose," that person must intend to make an offer or request.

Two other circuits considering whether CAFA requires courts determining if a joint trial has been "proposed" have adopted *Scimone's* reasoning that the

"natural reading of the provision is that the plaintiffs must actually want . . . what they are proposing." *Ramirez v. Vintage Pharms., LLC*, 852 F.3d 324, 331-32 (3d Cir. 2017) (quoting *Scimone*, 720 F.3d at 884); *see also Parson v. Johnson & Johnson*, 749 F.3d 879, 888 (10th Cir. 2014) (same).

One circuit has held otherwise. *Adams v. 3M Co.*, 65 F.4th 802 (6th Cir. 2023). In *Adams*, the Sixth Circuit refused to consider an intent-based argument and held that "[r]equiring district courts to divine counsels' unexpressed intentions" would run afoul of the usual maxim that jurisdictional rules be "simple." *Id.* at 805 (citing *Hertz Corp. v. Friend*, 559 U.S. 77, 95 (2010)). *Adams* thus conducted its inquiry into whether a joint trial was "proposed" without considering plaintiffs' intent. *Adams* instead relied on the definition of "proposal" provided in *Black's Law Dictionary*: "Something offered for consideration or acceptance." *Id.* at 804 (citing Black's Law Dictionary 854, 1255 (8th ed. 2004)). Defendants here urge us to adopt *Adams's* logic. *See* Appellant's Br. 15-16. We decline to do so.

Setting aside that *Adams* ignores common usage (and, as we explain below, legislative history), its logic is flawed on its own terms. We are unpersuaded by its assumption that a test that is restricted to the text of a document itself is "simpler" than one that reads that text in context. In this case, for example, we find that looking beyond the face of the Plaintiffs' motion readily clarifies the meaning of the motion, and thus presents us with a "simpler" resolution of the matter at hand.

Second, *Adams's* reliance on *Black's Law Dictionary* to avoid considering intent is misguided. In consulting dictionaries, we should avoid "an uncritical approach," Antonin Scalia & Bryan A. Garner, *A Note on the Use of*

Dictionaries, 16 Green Bag 2d 419, 420 (2013), and should "use more than one . . . check[ing] editions from the date of enactment as well as current," *id.* at 422 n.14 (*quoting* Michael B.W. Sinclair, *Guide to Statutory Interpretation* 137 (2000)). *Adams* cites *Black's* definition of the noun "proposal," presumably because *Black's* offers no definition for the verb "propose" or any variation thereof. But we should not assume that similar words used as different parts of speech have identical meanings. *Cf. FCC v. AT&T Inc.*, 562 U.S. 397, 402-03 (2011) (noting that different parts of speech sharing a root word "may have meanings as disparate as any two unrelated words").

Moreover, though *Black's* definition of the word "proposal" does not mention "intent," it does contemplate an action with an intended result: "Something offered *for consideration or acceptance*." Other dictionaries that do provide definitions of "propose" similarly describe an action with an intended result, usually consideration of a plan, and thereby make the intent element explicit. *Parson* and *Scimone* turn to Merriam-Webster publications with just such definitions. *Parson* cites *Merriam-Webster's Online Dictionary*, as in effect in March 2014, for its definition of "propose" as "to suggest (something, such as a plan or theory) to a person or group of people to consider" or "to plan or intend to do (something)." *Parson*, 749 F.3d at 888 (citing Merriam-Webster Online Dictionary). *Scimone* cites *Webster's Third New International Dictionary* (2002) for a similar definition of "propose." *Scimone*, 720 F.3d at 881[4]. We are

[4] Merriam-Webster Online has since changed its definition and currently defines "propose" or "proposed" as "to form or put forward a plan or intention." *Proposed*, Merriam-Webster Online Dictionary, http://www.merriam-webster.com/dictionary/proposed [https://perma.cc/DF7P- 7BY6] (visited January 29, 2024)).

therefore satisfied that, to the extent dictionaries are helpful, they in fact further confirm that to "propose" something requires an intent to do so.

CAFA's legislative history corroborates our analysis. The Senate Report accompanying CAFA describes the mass action provision as covering "any civil action in which 100 or more named parties *seek* to try their claims for monetary relief together." S. Rep. No. 109–14, at 44 (2005) (emphasis added). This is significant evidence that CAFA's authors did not intend CAFA's jurisdictional grant to spring into swift operation when triggered by the use of a magic word or citation. It indicates that CAFA's authors meant to confer federal subject-matter jurisdiction only when a court determines that plaintiffs acted with the intention of seeking a joint trial.

Legislative history, common usage, and the dictionaries hence all row together. Each affirms our conclusion that courts evaluating whether a plaintiff proposed a joint trial must center their analysis on whether it was the plaintiffs' intention to request such a trial.

B.

Second, Defendants forcefully argue that, even if Plaintiffs' intent is relevant, the plain text of Plaintiffs' motion itself evinces the intent to consolidate for trial, and that evidence from outside the motion cannot overcome the text of the motion itself. They contend that Plaintiffs' citation to Section 9-5 constitutes an "express proposal" for a joint trial because a party's citation to Section 9-5 can only mean that they seek a joint trial. Appellant's Br. 12. We disagree and find the text of the motion, read in context, consistent with Plaintiffs' desire to consolidate for pretrial purposes only.

Defendants' argument relies on the text of Section 9-5 itself, which twice refers to trials: "Whenever there are two or more separate actions which should be tried together, the judicial authority may, upon the motion of any party or upon its own motion, order that the actions be consolidated for trial." Conn. Prac. Book § 9-5(a). Plaintiffs, however, contend that local Connecticut practice regarding Section 9-5 does not in fact rely on the trial component. They argue that Connecticut courts have used Section 9-5 to effectuate consolidation for pretrial purposes, trial purposes, or both, and thus that their citation to Section 9-5 does not clearly propose a joint trial.

Plaintiffs point to several cases as examples of Connecticut's practice of using Section 9-5 for pretrial consolidation. The most significant of these is *DiBella v. Town of Greenwich*, No. X08-CV-09-5012500-S, 2012 WL 2899242 (Conn. Super. Ct. May 22, 2012). In *DiBella*, a case that had already been transferred to the CLD, the court consolidated two cases for pretrial management. *Id.* at *2. In so doing, it stated that "[a] motion to consolidate is governed by Practice Book § 9-5(a)." *Id.* at *1. Two sentences later, however, the court describes itself as retaining "inherent power to consolidate different causes . . . when the circumstances authorize such course." *Id.* (quoting *Rode v. Adley Express Co., Inc.*, 33 A.2d 329, 331 (Conn. 1943)).

Because *DiBella* asserts that the court possesses consolidation authority both pursuant to Section 9-5 and its "inherent power" to consolidate, it is not clear which authority the court relied upon. Alternatively, the court may have referred to its "inherent power" merely as support for the preceding statement that "[t]he question of whether two actions ought to be consolidated is addressed to the discretion of the trial court." *Id.* In any

event, *DiBella* cannot clearly be read either, as Defendants contend, to rely on "inherent power" to the exclusion of Section 9-5; or, as Plaintiffs contend, to rely on Section 9-5 to the exclusion of the "inherent power."[5]

There are, however, cases in which Connecticut state courts do cite Section 9-5 as allowing for consolidation "only . . . for purposes of trial." *Feinstein v. Keenan*, No. FSTCV106007235S, 2012 WL 2548274, at *2 n.3 (Conn. Super. Ct. June 6, 2012); *see also Chieffalo v. Hoffman-Olson*, No. FSTCV085007415S, 2010 WL 1052270, at *2 (Conn. Super. Ct. Feb. 22, 2010). On the other hand, one recent decision by the United States District Court for the District of Connecticut noted that two Connecticut state court cases "indicate that some Connecticut trial courts have interpreted [Section] 9-5 to allow consolidation for some or even all pre-trial purposes." *Caprio v. Gorawara*, 2019 WL 13222943, at *2 n.1 (D. Conn. 2019), *adhered to in relevant part on reconsideration*, 2019 WL 6463684 (D. Conn. Dec. 2, 2019) (citing *Post v. Brennan*, 2008 WL

[5] *DiBella* is one of a long line of decisions by Connecticut courts that cite Section 9-5 (or its predecessor, Section 84A) as governing consolidation, without separating trial consolidation from pretrial consolidation, but also reference the inherent power of the courts to manage actions. *See, e.g.*, *Clarke v. Ochart*, No. 68018, 1993 WL 119765, at *1 (Conn. Super. Ct. Apr. 13, 1993); *Nautilus Ins. Co. v. Baldino*, No. CV-02-0388855, 2002 WL 1952618, at *1 (Conn. Super. Ct. July 24, 2002); *Mut. Life Ins. v. Town of Westport*, No. CV-93 030 38 81, 1993 WL 407950, at *2 (Conn. Super. Ct. Sept. 30, 1993); *Pellecchia v. Connecticut Light & Power Co.*, No. HHD-X04-CV-08-6003273-S, 2009 WL 4069271, at *2 (Conn. Super. Ct. Oct. 28, 2009); *Mills v. Rita H. Carter Revocable Tr.*, No. CV126015038, 2013 WL 1110914, at *2 (Conn. Super. Ct. Feb. 19, 2013). The standard practice among Connecticut courts has been to cite Section 9-5 alongside a reference to the inherent power of the courts before discussing whether the actions present enough common questions to warrant consolidation.

2967094, at *1 (Conn. Super. Ct. July 16, 2008), and *Groth v. Redmond*, 194 A.2d 531, 532 (Conn. Super. Ct. 1962)).

Defendants assert that *Caprio* mistakenly interpreted *Post* and *Groth*. They also argue that *Caprio* is not an authoritative source for interpreting Connecticut law because it is unpublished. But ultimately the question is not what the correct understanding of Connecticut law is. Rather, it is what, given these cases, we can understand Plaintiffs' citation to Section 9-5 to mean. Accordingly, even if reading Section 9-5 and its surrounding caselaw as allowing the provision's usage for pretrial consolidation is not the best reading of the provision—indeed, even if it is ultimately a mistaken reading[6]—given the convoluted history of Section 9-5's application, we cannot say that a party's citation to Section 9-5 provides clear evidence of that party's intent to propose a joint trial.[7]

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[6] To understand what the Plaintiffs meant, it is important to understand the state of the law, but it is not important to understand whether the *DiBella* or *Caprio* courts were right or wrong. For that reason, certifying the question of Section 9-5's best interpretation to the Connecticut Supreme Court would be futile. Clarification of Section 9-5's proper uses would not tell us anything about what Plaintiffs meant in citing Section 9-5 at a time when the law was unclear.

[7] Defendants further argue that if Plaintiffs in fact sought only pretrial consolidation, they could have cited an "ordinary joinder" provision of the Connecticut practice book to effectuate consolidation instead of Section 9-5. As a result, Defendants say, Plaintiffs' decision to cite Section 9-5 is significant indicia of their intent. We agree that Plaintiffs' counsel could have drafted their motion more clearly. But we do not make much of the availability of other joinder provisions. Simply put, though there were other joinder provisions that Plaintiffs could have used, those provisions do not speak specifically to consolidation for only pretrial purposes. *See* Conn. Prac. Book §§ 9-3, 9-4. Given the confused law of Section 9-5, Plaintiffs could reasonably have believed that Section 9-5 fulfilled their purpose of seeking joinder for management purposes only.

In the final analysis, we cannot agree that the text of Plaintiffs' motion constitutes a plain declaration of their intent to seek a joint trial. To the contrary, when Plaintiffs' citation to Section 9-5 is read alongside their explanation in the motion that "[c]onsolidating these actions will allow for the court to *manage* all of them in an orderly and efficient manner," J. App'x 118 (emphasis added), and their consistent desire to avoid federal jurisdiction, it seems clear to us that Plaintiffs' motion sought to propose only pretrial consolidation.

CONCLUSION

Defendants have not met their burden to demonstrate that federal jurisdiction exists. Accordingly, we **AFFIRM** the judgment of the district court.

KEARSE, *Circuit Judge*, dissenting:

I respectfully dissent from the majority's affirmance of the district court's post-removal remand of this class action to state court on the basis that plaintiffs "did not propose consolidation for a joint trial of their claims but only that their actions be consolidated for purposes of pre-trial case management proceedings" (SpA.5). I have seen nothing in the state-court record showing that plaintiffs stated, prior to or in making their motion for consolidation, that they sought consolidation of these cases only for pretrial proceedings.

Rather, when plaintiffs sought consolidation of the nine cases, they repeatedly referred to the "actions," not to any limited stage of the actions. And they moved for consolidation under the Connecticut provision that states that

> [w]henever there are two or more separate actions *which should be tried together*, the judicial authority may, upon the motion of any party or upon its own motion, *order that the actions be consolidated for trial*."

Connecticut Practice Book § 9-5(a) (emphases added).

Plaintiffs maintain that they had made clear their desire to have the cases consolidated preparatory to seeking the consolidation action's placement on the "Connecticut's Complex Litigation Docket ('CLD')" (Bacher brief on appeal at 1). But while § 23-13 of the Connecticut Practice Book states that a case may be placed on the CLD and assigned "to a single judge for pretrial, trial, or both," plaintiffs did not refer to this section; and I do not see that plaintiffs' references to the CLD contained any suggestion that they desired CLD placement only for pretrial proceedings. Nor does it appear that such fragmentation of a case on the CLD

would be the norm. The very first section of the State's official description as to how the CLD works states that when a case is placed on the CLD,

> [a]n individual calendar method of case management will be employed; that is, an individual judge *will* preside *over all aspects* of the litigation, *including trial*.

State of Connecticut, *Facts About the Judicial Branch Complex Litigation Docket* at 1 (emphases added).

In sum, without stating that they sought consolidated proceedings only for the pretrial stage, plaintiffs moved for consolidation under a section that refers only to consolidation "for trial"; and they did so avowedly in order to seek the consolidation action's placement on the CLD, in which an individual judge presides over "all aspects of the litigation, including trial." In my view, the district court clearly erred in finding that plaintiffs proposed consolidation only for pretrial proceedings and "did not propose consolidation for a joint trial."

APPENDIX B

[FILED: JANUARY 17, 2023]

UNITED STATES DISTRICT COURT
DISTRICTOF CONNECTICUT

BETH BACHER, *et al.*, *Plaintiffs*, -v.- BOEHRINGER INGELHEIM PHARMACEUTICALS, INC. *et al.*, *Defendants*.	:	No. 3:22-cv-01432 (JAM)

ORDER GRANTING MOTION TO REMAND

The Class Action Fairness Act ("CAFA") generally allows for federal jurisdiction over cases that qualify as a "mass action." As relevant here, a "mass action" includes "any civil action … in which monetary relief claims of 100 or more persons are *proposed to be tried jointly* on the ground that the plaintiffs' claims involve common questions of law or fact." 28 U.S.C. § 1332(d)(11)(B)(i) (emphasis added).

The defendants invoked this "mass action" provision as grounds to remove this case and eight similar cases that the plaintiffs initially filed in Connecticut state court. The defendants filed their notices of removal after the plaintiffs filed a motion in state court to consolidate all nine of the cases. The defendants argue that by filing their motion to consolidate the plaintiffs proposed a joint trial of

the claims of more than 100 persons. The plaintiffs do not agree. They have moved to remand, arguing that they proposed consolidation solely for the purpose of pre-trial case management and not for a joint trial.

I conclude that the defendants have not carried their burden to show that there was a "mass action" to trigger federal jurisdiction under CAFA, because the defendants have not shown that the plaintiffs proposed a joint trial of their claims. Accordingly, I will grant the plaintiffs' motion to remand to state court.

BACKGROUND

This action is one of nine separate lawsuits involving highly similar personal injury claims by a total of more than 800 plaintiffs against several companies that manufacture or distribute a pharmaceutical product known as Zantac. All nine of the actions were initially filed during the Summer of 2022 in the Connecticut Superior Court for the Judicial District of Danbury, and each action includes somewhere between 80 to 99 plaintiffs.

In the Fall of 2022, counsel for plaintiffs and for one of the defendants communicated with respect to the plaintiffs' proposal to file a motion to consolidate the actions and for transfer of the actions to the specialized Complex Litigation Docket ("CLD") of the Connecticut Superior Court.[1] On October 21, 2022, defense counsel wrote the following email to plaintiffs' counsel:

> Before I start making my calls, I want to make sure my notes are accurate. Plaintiffs want all cases consolidated in the same court and as far as

[1]Docs. #30-2, #30-3, #40-1; *see also* State of Connecticut Judicial Branch, *Facts About the Connecticut Judicial Branch Complex Litigation Docket*, https://www.jud.ct.gov/external/super/FACTS_092021.pdf (last accessed January 17, 2023) [https://perma.cc/VJ8A-GGME].

> CLD designation, would like to designate: 1) Hartford, 2) Stamford. If I have that right, I will start making calls today and hopefully get back to you early next week.[2]

Five days later, counsel for plaintiffs wrote: "My guys are anxious to file the consolidation motions/CLD application. Any progress on your end?"[3] Defense counsel responded: "It appears all defendants are comfortable with recommending: 1) Hartford and 2) Stamford under CLD."[4] Plaintiffs' counsel responded "Thanks," and "We'll prepare the consolidation motion and CLD application."[5]

Several more days passed before defense counsel inquired of plaintiffs' counsel: "Any update on Plaintiffs' CLD application?"[6] Plaintiffs' counsel replied: "We're working on the consolidation motions today. Our thought is to get everything consolidated and then file the CLD so we can do it with one application. I expect will have step one on file this week."[7]

On that same day, the plaintiffs filed a motion in the Connecticut Superior Court for the Judicial District of Danbury to consolidate all nine actions.[8] The

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[2] Doc. #30-2 at 3.

[3] *Ibid.*

[4] *Id.* at 2.

[5] *Ibid.*

[6] Doc. #30-3 at 2.

[7] *Ibid.* Although it is not completely clear why the plaintiffs sought to consolidate the nine cases prior to transfer, "[p]ursuant to Connecticut General Statutes Sec. 52-259, there is a $335.00 fee for each case requested" for transfer to the CLD. *See Facts About the Connecticut Judicial Branch Complex Litigation Docket*, *supra* note 1, at 1.

[8] Doc. #1-2 at 84–85; *see also* Doc. #1 at 5 (¶ 12).

motion stated that it was filed "[p]ursuant to Conn. Prac. Book § 9-5" and set forth verbatim the following grounds:

1. These actions are all against the same Defendants.
2. All of the actions involve the same legal claims sounding in product liability related to the heartburn medication Zantac.
3. It is likely that issues raised in any one of the cases could impact the other cases.
4. Consolidating these actions will allow for the court to manage all of them in an orderly and efficient manner.
5. Plaintiffs are filing similar consolidation motions in each of the above-listed actions.
6. All Defendants consent to this proposed consolidation.[9]

There is no record that the state court acted on the motion to consolidate. Instead, on November 4, 2022, the chief administrative judge for the Connecticut Superior Court *sua sponte* issued an order conditionally ordering the transfer of the nine actions to the Complex Litigation Docket.[10]

But that transfer never happened because on November 10, 2022, the defendants filed notices of removal for all nine actions. The plaintiffs in turn have moved to remand all of the actions to the Connecticut Superior Court

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[9] Doc. #1-2 at 84–85. The defendants do not dispute that they consented to transfer to the CLD but dispute that they consented to the proposed consolidation. Doc. #40 at 8; Doc. #40-1 at 2–3 (¶¶ 9–10).

[10] Doc. #30 at 2; Doc. #30-1 at 2.

DISCUSSION

CAFA "expanded the jurisdiction of the federal courts to allow class actions originally filed in state courts that conform to particular requirements to be removed to federal district courts." *Purdue Pharma L.P. v. Kentucky*, 704 F.3d 208, 213 (2d Cir. 2013).[11] "In general, CAFA amended the diversity statute to confer federal jurisdiction over certain class actions where: (1) the proposed class contains at least 100 members (the 'numerosity' requirement); (2) minimal diversity exists between the parties, (i.e., where 'any member of a class of plaintiffs is a citizen of a State different from any defendant'); and (3) the aggregate amount in controversy exceeds $5,000,000." *Ibid.* (citing 28 U.S.C. § 1332(d)(2)–(6)).

"CAFA's reach, however, is limited in the first instance to actions that qualify as either a 'class action' or a 'mass action.'" *Ibid.* (citing 28 U.S.C. § 1332(d)(1)–(2), (11), and 28 U.S.C. § 1453(b)). According to CAFA, "a mass action shall be deemed to be a class action removable" from state court to federal court for the same reasons that a defendant may remove a class action. 28 U.S.C. § 1332(d)(11)(A). Thus, "defendants in civil suits may remove 'mass actions' from state to federal court." *See Mississippi ex rel. Hood v. AU Optronics Corp.*, 571 U.S. 161, 164 (2014).

CAFA defines a "mass action" in relevant part to mean "'any civil action … in which monetary relief claims of 100 or more persons are proposed to be tried jointly on the ground that the plaintiffs' claims involve common

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[11] Unless otherwise indicated, this ruling omits internal quotation marks, alterations, citations, and footnotes in text quoted from court decisions.

questions of law or fact." 28 U.S.C. § 1332(d)(11)(B)(i). Importantly, CAFA makes clear that a "mass action" does not include cases for which "the claims have been consolidated or coordinated solely for pretrial proceedings." 28 U.S.C. § 1332(d)(11)(B)(ii)(IV).

According to the defendants, they properly removed this case because the plaintiffs' filing in state court of their motion to consolidate satisfies CAFA's "mass action" requirement—specifically, that the actions now involve claims of more than 100 persons that have been "proposed to be tried jointly." By contrast, the plaintiffs argue that they did not propose a joint trial of their claims but only that their actions be consolidated for purposes of pre-trial case management proceedings.[12]

I agree with the plaintiffs. The body of their motion does not seek or propose a joint trial of the separate actions. The most natural interpretation of their motion and the context in which it was filed is that they sought consolidation only for purposes of pre-trial case management. Specifically, they stated in their motion that "[i]t is likely that issues raised in any one of the cases could impact the other cases" and that consolidation "will allow for the court to manage all of them in an orderly and efficient manner."

Moreover, the evidence of communications between counsel prior to the plaintiffs' filing of their motion to consolidate does not suggest that the plaintiffs were seeking or proposing to consolidate the cases for purposes of trial. As best as I can tell, the plaintiffs sought consolidation as no more than an expedient for an easier and less costly transfer of the cases to the Complex Litigation Docket for superior case management.

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[12] Doc. #30 at 4–10.

The defendants rely on the fact that the plaintiffs' motion cites § 9-5 of the Connecticut Practice Book. That provision provides in pertinent part: "Whenever there are two or more separate actions which should be tried together, the judicial authority may, upon the motion of any party or upon its own motion, order that the actions be consolidated for trial." Conn. Prac. Book § 9-5(a). It does not refer to consolidation for pre-trial case management purposes.

Does the fact that the plaintiffs cited a provision that by its terms refers only to consolidation for trial mean that the plaintiffs necessarily "proposed" a joint trial of their claims? At first glance, I thought so but on balance am not convinced in light of all the surrounding circumstances. To begin with, there is no other provision of the Connecticut Practice Book that expressly references and authorizes a motion to consolidate for pre-trial discovery and case management. So the fact that the plaintiffs cited the most nearly applicable rule of the Connecticut Practice Book—rather than citing no rule or provision at all—does not conclusively establish that they were proposing consolidation for purpose of trial.

Indeed, at least one Connecticut court has treated a motion filed for consolidation under § 9-5 of the Connecticut Practice Book as grounds to consolidate for pre-trial purposes only and not necessarily for purpose of trial. *See DiBella v. Town of Greenwich*, 2012 WL 2899242, at *2 (Conn. Super. Ct. 2012). In light of the *DiBella* decision, it was not unreasonable for the plaintiffs to cite § 9-5 of the Connecticut Practice Book and for all concerned to understand that the plaintiffs were *not* necessarily proposing consolidation for purpose of trial.

A recent decision of this Court cites two Connecticut state court cases in further support of this proposition,

noting that the two cases "[a]t most … indicate that some Connecticut trial courts have interpreted § 9-5 to allow consolidation for some or even all pre-trial purposes." *Caprio v. Gorawara*, 2019 WL 13222943, at *2 n.1 (D. Conn.) ((citing *Post v. Brennan*, 2008 WL 2967094, at *1 (Conn. Super. Ct. 2008), and *Groth v. Redmond*, 194 A.2d 531, 532 (Conn. Super. Ct. 1962)), *adhered to in relevant part on reconsideration*, 2019 WL 6463684 (D. Conn. 2019).

The defendants misplace their reliance on the Fifth Circuit's decision in *Lester v. Exxon Mobil Corp.*, 879 F.3d 582 (5th Cir. 2018). In *Lester*, the court affirmed the denial of a motion to remand where the plaintiffs' underlying motion to consolidate had cited a Louisiana law regarding which "Louisiana case law seems to have interpreted … to *only* permit consolidation for trial, as opposed to pretrial, purposes." *Id.* at 587 (emphasis in original). Here, as I have noted above, Connecticut case law has not so strictly interpreted § 9-5 of the Connecticut Practice Book to foreclose a court from granting consolidation for pre-trial purposes only.

Moreover, the motion filed by the plaintiffs in *Lester* expressly sought "to 'effect a consolidation *for purpose of trial*.'" *Ibid.* (emphasis added). Here, by contrast, the body of the plaintiffs' motion does not request consolidation for purpose of trial. The body of the motion seeks consolidation "for the court to manage all [the cases] in an orderly and efficient manner."

The other cases cited by the defendants similarly involved far more definitive evidence that the plaintiffs at issue had proposed a consolidation for purpose of trial. *See Corber v. Xanodyne Pharms., Inc.*, 771 F.3d 1218, 1225 (9th Cir. 2014) (*en banc*) (plaintiffs moved to consolidate "for all purposes"); *Atwell v. Bos. Sci. Corp.*, 740 F.3d

1160, 1161 (8th Cir. 2013) (plaintiffs "filed similar motions proposing that the state court assign each group 'to a single Judge for purposes of discovery and trial'"); *In re Abbott Lab'ys, Inc.*, 698 F.3d 568, 571 (7th Cir. 2012) ("[P]laintiffs said they were requesting consolidation of the cases 'through trial' and 'not solely for pretrial proceedings.'").

Could the plaintiffs have filed a motion that made their intent clearer, such as by expressly disclaiming any request to consolidate for trial? Yes, they could have—and no doubt wished they did. But my role is not to grade or foot-fault the quality of the plaintiffs' filings. I must decide if the plaintiffs actually proposed consolidation for a joint trial. They did not.

As the Tenth Circuit has noted, "the common usage of the word 'propose' involves an intentional act. *Parson v. Johnson & Johnson*, 749 F.3d 879, 888 (10th Cir. 2014). And as the Eleventh Circuit has suggested when grappling with the same CAFA provision, "we would hardly say that a mouse 'proposes' to be eaten by a cat when it makes the mistake of being seen by the cat, recognizes the danger, and then quickly scurries away." *Scimone v. Carnival Corp.,* 720 F.3d 876, 884 (11th Cir. 2013). Instead, "[t]he more natural reading of the provision is that the plaintiffs must actually want, or at least intend to bring about, what they are proposing." *Ibid.* The record before me does not show that the plaintiffs wanted or intended to bring about a joint trial of all their claims when they filed their motion to consolidate.

The defendants conceded at oral argument that it is their burden to establish the grounds for federal jurisdiction and that removal is proper. *See also Montefiore Med. Ctr. v. Teamsters Loc.* 272, 642 F.3d 321, 327 (2d Cir. 2011) ("A party seeking removal bears the

burden of showing that federal jurisdiction is proper."). The most that can be said for the defendants' position is that the plaintiffs cited a Practice Book provision that provides for consolidation for trial—even though under Connecticut law, moving to consolidate pursuant to § 9-5 does not necessarily entail consolidation for purpose of trial. This is too slim a reed to carry the defendants' burden to prove that the plaintiffs proposed to consolidate their nine cases for a joint trial. At best, the evidence is in equipoise, and that means I must rule for the plaintiffs.

Lastly, it is readily apparent that the plaintiffs lawfully structured their state court complaints, most of which are a single plaintiff shy of the 100-plaintiff federal removal threshold, in order to avoid the defendants' resort to CAFA to force the litigation to proceed in federal court. It would be odd—and unfair as well—to interpret the plaintiffs' motion to consolidate as an effort to invite removal to federal court and to undo their plans to litigate in a state court forum that they carefully chose in the first place.

CONCLUSION

The defendants have not carried their burden to show that the plaintiffs proposed to consolidate their nine separate actions for purpose of a joint trial. Accordingly, there was no proper ground for the defendants to remove this action. The Court GRANTS the plaintiffs' motion to remand (Doc. #29) and DENIES as moot the plaintiffs' motion for leave to withdraw and/or clarify their motion to consolidate (Doc. #31).

I will enter docket orders in the eight related cases adopting the result and reasoning of this ruling for the parallel motions to remand filed by the plaintiffs in each case. Absent a timely motion for reconsideration or further court order, the Clerk of Court shall remand this

action and the eight related actions in accordance with the timeline and procedures set forth by Rule 83.7 of the District of Connecticut Local Rules of Civil Procedure.

It is so ordered.

Dated at New Haven this 17th day of January 2023.

/s/ Jeffery Alker Meyer
Jeffrey Alker Meyer
United States District Judge

APPENDIX C

28 U.S.C. § 1332. Diversity of citizenship; amount in controversy; costs

(a) The district courts shall have original jurisdiction of all civil actions where the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs, and is between--

(1) citizens of different States;

(2) citizens of a State and citizens or subjects of a foreign state, except that the district courts shall not have original jurisdiction under this subsection of an action between citizens of a State and citizens or subjects of a foreign state who are lawfully admitted for permanent residence in the United States and are domiciled in the same State;

(3) citizens of different States and in which citizens or subjects of a foreign state are additional parties; and

(4) a foreign state, defined in section 1603(a) of this title, as plaintiff and citizens of a State or of different States.

(b) Except when express provision therefor is otherwise made in a statute of the United States, where the plaintiff who files the case originally in the Federal courts is finally adjudged to be entitled to recover less than the sum or value of $75,000, computed without regard to any setoff or counterclaim to which the defendant may be adjudged to be entitled, and exclusive of interest and costs, the district court may deny costs to the plaintiff and, in addition, may impose costs on the plaintiff.

(c) For the purposes of this section and section 1441 of this title--

(1) corporation shall be deemed to be a citizen of every State and foreign state by which it has been incorporated and of the State or foreign state where it has its principal place of business, except that in any direct action against the insurer of a policy or contract of liability insurance, whether incorporated or unincorporated, to which action the insured is not joined as a party-defendant, such insurer shall be deemed a citizen of--

(A) every State and foreign state of which the insured is a citizen;

(B) every State and foreign state by which the insurer has been incorporated; and

(C) the State or foreign state where the insurer has its principal place of business; and

(2) the legal representative of the estate of a decedent shall be deemed to be a citizen only of the same State as the decedent, and the legal representative of an infant or incompetent shall be deemed to be a citizen only of the same State as the infant or incompetent.

(d)(1) In this subsection--

(A) the term "class" means all of the class members in a class action;

(B) the term "class action" means any civil action filed under rule 23 of the Federal Rules of Civil Procedure or similar State statute or rule of judicial procedure authorizing an action to be brought by 1 or more representative persons as a class action;

(C) the term "class certification order" means an order issued by a court approving the treatment of some or all aspects of a civil action as a class action; and

(D) the term "class members" means the persons (named or unnamed) who fall within the definition of the proposed or certified class in a class action.

(2) The district courts shall have original jurisdiction of any civil action in which the matter in controversy exceeds the sum or value of $5,000,000, exclusive of interest and costs, and is a class action in which--

(A) any member of a class of plaintiffs is a citizen of a State different from any defendant;

(B) any member of a class of plaintiffs is a foreign state or a citizen or subject of a foreign state and any defendant is a citizen of a State; or

(C) any member of a class of plaintiffs is a citizen of a State and any defendant is a foreign state or a citizen or subject of a foreign state.

(3) A district court may, in the interests of justice and looking at the totality of the circumstances, decline to exercise jurisdiction under paragraph (2) over a class action in which greater than one-third but less than two-thirds of the members of all proposed plaintiff classes in the aggregate and the primary defendants are citizens of the State in which the action was originally filed based on consideration of--

(A) whether the claims asserted involve matters of national or interstate interest;

(B) whether the claims asserted will be governed by laws of the State in which the action was originally filed or by the laws of other States;

(C) whether the class action has been pleaded in a manner that seeks to avoid Federal jurisdiction;

(D) whether the action was brought in a forum with a distinct nexus with the class members, the alleged harm, or the defendants;

(E) whether the number of citizens of the State in which the action was originally filed in all proposed plaintiff classes in the aggregate is substantially larger than the number of citizens from any other State, and the citizenship of the other members of the proposed class is dispersed among a substantial number of States; and

(F) whether, during the 3-year period preceding the filing of that class action, 1 or more other class actions asserting the same or similar claims on behalf of the same or other persons have been filed.

(4) A district court shall decline to exercise jurisdiction under paragraph (2)--

(A)(i) over a class action in which--

(I) greater than two-thirds of the members of all proposed plaintiff classes in the

aggregate are citizens of the State in which the action was originally filed;

(II) at least 1 defendant is a defendant--

(aa) from whom significant relief is sought by members of the plaintiff class;

(bb) whose alleged conduct forms a significant basis for the claims asserted by the proposed plaintiff class; and

(cc) who is a citizen of the State in which the action was originally filed; and

(III) principal injuries resulting from the alleged conduct or any related conduct of each defendant were incurred in the State in which the action was originally filed; and

(ii) during the 3-year period preceding the filing of that class action, no other class action has been filed asserting the same or similar factual allegations against any of the defendants on behalf of the same or other persons; or

(B) two-thirds or more of the members of all proposed plaintiff classes in the aggregate, and the primary defendants, are citizens of the State in which the action was originally filed.

(5) Paragraphs (2) through (4) shall not apply to any class action in which--

(A) the primary defendants are States, State officials, or other governmental entities against whom the district court may be foreclosed from ordering relief; or

(B) the number of members of all proposed plaintiff classes in the aggregate is less than 100.

(6) In any class action, the claims of the individual class members shall be aggregated to determine whether the matter in controversy exceeds the sum or value of $5,000,000, exclusive of interest and costs.

(7) Citizenship of the members of the proposed plaintiff classes shall be determined for purposes of paragraphs (2) through (6) as of the date of filing of the complaint or amended complaint, or, if the case stated by the initial pleading is not subject to Federal jurisdiction, as of the date of service by plaintiffs of an amended pleading, motion, or other paper, indicating the existence of Federal jurisdiction.

(8) This subsection shall apply to any class action before or after the entry of a class certification order by the court with respect to that action.

(9) Paragraph (2) shall not apply to any class action that solely involves a claim--

(A) concerning a covered security as defined under 16(f)(3) of the Securities Act of 1933 (15 U.S.C. 78p(f)(3)) and section 28(f)(5)(E) of the Securities Exchange Act of 1934 (15 U.S.C. 78bb(f)(5)(E));

(B) that relates to the internal affairs or governance of a corporation or other form of business enterprise and that arises under or by virtue of the laws of the State in which such

corporation or business enterprise is incorporated or organized; or

(C) that relates to the rights, duties (including fiduciary duties), and obligations relating to or created by or pursuant to any security (as defined under section 2(a)(1) of the Securities Act of 1933 (15 U.S.C. 77b(a)(1)) and the regulations issued thereunder).

(10) For purposes of this subsection and section 1453, an unincorporated association shall be deemed to be a citizen of the State where it has its principal place of business and the State under whose laws it is organized.

(11)(A) For purposes of this subsection and section 1453, a mass action shall be deemed to be a class action removable under paragraphs (2) through (10) if it otherwise meets the provisions of those paragraphs.

(B)(i) As used in subparagraph (A), the term "mass action" means any civil action (except a civil action within the scope of section 1711(2)) in which monetary relief claims of 100 or more persons are proposed to be tried jointly on the ground that the plaintiffs' claims involve common questions of law or fact, except that jurisdiction shall exist only over those plaintiffs whose claims in a mass action satisfy the jurisdictional amount requirements under subsection (a).

(ii) As used in subparagraph (A), the term "mass action" shall not include any civil action in which--

(I) all of the claims in the action arise from an event or occurrence in the State in which the action was filed, and that allegedly resulted in injuries in that State or in States contiguous to that State;

(II) the claims are joined upon motion of a defendant;

(III) all of the claims in the action are asserted on behalf of the general public (and not on behalf of individual claimants or members of a purported class) pursuant to a State statute specifically authorizing such action; or

(IV) the claims have been consolidated or coordinated solely for pretrial proceedings.

(C)(i) Any action(s) removed to Federal court pursuant to this subsection shall not thereafter be transferred to any other court pursuant to section 1407, or the rules promulgated thereunder, unless a majority of the plaintiffs in the action request transfer pursuant to section 1407.

(ii) This subparagraph will not apply--

(I) to cases certified pursuant to rule 23 of the Federal Rules of Civil Procedure; or

(II) if plaintiffs propose that the action proceed as a class action pursuant to rule 23 of the Federal Rules of Civil Procedure.

(D) The limitations periods on any claims asserted in a mass action that is removed to Federal court pursuant to this subsection shall

be deemed tolled during the period that the action is pending in Federal court.

(e) The word "States", as used in this section, includes the Territories, the District of Columbia, and the Commonwealth of Puerto Rico.

APPENDIX D

28 U.S.C. § 1453. Removal of class actions

(a) Definitions.--In this section, the terms "class", "class action", "class certification order", and "class member" shall have the meanings given such terms under section 1332(d)(1).

(b) In general.--A class action may be removed to a district court of the United States in accordance with section 1446 (except that the 1-year limitation under section 1446(c)(1) shall not apply), without regard to whether any defendant is a citizen of the State in which the action is brought, except that such action may be removed by any defendant without the consent of all defendants.

(c) Review of remand orders.--

(1) In general.--Section 1447 shall apply to any removal of a case under this section, except that notwithstanding section 1447(d), a court of appeals may accept an appeal from an order of a district court granting or denying a motion to remand a class action to the State court from which it was removed if application is made to the court of appeals not more than 10 days after entry of the order.

(2) Time period for judgment.--If the court of appeals accepts an appeal under paragraph (1), the court shall complete all action on such appeal, including rendering judgment, not later than 60 days after the date on which such appeal was filed, unless an extension is granted under paragraph (3).

(3) Extension of time period.--The court of appeals may grant an extension of the 60-day period described in paragraph (2) if--

(A) all parties to the proceeding agree to such extension, for any period of time; or

(B) such extension is for good cause shown and in the interests of justice, for a period not to exceed 10 days.

(4) Denial of appeal.--If a final judgment on the appeal under paragraph (1) is not issued before the end of the period described in paragraph (2), including any extension under paragraph (3), the appeal shall be denied.

(d) Exception.--This section shall not apply to any class action that solely involves--

(1) a claim concerning a covered security as defined under section 16(f)(3) of the Securities Act of 1933 (15 U.S.C. 78p(f)(3)) and section 28(f)(5)(E) of the Securities Exchange Act of 1934 (15 U.S.C. 78bb(f)(5)(E));

(2) a claim that relates to the internal affairs or governance of a corporation or other form of business enterprise and arises under or by virtue of the laws of the State in which such corporation or business enterprise is incorporated or organized; or

(3) a claim that relates to the rights, duties (including fiduciary duties), and obligations relating to or created by or pursuant to any security (as defined under section 2(a)(1) of the Securities Act of 1933 (15 U.S.C. 77b(a)(1)) and the regulations issued thereunder).

APPENDIX E

Connecticut Practice Book § 9-5
Consolidation of Actions

(a) Whenever there are two or more separate actions which should be tried together, the judicial authority may, upon the motion of any party or upon its own motion, order that the actions be consolidated for trial.

(b) If a party seeks consolidation, the motion to consolidate shall be filed in all of the court files proposed to be consolidated, shall include the docket number and judicial district of each of the cases, and shall contain a certification specifically stating that the motion was served in accordance with Sections 10-12 through 10-17 on all parties to such actions. The certification shall specifically recite the name and address of each counsel and self-represented party served, the date of such service and the name and docket number of the case in which that person has appeared. The moving party shall give reasonable notice to all such parties of the date on which the motion will be heard on short calendar. The judicial authority shall not consider the motion unless it is satisfied that such notice was given.

(c) The court files in any actions consolidated pursuant to this section shall be maintained as separate files and all documents submitted by counsel or the parties shall bear only the docket number and case title of the file in which it is to be filed.

APPENDIX F

[EXCERPT OF *BACHER* COMPLAINT]

[FILED: NOVEMBER 10, 2022]

RETURN DATE: AUGUST 30, 2022

BETH BACHER,	:	SUPERIOUR
PLAINTIFF	:	COURT
REPRESENTATIVE FOR	:	
PAUL BACHER	:	JUDICIAL
(DECEASED); ASHA	:	DISRICT OF
ATKINS; ANTHONY	:	DANBURY
BALDWIN; LASHAUNNA	:	
DENISE BANKS; NIEMA	:	
BAPTISTA; CALANTHE	:	JULY 29, 2022
BATISTE; JASON	:	
BEHRENS; CHASITY	:	
BELLARD; JESSE BLAKE;	:	
WILLIAM BLOCK;	:	
JEFFREY BOLEN;	:	
CHRISTOPHER BROPHY,	:	
SR.; KENISHIA BUNDAGE;	:	
MAURICE CALHOUN;	:	
SONJA CHAMBERLAIN;	:	
STEPHEN CHAMPINE;	:	
LINDSEY CHARLES;	:	
DOUGLAS CHOUINARD;	:	
BILLIE JO CLEM; RON	:	
MAZUN COLLINS;	:	
CHAUNCEY CONWAY;	:	
FLORENCE COUCHIE;	:	
TRINA DAU; KENNETH	:	
DAVIS; ROGER ALLAN	:	
DEFRANG; RUSTY	:	
DELANEY; RANDY	:	

DERCKS; ALVESTER :
DONES; CHASTITY :
DOTSON; HORACE DOTY; :
TEDDY DOUCET; DETRIC :
DREWERY; CONNIE :
DUGDALE; HARRIS :
DUGGER; TANTASHA :
DUTYE; LAURA :
EDWARDS; LORI A :
EISCHEN; CINDY :
EKLUND; LAURA ELLIS; :
DARELL ENLOE; LILLIE :
EVANS; AUSTIN :
FERGUSON; DOLLIE :
FIELDS; WILLIAM LYNN :
FISHER; KEVIN :
HERBERT KAY :
FIVECOAIT; PAUL :
FLUESMEIER; EDWARD :
L FORREST; LEAH :
FRANCIS; VIOLA :
FRANCIS; MARK :
FRANKLIN; TAMARA :
FREDERICK; CELESTE :
FREEMAN; ROBERT :
FROMMER; TERRANCE :
GAINES; TRAVEON :
GAINES; LADORIS :
GALBERT; ROBERT :
GARDNER; LINDA GILL; :
MICHAEL GLIDDEN; :
JOHN GOINGS; JASON :
GOLDEN; ROY GOODMAN; :
JUSTIN GORHAM; DALE :
GRAHAM; CALANDRA :

GREY; MARIO GUALTIERI; ARNOLDO GUTIERREZ; MILDRED HAGGERTY; BRYTTNY HALL; DELLA HAMM; TREMIAN HAMPTON; ZACK HANSANA;

BRIDGETTE HARDY; ROBERT HARMAN

JOANN ADAMS, PLAINTIFF REPRESENTATIVE FOR ROBERT EUGENE ADAMS (DECEASED);

JOHN BAGACO, PLAINTIFF REPRESENTATIVE FOR JOAO BAGACO, (DECEASED);

ILENE BARAJAS, PLAINTIFF REPRESENTATIVE FOR MARTIN BARAJAS, (DECEASED);

RICKY DOYLE, PLAINTIFF REPRESENTATIVE FOR ANITA BENNETE (DECEASED);

MARK BLEUER, PLAINTIFF REPRESENTATIVE FOR

KAREN BLEUER (DECEASED);

JULIE RUDOLPH, PLAINTIFF REPRESENTATIVE FOR ANDREW BOISVERT (DECEASED);

DARLA BOOKER, PLAINTIFF REPRESENTATIVE FOR DOUGLAS LYDELL BOOKER (DECEASED);

JOSEPH BUCCERI, PLAINTIFF REPRESENTATIVE FOR BARBARA BUCCERI (DECEASED);

ROBBIE CAHOON, PLAINTIFF REPRESENTATIVE FOR DUSTY CAHOON (DECEASED);

SHERMECKA DUBOSE, PLAINTIFF REPRESENTATIVE FOR PATRICIA COBB (DECEASED);

TERESA GHOSIO, PLAINTIFF REPRESENTATIVE FOR SUSAN CALLARI (DECEASED);

TRACIE CATO, PLAINTIFF REPRESENTATIVE FOR SANDRA CATO (DECEASED);

FORESTINE CLARK, PLAINTIFF REPRESENTATIVE FOR EDWARD CLARK (DECEASED);

SONJA CONTRERAS, PLAINTIFF REPRESENTATIVE FOR ENRIQUE CONTRERAS (DECEASED);

JAQUELINE CORTEZ-BATEMAN, PLAINTIFF REPRESENTATIVE FOR WILLIAM CORTEZ (DECEASED);

NICHOLAS CRISTINO, PLAINTIFF REPRESENTATIVE FOR FRANCIS CRISTINO (DECEASED);

AARON CURRIE, PLAINTIFF REPRESENTATIVE FOR BONITA CURRIE (DECEASED);

SUSAN VERBACK, PLAINTIFF

REPRESENTATIVE FOR VIRGINA CWIAKALA (DECEASED);

DIANE DAHL, PLAINTIFF REPRESENTATIVE FOR MICHAEL A. DAHL SR. (DECEASED);

DIANA DASENT, PLAINTIFF REPRESENTATIVE FOR MARY DASENT (DECEASED);

JOANNE YOBAK, PLAINTIFF REPRESENTATIVE FOR RITA JANE DONOHUE (DECEASED);

THOMAS ECCLES, PLAINTIFF REPRESENTATIVE FOR PATRICIA ECCLES (DECEASED);

DANA DUGAS, PLAINTIFF REPRESENTATIVE FOR BONNIE EDWARDS (DECEASED);

LILLIAN FEARS, PLAINTIFF REPRSENTATIVE FOR WAYNE FEARS (DECEASED);

LISA RICHIE, PLAINTIFF REPRESENTATIVE FOR DANIEL MOLZ (DECEASED);	:
Plaintiffs,	:
v.	:
BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; BOEHRINGER INGELHEIM CORPORATION; BOEHRINGER INGELHEIM USA CORPORATION; GLAXOSMITHKLINE, LLC; GLAXOSMITHKLINE HOLDINGS (AMERICAS), INC.; PFIZER, INC.; SANOFI-AVENTIS U.S. LLC; SANOFI U.S. SERVICES, INC.	:
Defendants.	:

The above-captioned Plaintiffs ("Plaintiffs"), by and through their undersigned attorneys, allege as follows:

INTRODUCTION

1. Zantac is the branded name for ranitidine, a "blockbuster" drug sold to treat heartburn. For decades, Zantac and/or its generic equivalent ranitidine, were promoted by Defendants as a safe and effective treatment for heartburn. Indeed, Defendants had little incentive to

investigate the dangers in a product that was producing over $1 billion in annual sales.

2. Instead, Defendants turned a blind eye to the fact that ranitidine transforms, over time and under particular conditions, into high levels of N-Nitrosodimethylamine ("NDMA"), a well-known cancer-causing compound. NDMA has no medicinal or beneficial purpose whatsoever: its only function is to cause cancer and its only use is to induce tumors in animals as part of laboratory experiments. The U.S. Food and Drug Administration's ("FDA") allowable daily limit of NDMA is 96 nanograms. A single dose of Zantac contains over 3 million nanograms of NDMA.

3. In 2019, revelations by independent researchers that ranitidine transforms into NDMA, caused widespread recalls of Zantac and its generic equivalents. On April 1, 2020, the FDA ordered the immediate withdrawal of all ranitidine-containing products sold in the United States, citing unacceptable levels of NDMA accumulation.

4. Plaintiffs regularly took various forms of brand name Zantac, including over the counter ("OTC") Zantac, and/or generic ranitidine products, including OTC ranitidine products. These products were manufactured and sold by Defendants. Plaintiffs developed cancer as a result of taking medication that Defendants designed, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold. Plaintiffs bring this action seeking damages against the Defendants for causing Plaintiffs' cancer.

PARTIES

Plaintiffs

5. Plaintiffs, (hereinafter "Plaintiffs"), are individuals who suffered personal injuries and/or death as a result of using Defendants' dangerously defective ranitidine-containing products. Plaintiffs are citizens of various states, including the State of Connecticut as set forth in the list of Plaintiffs, attached hereto as Exhibit A.

Defendants

6. Defendants Boehringer Ingelheim, GSK, Pfizer, and Sanofi (collectively "Defendants") designed, manufactured, marketed, distributed, labeled, packaged, handled, stored, and/or sold ranitidine-containing products, including the ranitidine-containing products ingested by Plaintiffs. Defendants have conducted business and derived substantial revenue from marketing, handling, distributing, storing, and selling ranitidine-containing products within each of the States and Territories of the United States, including Connecticut.

BOEHRINGER INGELHEIM

7. Boehringer Ingelheim Pharmaceuticals, Inc.,[1] is a Delaware corporation with its principal place of business located at 900 Ridgebury Road, Ridgefield, Connecticut 06877.

8. Boehringer Ingelheim Corporation is a Nevada corporation with its principal place of business located at 900 Ridgebury Road, Ridgefield, Connecticut 06877.

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[1] Defendants Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation shall be collectively referred to as "Boehringer Ingelheim" or "BI."

9. Boehringer Ingelheim USA Corporation is a Delaware corporation with its principal place of business located at 900 Ridgebury Rd., Ridgefield, Connecticut 06877.

GSK

10. GlaxoSmithKline, LLC[2] is a Delaware corporation with its principal place of business located at Five Crescent Drive, Philadelphia, Pennsylvania 19112. Defendant GlaxoSmithKline, LLC's sole member is Defendant GlaxoSmithKline Holdings (America) Inc.

11. GlaxoSmithKline Holdings (Americas) Inc. is a Delaware corporation with its principal place of business located at 1105 N. Market Street, Suite 622, Wilmington, Delaware 19801.

PFIZER

12. Pfizer, Inc. ("Pfizer") is a Delaware corporation with its principal place of business located at 235 East 42nd Street, New York, New York 10017.

SANOFI

13. Sanofi-Aventis U.S. LLC[3] is a Delaware limited liability company with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi-Aventis U.S., LLC's sole member is Defendant Sanofi U.S. Services, Inc.

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[2] Defendants GlaxoSmithKline, LLC, and GlaxoSmithKline (America), Inc. shall be collectively referred to as "GSK."

[3] Sanofi U.S. Services, Inc. and Defendant Sanofi-Aventis U.S., LLC shall be collectively referred to as "Sanofi."

14. Sanofi U.S. Services, Inc. is a Delaware corporation with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

JURISDICTION & VENUE

15. This Court has jurisdiction over the subject matter of this action and the parties.

16. The causes of action alleged in this Complaint arise out of or relate to the Defendants' contacts with Connecticut. Substantial activities relating to the design, development, marketing, promotion and sales of ranitidine-containing products were performed by Defendants in Connecticut. Defendants made decisions regarding the design, testing, regulatory communications and processes, marketing strategy, labeling and warnings content for ranitidine containing products in the State of Connecticut.

17. This Court has personal jurisdiction over Defendants pursuant to, and consistent with, Connecticut's long-arm statute, *Conn. Gen. Stat. § 52-59b,* and the requirements of Due Process in so far that Defendants, acting through agents or apparent agents, committed one or more of the following:

a. Defendants transacted, and continue to transact, continuous and systematic business in Connecticut and regularly conduct business, receive substantial revenues, and sell products and perform services in Connecticut;

b. Defendants engaged in pattern of marketing, selling, and promoting Zantac in every state in the country, including Connecticut;

c. Defendants caused tortious injury in Connecticut by an act or omission in Connecticut;

d. Defendants have caused tortious injury in Connecticut by an act or omission outside of Connecticut and Defendants regularly do or solicit business in Connecticut, engage in any other persistent course of conduct in Connecticut or derive substantial revenue goods used or consumed or services rendered in Connecticut or expect or should reasonably expect their acts to have consequences in Connecticut and they derive substantial revenue from interstate or international commerce;

e. Defendants have an interest in, use or possess real property in Connecticut;

f. Upon information and belief, Defendant Pfizer engaged in research, development and/or safety and regulatory analysis of the Zantac product, during the relevant time period at issue herein, at their facility located in Groton, CT.

g. Defendants purposely availed themselves of the privileges of conducting business in Connecticut invoking the benefits and protections of Connecticut law.

h. Requiring Defendants to litigate this claim in Connecticut does not offend traditional notions of fair play and substantial justice and is permitted by the United States Constitution.

18. Venue in this action properly lies in Connecticut because a Plaintiff is a citizen of Connecticut and certain Defendants are Connecticut entities as alleged in this complaint.

19. Plaintiff/Decedent Bacher purchased and ingested prescription and over-the- counter ("OTC") Zantac and generic ranitidine in Connecticut from 2000-

2019, which corresponds to the times that each Defendant manufactured the product. Specifically, GSK manufactured prescription Zantac from 1983-2017, Pfizer manufactured OTC Zantac from 1995-2006, BI manufactured OTC Zantac from 2006-2019, and Sanofi, in conjunction with BI, controlled the ANDA for OTC Zantac and manufactured OTC Zantac from 2017-2020.

20. As described herein, Plaintiff/Decedent Bacher sustained significant injuries as described herein as a result of his ingestion of Zantac in Connecticut.

21. This lawsuit is not subject to removal based on the existence of a federal question. Plaintiffs assert common law and/or statutory claims under state law. These claims do not arise under the Constitution, laws, or treaties of the United States. 28 U.S.C. § 1447(c). There is no federal jurisdiction over this matter because all Plaintiffs assert claims against a forum defendant, Boehringer Ingelheim. One of the Plaintiffs is a citizen of Connecticut as alleged herein. Defendants are therefore precluded from removing this civil action due to the presence of a forum defendant, Boehringer Ingelheim, with respect to each Plaintiff named herein. 28 U.S.C. § 1441(b)(2) ("A civil action . . . may not be removed if any of the parties properly joined and served as defendants is a citizen of the State in which such action is brought.").

FACTUAL ALLEGATIONS

I. The Creation of Ranitidine-Containing Products and their Introduction to the Market.

22. Zantac (or ranitidine) was developed by GSK[4] in 1976. GSK, and specifically Glaxo Holdings, Ltd., developed ranitidine in response to the success of the then leading H2 blocker Tagamet (chemically known as cimetidine). The drug belongs to a class of medications called histamine H2-receptor antagonists (or H2 blockers), which decrease the amount of acid produced by the stomach and are used to treat gastric ulcers, heartburn, acid indigestion, sour stomach and other gastrointestinal conditions. In 1983, once the FDA granted approval to GlaxoSmithKline to sell ranitidine under the brand name Zantac, pursuant to the New Drug Application ("NDA") No. 18-703, it quickly became GlaxoSmithKline's most successful product. Indeed, ranitidine became the first prescription drug in history to reach $1 billion in sales.

23. To get to that goal, GlaxoSmithKline entered into a joint promotion agreement with Hoffmann-LaRoche, Inc., which increased Zantac's U.S. sales force from 400 people to approximately 1,200. More salespersons drove more sales and more profits for GlaxoSmithKline.

24. In 1993, GlaxoSmithKline entered into a joint venture with Pfizer-predecessor company Warner-Lambert Co. to develop an OTC version of Zantac. In 1995,

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[4] GSK, as it is known today, was created through a series of mergers and acquisitions: In 1989, Smith, Kline & French merged with the Beecham Group to form SmithKline Beecham plc. In 1995, Glaxo merged with the Wellcome Foundation to become Glaxo Wellcome plc. In 2000, Glaxo Wellcome plc merged with SmithKline Beecham plc to form GlaxoSmithKline plc and GlaxoSmithKline LLC.

the FDA approved Zantac 75 mg tablets through NDA 20-520. In 1998, the FDA approved Zantac 75 mg effervescent tablets through NDA 20-745.

25. In 1998, GlaxoSmithKline and Warner-Lambert Co. ended their joint venture. As part of the separation, Warner-Lambert Co. retained control over the OTC NDA for Zantac and the Zantac trademark in the United States and Canada, but was required to obtain approval from GlaxoSmithKline prior to making any product or trademark improvements or changes. GlaxoSmithKline retained rights to sell OTC Zantac outside of the United States and Canada, and it retained control over the Zantac trademark internationally.

26. GlaxoSmithKline's retention of the right to require GlaxoSmithKline's approval for any product improvements or changes came with an inherent duty on the part of GlaxoSmithKline to assure that OTC Zantac remained safe and free from any defects and/or unreasonable risks of danger to the consumers who would ingest OTC Zantac.

27. In 2000, Pfizer acquired Warner-Lambert Co. and, thereafter, Pfizer controlled the OTC Zantac NDAs until December 2006.

28. In October 2000, GlaxoSmithKline sold to Pfizer the full rights to OTC Zantac in the United States and Canada pursuant to a divestiture and transfer agreement. As part of that agreement, GlaxoSmithKline divested all domestic OTC Zantac assets to Pfizer, including all trademark rights. The agreement removed the restrictions on Pfizer's ability to seek product line extensions or the approval for higher doses of OTC Zantac. GlaxoSmithKline retained the right to the exclusive use of the Zantac name for any prescription ranitidine-

containing product in the United States.

29. In October 2003, Pfizer submitted NDA 21-698 for approval to market OTC Zantac 150 mg. Preparation of an NDA requires substantial research, development and regulatory work concerning, for example, safety, dosing and manufacturing, including clinical tests and animal studies. See, e.g. https://www.fda.gov/drugs/types-applications/new-drug-application-nda. Upon information and belief, Pfizer performed this work in Groton, Connecticut. The FDA approved NDA 21-698 on August 31, 2004.

30. Throughout the time that Pfizer owned the rights to OTC Zantac, GlaxoSmithKline continued to manufacture the product.

31. In 2006, pursuant to a Stock and Asset Purchase Agreement, Pfizer sold and divested its entire consumer health division (including employees and documents) to Johnson & Johnson ("J&J"). Because of antitrust issues, however, OTC Zantac was transferred to Boehringer Ingelheim.

32. Pfizer, through a divestiture agreement, transferred all assets pertaining to its OTC Zantac line of products, including the rights to sell and market all formulations of OTC Zantac in the United States and Canada, as well as all intellectual property, R&D, and customer and supply contracts to Boehringer Ingelheim. As part of that deal, Boehringer Ingelheim obtained control and responsibility over all of the OTC Zantac NDAs.

33. GlaxoSmithKline continued marketing prescription Zantac in the United States until 2017, and it still holds the NDAs for several prescription formulations of Zantac. GlaxoSmithKline continued to maintain

manufacturing and supply agreements relating to various formulations of both prescription and OTC Zantac.

34. Boehringer Ingelheim owned and controlled the NDAs for OTC Zantac between December 2006 and January 2017, and Boehringer Ingelheim manufactured, marketed, and distributed the drug in the United States during that period.

35. In 2017, Boehringer Ingelheim sold the rights of OTC Zantac to Sanofi pursuant to an asset swap agreement. As part of that deal, Sanofi obtained control and responsibility over Boehringer Ingelheim's entire consumer healthcare business, including the OTC Zantac NDAs. As part of this agreement, Boehringer Ingelheim and Sanofi entered into a manufacturing agreement wherein Boehringer continued to manufacture OTC Zantac for Sanofi. Sanofi has controlled the OTC Zantac NDAs and marketed, sold, and distributed Zantac in the United States from January 2017 until 2019 when it issued a recall and ceased marketing, selling, and distributing OTC Zantac.

36. Sanofi voluntarily recalled all brand-name OTC Zantac on October 18, 2019.

37. Zantac became available without a prescription in 1996, and generic versions of Zantac (ranitidine) became available in approximately 1997. Although sales of brand-name Zantac declined as a result of generic and alternative products, Zantac sales have remained strong over time. As recently as 2018, Zantac was one of the top 10 antacid tablet brands in the United States, with sales of Zantac 150 totaling $128.9 million – a 3.1% increase from the previous year.

38. The times during which each Defendant manufactured and sold branded Zantac pills are alleged

below:

Defendant	Prescription or OTC	Sale Start Date Year	Sale End Date Year
GSK	Prescription	1983	2017
Pfizer	OTC	1995	2006
Boehringer Ingelheim	OTC	2006	2019
Sanofi	OTC	2017	2020

II. The Dangers of NDMA.

39. NDMA is a semi-volatile organic chemical that forms in both industrial and natural processes. It is a member of N-nitrosamines, a family of potent carcinogens. The dangers that NDMA poses to human health have long been recognized. A news article published in 1979 noted that "NDMA has caused cancer in nearly every laboratory animal tested so far."[5] NDMA is no longer produced or commercially used in the United States, except for research, such as a tumor initiator in certain animal bioassays. In other words, it is only a

[5] Jane Brody, *Bottoms Up: Alcohol in moderation can extend life,* THE GLOBE AND MAIL (CANADA) (Oct. 11, 1979); *see* Rudy Platiel, *Anger grows as officials unable to trace poison in reserve's water,* THE GLOBE AND MAIL CANADA) (Jan. 6, 1990) (reporting that residents of Six Nations Indian Reserve "have been advised not to drink, cook or wash in the water because testing has found high levels of N-nitrosodimethylamine (NDMA), an industrial by-product chemical that has been linked to cancer"); Kyrtopoulos et al, *DNA adducts in humans after exposure to methylating agents,* 405 MUTAT. RESEAR. 135 (1998) (noting that "chronic exposure of rats to very low doses of NDMA gives rise predominantly to liver tumors, including tumors of the liver cells (hepatocellular carcinomas), bile ducts, blood vessels and Kupffer cells").

poison.

40. Both the Environmental Protection Agency ("EPA") and the International Agency for Research on Cancer ("IARC") have classified NDMA as a probable human carcinogen.

41. The World Health Organization ("WHO") states that there is "conclusive evidence that NDMA is a potent carcinogen" and that there is "clear evidence of carcinogenicity."[6] The WHO has stated that scientific testing indicates that NDMA consumption is positively associated with either gastric or colorectal cancer and suggests that humans may be especially sensitive to the carcinogenicity of NDMA.

42. The Department of Health and Human Services ("DHHS") states that NDMA is reasonably anticipated to be a human carcinogen.[7] This classification is based upon DHHS's findings that NDMA caused tumors in numerous species of experimental animals, at several different tissue sites, and by several routes of exposure, with tumors occurring primarily in the liver, respiratory tract, kidney, and blood vessels.[8]

43. As early as 1980, consumer products containing unsafe levels of NDMA and other nitrosamines have been recalled by manufacturers, either voluntarily or at the direction of the FDA.

44. Most recently, beginning in the summer of 2018,

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[6] World Health Org., *Guidelines for Drinking Water Quality, N-Nitrosodimethylamine (NDMA)* (3d ed. 2008), https://www.who.int/water_sanitation_health/dwq/chemicals/ndma-summary_2ndadd.pdf.

[7] *Id.* at 3.

[8] *Id.*

several generic drugs used to treat high blood pressure and heart failure – valsartan, losartan, and irbesartan – were recalled because the medications contained nitrosamine impurities that do not meet the FDA's safety standards.

45. The FDA has established a permissible daily intake limit for the probable human carcinogen, NDMA, of 96 ng (nanograms). One filtered cigarette contains between 5 - 43 ng of NDMA. Recent testing shows that a single pill of ranitidine may contain staggering NDMA levels in excess of 3,000,000 ng.

46. Numerous *in vitro* studies confirm that NDMA is a mutagen – causing mutations in human and animal cells.

47. In mouse studies examining the carcinogenicity of NDMA through oral administration, animals exposed to NDMA developed cancer in the kidney, bladder, liver, and lung. In comparable rat studies, similar cancers were observed in the liver, kidney, pancreas, and lung. In comparable hamster studies, similar cancers were observed in the liver, pancreas, and stomach. In comparable guinea pig studies, similar cancers were observed in the liver and lung. In comparable rabbit studies, similar cancers were observed in the liver and lung.

48. In other long-term animal studies of mice and rats utilizing different routes of exposures – inhalation, subcutaneous injection, and intraperitoneal (abdomen injection) – cancer was observed in the lung, liver, kidney, nasal cavity, and stomach.

49. Overall, the animal studies demonstrate that NDMA is carcinogenic in all animal species tested: mice; rats; Syrian golden, Chinese, and European hamsters; guinea pigs; rabbits; ducks; mastomys; fish; newts; and

frogs.

50. Pursuant to the EPA's cancer guidelines, "tumors observed in animals are generally assumed to indicate that an agent may produce tumors in humans."

51. In addition to the overwhelming animal data linking NDMA to cancer, there are numerous human epidemiological studies exploring the effects of dietary exposure to various cancers. While these studies (several discussed below) consistently show increased risks of various cancers, the exposure levels considered in these studies are a very small fraction – as little as 1 millionth – of the exposures noted in a single Zantac capsule, i.e., 0.191 ng/day (dietary) v. 304,500 ng/day (Zantac).

52. In a 1995 epidemiological case-control study looking at NDMA dietary exposure with 220 cases, researchers observed a statistically significant 700% increased risk of gastric cancer in persons exposed to more than 0.51 ng/day of NDMA.[9]

53. In a 1995 epidemiological case-control study of NDMA dietary exposure in 746 cases, researchers observed statistically significant elevated rates of gastric cancer in persons exposed to more than 0.191 ng/day.[10]

54. In another 1995 epidemiological case-control study of, in part, the effects of dietary consumption on cancer, researchers observed a statistically significant elevated risk of developing aerodigestive cancer after being

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[9] Pobel et al, *Nitrosamine, nitrate and nitrite in relation to gastric cancer: a case-control study in Marseille, France,*11 EUROP. J. EPIDEMIOL. 67-73 (1995).

[10] La Vecchia et al, *Nitrosamine intake and gastric cancer risk,* 4 EUROP. J. CANCER. PREV. 469-474 (1995).

exposed to NDMA at 0.179 ng/day.[11]

55. In a 1999 epidemiological cohort study of NDMA dietary exposure in 189 cases and a follow up of 24 years, researchers noted that "N-nitroso compounds are potent carcinogens" and that dietary exposure to NDMA more than doubled the risk of developing colorectal cancer.[12]

56. In a 2000 epidemiological cohort study of occupational exposure of workers in the rubber industry, researchers observed significant increased risks for NDMA exposure for esophagus, oral cavity, pharynx, prostate, and brain cancer.[13]

57. In a 2011 epidemiological cohort study of NDMA dietary exposure in 3,268 cases and a follow up of 11.4 years, researchers concluded that "[d]ietary NDMA intake was significantly associated with increased cancer risk in men and women" for all cancers, and that "NDMA was associated with increased risk of gastrointestinal cancers" including rectal cancers.[14]

58. In a 2014 epidemiological case-control study of NDMA dietary exposure in 2,481 cases, researchers found a statistically significant elevated association between

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[11] Rogers et al, *Consumption of nitrate, nitrite, and nitrosodimethylamine and the risk of upper aerodigestive tract cancer,* 5 CANCEREPIDEMIOL. BIOMARKERS PREV. 29-36 (1995).

[12] Knekt et al, *Risk of Colorectal and Other Gastro-lntestinal Cancers after Exposure to Nitrate, Nitrite and N-nitroso Compounds: A Follow-Up Study,* 80 INT. J. CANCER 852-856 (1999).

[13] Straif et al, Exposure to high concentrations of nitrosamines and cancer mortality among a cohort of rubber workers, 57 OCCUP ENVIRON MED 180-187 (2000).

[14] Loh et al, N-nitroso compounds and cancer incidence: the European Prospective Investigation into Cancer and Nutrition (EPIC)-Norfolk Study, 93 AM J CLIN NUTR. 1053-61 (2011).

NDMA exposure and colorectal cancer.[15]

59. In addition, NDMA breaks down into various derivative molecules that, themselves, are associated with causing cancer. In animal studies, derivatives of NDMA induced cancer in the stomach and intestine, including colon.

60. In animal experiments, for those animals exposed to NDMA during pregnancy, the offspring had elevated rates of cancer in the liver and kidneys.

III. How Ranitidine Transforms into NDMA Within the Body and Through Exposure to Heat, Moisture and/or Time.

61. At the time that ranitidine was developed, there was scientific literature suggesting that drugs like ranitidine, which contain a dimethylamine ("DMA") group within the molecule, are highly likely to form NDMA, when combined with other nitrates in the body. Indeed, nitrate is not only naturally found in the body, but bacteria and enzymes in the body reduce the nitrates (NO3) found in food into nitrites (NO2-). In addition, many foods and preservatives contain nitrates.

62. Because of the presence of nitrates in the body, Glaxo scientists should have known that human physiology and diet would lead to the development of NDMA in the human body after the ingestion of ranitidine.

63. The high levels of NDMA produced by Zantac are inherent to the molecular structure of ranitidine, the active ingredient in Zantac. The ranitidine molecule contains both a nitrite ("NO3") and a dimethylamine

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[15] Zhu et al, *Dietary N-nitroso compounds and risk of colorectal cancer: a case-control study in Newfoundland and Labrador and Ontario, Canada,* 111 BR JNUTR. 6, 1109-1117 (2014).

("DMA") group which are well known to combine to form NDMA. Thus, ranitidine produces NDMA by "react[ing] with itself," which means that *every dosage and form of ranitidine,* including Zantac, exposes users to NDMA.

64. The formation of NDMA by the reaction of DMA and a nitroso source (such as a nitrite) is well characterized in the scientific literature and has been identified as a concern for contamination of the American water supply.[16] Indeed, in 2003, alarming levels of NDMA in drinking water processed by wastewater treatment plants were specifically linked to the presence of ranitidine.[17]

65. In 1981, the year Zantac was launched commercially outside of the United States, two exchanges in *The Lancet*—one of the most widely read and respected medical and scientific publications—discussed the potential toxicity of cimetidine and ranitidine. Cimetidine, also an H2 blocker, has a similar chemical structure to ranitidine.

66. Dr. Silvio de Flora, an Italian researcher from the University of Genoa, wrote about experiments he conducted regarding cimetidine and ranitidine in human gastric fluid. When ranitidine was exposed to gastric fluid in combination with nitrites, his experiment showed "toxic and mutagenic effects [.]"[18] Dr. de Flora hypothesized that these effects could have been caused by the "formation of

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[16] Ogawa et al, *Purification and properties of a new enzyme, NG, NG-dimethylarginine dimethylaminohydrolase, from rat kidney,* 264 J. BIO. CHEM. 17, 10205-10209 (1989).

[17] Mitch et al, *N-Nitrosodimethylamine (NDMA) as a Drinking Water Contaminant: A Review,* 20 ENV. ENG, SCI. 5, 389-404 (2003).

[18] De Flora, *Cimetidine, Ranitidine, and Their Mutagenic Nitroso Derivatives*, THE LANCET 993-994 (Oct. 31, 1981).

more than one nitroso derivative [which includes NDMA] under our experimental conditions." Concerned with these results, Dr. de Flora cautioned that, in the context of ranitidine ingestion, "it would seem prudent to avoid nitrosation as far as possible by, for example, suggesting a diet low in nitrates and nitrites, by asking patients not to take these at times close to (or with) meals, or by giving inhibitors of nitrosation such as ascorbic acid."

67. GSK responded to Dr. de Flora's concern.[19] A group of GSK researchers specifically noted they were "obviously concerned as to whether or not a mutagenic N-nitroso derivative of ranitidine could be formed in the stomach." GSK acknowledged that in the presence of nitrites, a "N-nitroso nitrolic acid derivative was formed" that was "mutagenic [.]" GSK, however, dismissed this finding because the levels of nitrate used were much higher than what would be expected to occur after a meal, and, therefore, any N-nitroso compound found would not likely occur in a person in real world experiences. GSK asserted that "no mutagenic nitrosated product of ranitidine is likely to be formed in man under any conceivable physiological conditions [.]"

68. In 1983, the same year Zantac was approved in the United States, seven researchers from the University of Genoa published a study discussing the nitrosation of ranitidine and its genotoxic effects (ability to harm DNA).[20] The researchers concluded:

> [I]t appears that reaction of ranitidine with excess sodium nitrite under acid conditions gives

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[19] Brittain et al, *The Safety of Ranitidine*, THE LANCET 1119 (Nov. 14, 1981).

[20] Maura et al, *DNA Damage Induced by Nitrosated Ranitidine in Cultured Mammalian Cells*, 18 TOX. LTTRS. 97- 102 (1983).

> rise to a nitroso-derivative (or derivatives) [like NDMA] capable of including damage in mammalian cells. […] These findings are consistent with those of Dr. de Flora, who showed that preincubation of ranitidine with excess nitrite in human gastric juice resulted in mutagenic effects.

69. Also in 1983, Dr. de Flora, along with four other researchers, published the complete findings.[21] The results "confirm our preliminary findings on the formation of genotoxic derivatives from nitrite and ranitidine [.]" *Id.* Again, the authors noted that, "the widespread clinical use [of ranitidine] and the possibility of a long-term maintenance therapy suggest the prudent adoption of some simple measures, such as a diet low in nitrates and nitrites or the prescription of these anti-ulcer drugs at a suitable interval from meals […] Absorbic acid has been proposed as an inhibitor of nitrosation combined with nitrosatable drugs and appears to block efficiently the formation of mutagenic derivatives from […] ranitidine." *Id.*

70. The high instability of the ranitidine molecule was elucidated in scientific studies investigating ranitidine as a source of NDMA in drinking water and specific mechanisms for the breakdown of ranitidine were proposed.[22] These studies underscore the instability of the NDMA group on the ranitidine molecule and its ability to form NDMA in water treatment plants which supply many

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[21] De Flora et al, *Genotoxicity of nitrosated ranitidine*, 4 CARCINOGENESIS 3, 255-260 (1983).

[22] Le Roux et al, *NDMA Formation by Chloramination of Ranitidine: Kinetics and Mechanism*, 46 *Environ. Sci. Technol.* 20, 11095-11103 (2012)

American cities with water.

71. These studies did not appreciate the full extent of NDMA formation risk from ranitidine; specifically, the added danger of this drug having not only a labile, or easily broken down, DMA group but also a readily available nitroso source in its nitrite group on the opposite terminus of the molecule. Recent testing of NDMA levels in ranitidine batches are so high that the nitroso for NDMA likely comes from no other source than the ranitidine molecule itself.

72. Valisure, LLC ("Valisure") is an online pharmacy that also runs an analytical laboratory that is accredited by the International Organization for Standardization ("ISO")—an accreditation recognizing the laboratories technical competence for regulatory compliance. Valisure's mission is to help ensure the safety, quality, and consistency of medications and supplements in the market. In response to rising concerns about counterfeit medications, generics, and overseas manufacturing, Valisure developed proprietary analytical technologies that it uses in addition to FDA standard assays to test every batch of every medication it dispenses.

73. As part of its testing of Zantac, and other ranitidine products, in every lot tested, Valisure discovered exceedingly high levels of NDMA. Valisure's ISO 17025 accredited laboratory used FDA recommended GC/MS headspace analysis method FY 19-005-DPA8 for the determination of NDMA levels. As per the FDA protocol, this method was validated to a lower limit of detection of 25 ng.[23]

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[23] US Food and Drug Administration. (updated 01/25/2019). Combined N-Nitrosodimethlyamine (NDMA) and N- Nitrosodiethylamine (NDEA) Impurity Assay, *FY*19-005-DPA-S.

74. Valisure's testing shows, on average, 2,692,291 ng of NDMA in a 150 mg Zantac tablet. Considering the FDA's permissible limit is 96 ng, this would put the level of NDMA at ***28,000 times*** the legal limit. In terms of smoking, a person would need to smoke at least 6,200 cigarettes to achieve the same levels of NDMA found in one 150 mg dose of Zantac.

75. Valisure was concerned that the extremely high levels of NDMA observed in its testing were a product of the modest oven heating parameter of 130 °C in the FDA recommended GC/MS protocol. Thus, Valisure developed a low temperature GC/MS method to see if it could still detect NDMA at 37°C, the average temperature of the human body.

76. Valisure tested ranitidine tablets by themselves and in conditions simulating the human stomach. Industry standard "Simulated Gastric Fluid" ("SGF" 50 mM potassium chloride, 85 mM hydrochloric acid adjusted to pH 1.2 with 1.25 g pepsin per liter) and "Simulated Intestinal Fluid" ("SIF" 50 mM potassium chloride, 50 mM potassium phosphate monobasic adjusted to pH 6.8 with hydrochloric acid and sodium hydroxide) were used alone and in combination with various concentrations of nitrite, which is commonly ingested in foods like processed meats and is elevated in the stomach by antacid drugs. Indeed, Zantac was specifically advertised to be used when consuming foods containing high levels of nitrates, like tacos, pizza, etc.[24]

77. The results of Valisure's tests on ranitidine tablets in biologically relevant conditions demonstrate

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[24] *See, e.g.,* https://www.ispot.tv/ad/dY7n/zantac-family-taco-night; https://youtu.be/jzS2kuB5_wg; https://youtu.be/Z3QMwkSUIEg ; https://youtu.be/qvh9gyWgQns.

significant NDMA formation under simulated gastric conditions with nitrite present.

Table 2 - Valisure Biologically relevant tests for NDMA formation		
Ranitidine Tablet Studies	**NDMA (ng/mL)**	**NDMA per tablet (ng)**
Tablet without Solvent	Not Detected	Not Detected

Table 2 - Valisure Biologically relevant tests for NDMA formation		
Ranitidine Tablet Studies	**NDMA (ng/mL)**	**NDMA per tablet (ng)**
Tablet	Not Detected	Not Detected
Simulated Gastric Fluid (“SGF”)	Not Detected	Not Detected
Simulated Intestinal Fluid	Not Detected	Not Detected
SGF with 10 mM Sodium Nitrite	Not Detected	Not Detected
SGF with 25 mM Sodium Nitrite	236	23,600
SGF with 50 mM Sodium Nitrite	3,045	304,500

78. Under biologically relevant conditions, when sufficient nitrites are present, staggeringly high levels of NDMA are found in one dose of 150 mg Zantac, ranging between 245 and 3,100 times above the FDA allowable limit. In terms of smoking, one would need to smoke over

500 cigarettes to achieve the same levels of NDMA found in one dose of 150 mg Zantac at the 25 ng level (over 7,000 for the 50 μg level).

79. Antacid drugs are known to increase stomach pH and thereby increase the growth of nitrite-reducing bacteria which further elevate levels of nitrite. This fact is well known and even present in the warning labels of antacids like Prevacid (lansoprazole) and was specifically studied with ranitidine in the original approval of the drug. Thus, higher levels of nitrites in patients regularly taking Zantac would be expected.

80. In fact, NDMA formation in the stomach has been a concern for many years, and ranitidine has been specifically implicated as a cause of NDMA formation by multiple research groups, including those at Stanford University.

81. Existing research shows that ranitidine interacts with nitrites and acids in the chemical environment of the human stomach to form NDMA. *In vitro* tests demonstrate that when ranitidine undergoes "nitrosation" (the process of a compound being converted into nitroso derivatives) by interacting with gastric fluids in the human stomach, the byproduct created is dimethylamine ("DMA")—which is an amine present in ranitidine itself. When DMA is released, it can be nitrosated even further to form NDMA, a secondary N-nitrosamine.

82. Moreover, in addition to the gastric fluid mechanisms investigated in the scientific literature, Valisure identified a possible enzymatic mechanism for the liberation of ranitidine's DMA group via the human enzyme dimethylarginine dimethylaminohydrolase ("DDAH") which can occur in other tissues and organs separate from the stomach.

83. Liberated DMA can lead to the formation of NDMA when exposed to nitrite present on the ranitidine molecule, nitrite freely circulating in the body, or other potential sources— particularly in weak acidic conditions such as those in the kidney or bladder. The original scientific paper detailing the discovery of the DDAH enzyme in 1989 specifically comments on the propensity of DMA to form NDMA: "This report also provides a useful knowledge for an understanding of the endogenous source of dimethylamine as a precursor of a potent carcinogen, dimethylnitrosamine [NDMA]."[25]

84. Computational modelling demonstrates that ranitidine can readily bind to the DDAH-1 enzyme in a manner similar to the natural substrate of DDAH-1 known as asymmetric dimethylarginine ("ADMA").

85. These results indicate that the enzyme DDAH-1 increases formation of NDMA in the human body when ranitidine is present; therefore, the expression of the DDAH-1 gene is useful for identifying organs most susceptible to this action.

86. DDAH-1 is most strongly expressed in the kidneys but also broadly distributed throughout the body, such as in the liver, stomach, bladder, brain, colon, and prostate. This offers both a general mechanism for NDMA formation in the human body from ranitidine and specifically raises concern for the effects of NDMA on numerous organs, including the bladder.

87. In addition to the aforementioned *in vitro* studies that suggest a strong connection between ranitidine and NDMA formation, *in vivo* clinical studies in living animals

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[25] Ogawa et ai *Purification and properties of a new enzyme, NG, NG-dimethylarginine dimethylaminohydrolase, from rat kidney,* 264 J. *BIO. CHEM* 17, 10205-10209 (1989).

add further weight to concern over this action and overall potential carcinogenicity. A study published in the journal *Carcinogenesis* in 1983 titled "Genotoxic effects in rodents given high oral doses of ranitidine and sodium nitrite" specifically suspected the carcinogenic nature of ranitidine in combination with nitrite. The authors of this study concluded: "Our experimental findings have shown that simultaneous oral administration in rats of high doses of ranitidine and NaNO2 [nitrite] can produce DNA fragmentation either in liver or in gastric mucosa."[26]

88. The human data is also concerning. In 2002, a study indicated that NDMA was found in the urine and gastric fluid of children after taking ranitidine for four weeks.[27] Yet, Defendants didn't undertake an investigation or take any steps to prevent harm to the millions of children that were unknowingly ingesting a carcinogen all over the world. Instead, Defendants continued to maliciously, recklessly, and aggressively market and sell Zantac as safe for use during pregnancy and for pediatric use.

89. A study completed and published in 2016 by Stanford University observed that healthy individuals, both male and female, who ingested Zantac 150 mg tablets produced roughly 400 times elevated amounts of NDMA in their urine (over 47,000 ng) in the proceeding 24 hours after ingestion.[28]

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[26] Brambilla et al., *Genotoxic effects in rodents given high oral doses of ranitidine and sodium nitrite,* 4 CARCINOGENESIS 10, 1281-1285 (1983).

[27] Krawczynski, et al. *Nitrozamines in Children with Chronic Gastritis*; Journal of Polish Paediatric Society (2002); 0031-3939.

[28] Zeng et al, *Oral intake of ranitidine increases urinary excretion of N-nitrosodimethylamine,*37 CARCINOGENESIS 625-634 (2016).

90. A 2004 study published by the National Cancer Institute investigated 414 cases of peptic ulcer disease reported in 1986 and followed the individual cases for 14 years.[29] One of the variables investigated by the authors was the patients' consumption of a prescription antacid, either Tagamet (cimetidine) or Zantac (ranitidine). The authors concluded that "[r]ecent use of ulcer treatment medication (Tagamet and Zantac) was also related to the risk of bladder cancer, and this association was independent of the elevated risk observed with gastric ulcers." Specifically, the authors note that "N-Nitrosamines are known carcinogens, and nitrate ingestion has been related to bladder cancer risk." NDMA is among the most common of the N-Nitrosamines.

91. A 1982 clinical study in rats compared ranitidine and cimetidine exposure in combination with nitrite. When investigating DNA fragmentation in the rats' livers, no effect was observed for cimetidine administered with nitrite, but ranitidine administered with nitrite resulted in a significant DNA fragmentation.[30]

92. A new study published in 2001 by doctors from the Memorial Sloan Kettering Cancer Center confirmed the link between Zantac and NDMA.[31]

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[29] Michaud et al, *Peptic ulcer disease and the risk of bladder cancer in a prospective study of male health professionals,* 13 CANCER EPIDEMIOL BIOMARKERS PREY. 2, 250-254 (2004).

[30] Brambilla et al, Genotoxic Effects of Drugs: Experimental Findings Concerning Some Chemical Families of Therapeutic Relevance, Nicolini C. (eds) Chemical Carcinogenesis. NATO Advanced Study Institutes Series (Series A: Life Sciences), Vol 52. Springer, Boston, MA (1982).

[31] Braunstein LZ, Kantor ED, O'Connell K, et al. Analysis of Ranitidine-Associated *N*-Nitrosodimethylamine Production Under

93. The risk of creating NDMA by exposing ranitidine to heat has been well-known and documented. Early studies, including the one conducted by GSK in the early 1980s, demonstrated that nitrosamines were formed when ranitidine was exposed to heat. This point was underscored in the Valisure petition, which initially used a high-heat testing method.

94. On January 2, 2020, Emery Pharma, an FDA-certified pharmaceutical testing laboratory, conducted a series of tests on ranitidine. The researchers exposed ranitidine to 70 degrees Celsius for varying periods of time. The results showed that increasing levels of NDMA formed based on exposure to heat. Emery Pharma reported on how NDMA accumulates over time when exposed to 70 degrees Celsius.

95. The researchers cautioned:

> NDMA accumulates in ranitidine-containing drug products on exposure to elevated temperatures, which would be routinely reached during shipment and during storage. More importantly, these conditions occur post-lot release by the manufacturer. Hence, while NDMA levels in ranitidine may be acceptable at the source, they may not be so when the drug is purchased and subsequently at the time of consumption by the consumer.

96. The results of this data demonstrate that in normal transport and storage, and especially when exposed to heat or humidity, the ranitidine molecule systematically breaks down into NDMA, accumulating

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Simulated Physiologic Conditions. *JAMA Netw Open.* 2021;4(1):e2034766. doi:10.1001/jamanetworkopen.2020.34766

over time in the finished product. Considering ranitidine-containing products have an approved shelf life of 36 months, the possibility of the drug accumulating dangerously high levels of NDMA prior to consumption is underscored by the FDA's swift removal of the product from the market.

97. In fact, the FDA acknowledged that testing revealed that NDMA levels in ranitidine products stored at room temperature can increase with time to unacceptable levels.

IV. Defendants Knew of the NDMA Defect but Failed to Take Permitted (or Required) Actions to Address Known Risks.

98. During the time that Defendants manufactured, distributed, transported, stored, and sold ranitidine-containing products in the United States, the weight of scientific evidence showed that ranitidine-containing products exposed users to unsafe levels of NDMA. Defendants failed to disclose this risk to consumers on the drug's label - or through any other means - and Defendants failed to report these risks to the public.

99. Going back as far as 1981, two years before Zantac entered the market, research showed elevated rates of NDMA when properly tested. This was known or should have been known by Defendants.

100. Defendants were required to act to address the known risks of the ranitidine- containing products they manufactured and sold. By registering with the FDA to manufacture, label, distribute, and sell ranitidine-containing products within the US, all Defendants holding

an ANDA,[32] NDC Code[33] or which registered an establishment[34] had an obligation to comply with federal law.[35]

A. Defendants Failed to Adequately Warn Physicians, Patients, and the Public About the NDMA Risk.

101. Defendants concealed the Zantac–NDMA link from consumers in part by not reporting it to the FDA, which relies on drug manufacturers to bring new information about an approved drug like Zantac to the agency's attention. Defendants disregarded the scientific evidence available to them and did not report to the FDA significant information alleged above affecting the safety

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[32] Once a manufacturer's ANDA is approved, that manufacturer is subject to post-market obligations. These obligations include submitting annual reports to the FDA, tracking and reporting adverse events, and tracking and reporting relevant medical literature among other things.

[33] All Defendants who have the power of labeling and listing drugs within the United States must obtain a National Drug Code ("NDC"). All NDC holders are required to register all drugs and list them with the FDA.

[34] All Defendants who have registered establishments with the FDA must provide "[c]omplete, accurate and up-to-date establishment registration and drug listing information [which] is essential to promote patient safety. FDA relies on establishment registration and drug listing information for several key programs, including: drug establishment inspections, post market surveillance, counterterrorism, recalls, drug quality reports, adverse event reports, monitoring of drug shortages and availability, supply chain security, drug import and export, and identification of products that are marketed without an approved application"

[35] Plaintiffs reference federal law herein not in any attempt to enforce it, but only to demonstrate that their state-law tort claims do not impose any additional obligations on Defendants beyond what is already required for them under federal law.

or labeling of Zantac. Defendants did not propose a disclosure that would warn healthcare providers and patients of the link between ranitidine and NDMA.

102. Defendants also never disclosed the relevant studies to the public, nor did they publicly disclose the link between ranitidine and NDMA.

103. In a 1981 study published by GSK, the innovator of the ranitidine molecule, the metabolites of ranitidine in urine were studied using liquid chromatography.[36] Many metabolites were listed, though there is no indication that the study looked for NDMA. Upon information and belief, this was intentional – a gambit by the manufacturer to avoid detecting a carcinogen in their product.

104. Indeed, Dr. de Flora published a note in *The Lancet* discussing the results of his experiments showing that ranitidine was turning into mutagenic N-nitroso compounds, of which NDMA is one, in human gastric fluid when accompanied by nitrites. Defendants were aware of this as GSK specifically responded to the note and attempted to discredit it. Notwithstanding this legal risk signal, GSK did not test for this alarming cancer risk, and it did so intentionally.

105. By 1987, after numerous studies raised concerns over ranitidine and cancerous nitroso compounds (discussed previously), GSK published a clinical study specifically investigating gastric contents in human

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[36] Carey et al, *Determination of ranitidine and its metabolites in human urine by reversed-phase ion-pair high- performance liquid chromatography,* 255 J. CHROMATOGRAPHY B: BIOMEDICAL SCI. & APPL. 1, 161-168 (1981).

patients and N-nitroso compounds.[37] This study specifically indicated that there were no elevated levels of N-nitroso compounds (of which NDMA is one). However, the study was rigged to fail. It used an analytical system called a "nitrogen oxide assay" for the determination of N-nitrosamines, which was developed for analyzing food and is a detection method that indirectly and non-specifically measures N-nitrosamines. Furthermore, in addition to this approach being less accurate, GSK also removed all gastric samples that contained ranitidine out of concern that samples with ranitidine would contain "high concentrations of N-nitroso compounds being recorded." So, without the chemical being present in any sample, any degradation into NDMA could not, by design, be observed. This spurious test was intentionally designed to mask any potential cancer risk.

106. In fact, on information and belief, none of the Defendants ever used a mass spectrometry assay to test for the presence of nitrosamines in any of the studies and trials they did in connection with its trials associated with the ranitidine NDA. This is because when using mass spectrometry, it requires heating of up to 130 °C which can result in excessive amounts of nitrosamines being formed. Had the Defendants used a mass spectrometry assay, the results would have revealed large amounts of NDMA, and the FDA would never have approved Zantac as being safe.

107. There are multiple alternatives to Zantac that do not pose the same risk, such as Cimetidine (Tagamet), Famotidine (Pepcid), Omeprazole (Prilosec), Esomeprazole (Nexium), and Lansoprazole (Prevacid).

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[37] Thomas et al, *Effects of one year's treatment with ranitidine and of truncal vagotomy on gastric contents,* 6 *GUT*. Vol. 28, 726-738 (1987).

B. Defendants Failed to Notify the FDA About the Presence of NDMA in Ranitidine-Containing Products.

108. Manufacturers of an approved drug are required by regulation to submit an annual report to the FDA containing, among other things, new information regarding the drug's safety pursuant to 21 C.F.R. § 314.81(b)(2):

> The report is required to contain . . . [a] brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product. The report is also required to contain a brief description of actions the applicant has taken or intends to take as a result of this new information, for example, submit a labeling supplement, add a warning to the labeling, or initiate a new study.

109. 21 C.F.R. § 314.81(b)(2)(v) provides that the manufacturer's annual report must also contain:

> Copies of unpublished reports and summaries of published reports of new toxicological findings in animal studies and in vitro studies (e.g., mutagenicity) conducted by, or otherwise obtained by, the [manufacturer] concerning the ingredients in the drug product.

110. Defendants ignored these regulations and, disregarding the scientific evidence available to them regarding the presence of NDMA in their products and the risks associated with NDMA, did not report to the FDA significant information affecting the safety or labeling of ranitidine-containing products.

111. Knowledge regarding the risk of NDMA in ranitidine was sufficiently available in the publicly available scientific literature such that any Defendant, consistent with its heightened obligations to ensure the safety of its products, knew or should have known about the potential NDMA risks associated with ranitidine consumption.

112. Defendants never conducted or provided the relevant studies to the FDA, nor did they present the FDA with a proposed disclosure noting the various ways that ranitidine transforms into NDMA. Accordingly, because Defendants never properly disclosed the risks to the FDA, they never proposed any labeling or storage / transportation guidelines that would have addressed this risk. Thus, the FDA was never able to reject any proposed warning or proposal for transport / storage.

113. When the FDA eventually learned about the NDMA risks posed by ranitidine- containing products, it ordered manufacturers to voluntarily remove the products from the market. Thus, had any Defendant alerted the FDA to the risks of NDMA, the FDA would have required the manufacturers to remove ranitidine-containing products from the market earlier.

C. Defendants Failed to Adhere to Proper Manufacturing and Storage Practices.

114. Defendants stored Ranitidine-Containing Products in preparation for their sale. Under federal law, a manufacturer must manufacture, store, warehouse, and distribute pharmaceutical drugs in accordance with "Current Good Manufacturing Practices" ("CGMPs") to ensure they meet safety, quality, purity, identity, and strength standards. 21 C.F.R. § 210.1(a) states that the CGMPs establish "minimum current good manufacturing

practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." Entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

115. Pursuant to 21 C.F.R. § 211.142(b), the warehousing of drug products shall provide for "[s]torage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected." In other words, Defendants had a duty and were obligated to properly store, handle, and warehouse ranitidine.

116. Testing conducted by the FDA confirms that under accelerated conditions, elevated temperatures can lead to the presence of NDMA in the drug product.

117. FDA has also concluded that NDMA can increase in ranitidine under storage conditions allowed by the labels, and NDMA has been found to increase significantly in samples stored at higher temperatures, including temperatures the product may be exposed to during normal distribution and handling. FDA's testing also showed that the level of NDMA in ranitidine-containing products increases with time. And while Emery's Citizen Petition sought to obtain a directive regarding temperature- controlled shipping of ranitidine, which was necessary given the time and temperature sensitivity of the drug, that request was deemed moot by the FDA because the agency sought to withdraw ranitidine-containing products altogether.

118. Nothing prevented any Defendant from, on their own, taking actions to prevent accumulation of NDMA in ranitidine-containing products by ensuring that ranitidine was not exposed to heat or moisture over long periods.

119. Defendants could dictate and control the conditions under which Zantac, in both its API and finished dose forms, were transported, packaged and stored. Yet, Defendants failed to ensure that their ranitidine-containing products were kept safely from excessive heat and humidity.

V. Zantac and Ranitidine-Containing Products Are Pulled From the Market.

120. On September 13, 2019, in response to a citizen's petition filed by Valisure, LLC (discussed in detail below), U.S. and European regulators stated that they are reviewing the safety of ranitidine.

121. On October 2, 2019, the FDA stated that it was ordering all manufacturers of Zantac and ranitidine products to conduct testing for NDMA and that preliminary results indicated unacceptable levels of NDMA so far.

122. On November 1, 2019, the FDA released its preliminary results, showing unsafe levels of NDMA in various ranitidine products, including Zantac.

123. At no time did any Defendant attempt to include a warning about NDMA or any cancer, nor did the FDA ever reject such a warning. Defendants had the ability to unilaterally add an NDMA and/or cancer warning to the Zantac label (for both prescription and OTC). Had any Defendant attempted to add an NDMA warning to the Zantac label (either for prescription or OTC), the FDA would likely not have rejected it.

VI. Plaintiff-Specific Allegations

124. Plaintiffs regularly took brand name prescription, generic, and/or OTC Zantac. Upon information and belief, these products were manufactured and sold by Defendants, including the Boehringer Ingelheim entities, during all relevant times.[38] *See* Exhibit A.

125. Plaintiffs were diagnosed with various types of cancer, including but not limited to: stomach cancer, colorectal cancer, pancreatic cancer, kidney cancer, bladder cancer, prostate cancer, thyroid cancer, and liver cancer.

126. Based on prevailing scientific evidence, exposure to Zantac (and the attendant NDMA) can cause cancer in humans.

127. Plaintiffs' cancers were caused by ingestion of Zantac.

128. Had any Defendant warned that Zantac could lead to exposure to NDMA or, in turn, cancer, Plaintiffs would not have taken Zantac. Plaintiffs would not have taken ranitidine had Plaintiffs known of or been fully and adequately informed by Defendants, or by Plaintiffs' physicians of the true increased risks and serious dangers of taking the drug.

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[38] The dates a particular Defendant manufactured Zantac do not capture the entire time period that its version of Zantac was available for consumption. For example, a Zantac pill manufactured in 2016 likely takes months or years before it eventually reaches store shelves and then a consumer. Further, then, it could be an additional months or years before that particular pill was ingested by a consumer or Plaintiff. Therefore, the mere fact that a Defendant ceased manufacturing Zantac in a given year does not absolve that Defendant from liability stemming from Plaintiffs' ingestion of Zantac in the following years.

VIII. Exemplary/Punitive Damages Allegations.

129. Defendants' conduct as alleged herein was done with intentional and/or reckless disregard for human life, oppression, and malice. Defendants were fully aware of the safety risks of Zantac, particularly the carcinogenic potential of Zantac as it transforms into NDMA within the chemical environment of the human body. Nonetheless, Defendants deliberately crafted their label, marketing, and promotion to mislead consumers.

130. This was not done by accident or through some justifiable negligence. Rather, Defendants knew that it could turn a profit by convincing consumers that Zantac was harmless to humans, and that full disclosure of the true risks of Zantac would limit the amount of money Defendants would make selling Zantac. Defendants' object was accomplished not only through their misleading label, but through a comprehensive scheme of selective misleading research and testing, false advertising, and deceptive omissions as more fully alleged throughout this Complaint. Plaintiffs were denied the right to make an informed decision about whether to purchase and use Zantac, knowing the full risks attendant to that use. Such conduct was done with conscious disregard of Plaintiffs' rights.

131. Accordingly, Plaintiffs request punitive damages against Defendants for the harms caused to Plaintiffs.

TOLLING, DISCOVERY RULE, FRAUDULENT CONCEALMENT, ESTOPPEL

132. Plaintiffs assert all applicable statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including estoppel, equitable tolling, delayed discovery, discovery rule and/or fraudulent concealment.

133. Defendants are estopped from relying on any statute of limitations because of their concealment of the truth regarding the safety of Zantac. Defendants had a duty to disclose the true character, quality, and nature of Zantac because this was non-public information over which Defendants continue to have control. Defendants knew that this information was not available to Plaintiffs, Plaintiffs' medical providers, and/or health facilities, yet Defendants failed to disclose the information to the public, including to the Plaintiffs.

134. The expiration of any applicable statute of limitations has been equitably tolled by reason of Defendants' misrepresentations and concealment. Through affirmative misrepresentations and omissions, Defendants actively concealed from Plaintiffs the true risks associated with use of Zantac. Due to Defendants' acts and omissions, Plaintiffs' physicians were unaware of the increased risk of multiple types of cancer associated with the use of ranitidine due to its degradation into NDMA. Plaintiffs' physicians did not warn Plaintiffs of the true risks of ingesting Zantac including the increased risk of cancer. During the limitations period, Plaintiffs could not reasonably have known or learned through reasonable diligence that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

135. Within the time period of any applicable statute of limitations, Plaintiffs could not have discovered through the exercise of reasonable diligence that exposure to Zantac is injurious to human health. Plaintiffs' physicians did not warn Plaintiffs that the true risks of ingesting NDMA in ranitidine included the increased risk of cancer. Plaintiffs and/or their representatives did not discover and

did not know of facts that would cause a reasonable person to suspect the risk associated with the use of Zantac, nor would a reasonable and diligent investigation by Plaintiffs and/or their representatives have disclosed that Zantac would cause Plaintiffs' injuries and/or deaths.

136. Despite acting with reasonable diligence, Plaintiffs did not learn of the link between their cancers and ranitidine exposure until a time within the statute of limitations for filing of Plaintiffs' claims.

137. Plaintiffs bring the following causes of action pursuant to the Connecticut Product Liability Act §52 572m, *et seq*., various applicable state products liability statutes for the states listed in Exhibit A, and applicable common law for the states listed in Exhibit A.

CAUSES OF ACTION

COUNT I: NEGLIGENCE – DESIGN

138. Plaintiffs incorporate by reference each allegation set forth in preceding paragraphs as if fully stated herein.

139. Defendants were responsible for the manufacture, packaging, marketing, shipping, storage, handling, distribution and/or selling of prescription and OTC Zantac purchased and ingested by Plaintiffs.

140. Defendants, directly or indirectly, caused Zantac to be sold, distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiffs. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and/or sold Zantac within the State of Connecticut and throughout the United States.

141. At all relevant times, Defendants had a duty to exercise reasonable care in the manufacture, marketing, advertisement, supply, storage, transport, packaging,

sale, and/or distribution of Zantac products, including the duty to take all reasonable steps necessary to manufacture, promote, and/or sell a product that was not unreasonably dangerous to consumers and users of the product.

142. Defendants' duty of care owed to consumers, healthcare providers and the general public included providing accurate, true, and correct information concerning the risks of using Zantac, the risks of improper storage and exposure to heat and humidity, and appropriate, complete, and accurate warnings concerning the potential adverse effects of Zantac and, in particular, its ability to degrade into the carcinogenic compound NDMA under certain conditions.

143. At all relevant times, Defendants knew or, in the exercise of reasonable care, should have known of the hazards and dangers of Zantac and, specifically, the carcinogenic properties of NDMA when these products were ingested.

144. Accordingly, at all relevant times, Defendants knew or, in the exercise of reasonable care, should have known that use of Zantac could cause Plaintiffs' injuries, and thus, created a dangerous and unreasonable risk of injury to the users of these products. Defendants also knew or, in the exercise of reasonable care, should have known that users and consumers were unaware of the risks and the magnitude of the risks associated with use of Zantac.

131. As such, Defendants breached their duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, storage, testing, marketing, supply, promotion, advertisement, packaging, sale, and distribution of Zantac products, in that Defendants manufactured and produced defective

Zantac which carries the potential to transform into the carcinogenic compound NDMA; knew or had reason to know of the defects inherent in their products; knew or had reason to know that a user's or consumer's storage and handling and use of the products created a significant risk of harm and unreasonably dangerous side effects; and failed to prevent or adequately warn of these risks and injuries.

145. Defendants were negligent in their promotion of Zantac, outside of the labeling context, by failing to disclose material risk information as part of their promotion and marketing of Zantac, including the internet, television, print advertisements, etc. Nothing prevented Defendants from being honest in their promotional activities, and, in fact, Defendants had a duty to disclose the truth about the risks associated with Zantac in their promotional efforts, outside of the context of labeling.

146. Readily available testing methods revealed the dangers of Defendants' Zantac and ranitidine-containing products. For example, gas chromatography-mass spectrometry, the technique Valisure employed in 2019 to identify NDMA forming in ranitidine, was a widely available, cost-effective, industry-standard testing method. If this testing method had been used by Defendants to test Zantac and ranitidine, they could have determined that Zantac and ranitidine transform into NDMA when subjected to heat.

147. No Defendant tested the effects of temperature, time, humidity, light, or other relevant storage or transportation conditions on the quantity of NDMA in ranitidine-containing products.

148. Testing of the ranitidine molecule at any time

would have revealed that hotter temperatures, longer time periods, and higher humidity each increases the amount of NDMA.

149. Testing of the ranitidine molecule at any time also would have revealed that the typical temperature, time-period, and humidity that ranitidine-containing products were exposed to before being consumed resulted in dangerously high levels of NDMA.

150. Defendants knew or should have known that ranitidine-containing products posed a grave risk of harm. The dangerous propensities of their products and the carcinogenic characteristics of NDMA as produced within the human body as a result of ingesting ranitidine, as described above, were known to Defendants, or scientifically knowable to Defendants through appropriate research and testing by known methods, at the time they designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold the product, but were not known to end users and consumers, including Plaintiffs.

151. For example, Defendants knew that ranitidine had an inherent risk of degrading into NDMA because it has both a nitroso (N) and dimethylamine (DMA), which are all the ingredients needed to form NDMA.

152. Defendants also were on notice of the need to test and fully evaluate the carcinogenicity of ranitidine based on the research performed by Dr. de Flora and GSK scientists in the 1980s, which would have alerted the reasonable manufacturer of Zantac and/or ranitidine to beware of the potential for NDMA to form in the drug and/or in the human body.

153. Any of a variety of tests for NDMA would have sparked quick action. The FDA initiated a voluntary recall

only seven months after Valisure first publicized its NDMA testing results in September 2019. If any Defendant had performed and publicized a similar test at an earlier time, the FDA and broader market would have acted as quickly and decisively as happened in 2019, since the dangerous properties of NDMA were widely understood at all relevant times.

154. Defendants, directly or indirectly, manufactured, labeled, packaged, tested, and/or sold ranitidine-containing products that were used by Plaintiffs.

155. Defendants had a duty to warn Plaintiffs of the risk of cancer from exposure to NDMA in Zantac.

156. Defendants had a duty to impose safe expiration dates and storage conditions that would decrease the risk of harm to Plaintiffs. None did.

157. At all relevant times, Defendants had reason to know of the need for testing to reveal the hazards and dangers of Zantac and ranitidine and, specifically, the carcinogenic properties of NDMA when ranitidine-containing products are ingested and/or the elevated levels of NDMA that occurs when ranitidine-containing products are transported and stored based on studies conducted in the 1980s. Despite their ability and means to investigate, study, and test the products and to provide adequate warnings and instructions of the risk and safe expiration and storage conditions, Defendants failed to do so. Indeed, Defendants wrongfully concealed information and further made false and/or misleading statements concerning the safety and use of Zantac.

158. Defendants' negligence included:

a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling,

and/or distributing Zantac without thorough and adequate pre- and post-market testing;

b. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and/or distributing Zantac while negligently and/or intentionally concealing and failing to disclose the results of trials, tests, and studies of Zantac and the carcinogenic potential of NDMA as created in the human body as a result of ingesting Zantac, and, consequently, the risk of serious harm associated with human use of Zantac;

c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Zantac products were safe for their intended consumer use;

d. Failing to use reasonable and prudent care in testing, research, manufacture, storage, transport and development of Zantac products so as to avoid the risk of serious harm associated with the prevalent use of Zantac products;

e. Failing to design and manufacture Zantac so as to ensure it was at least as safe and effective as other medications on the market intended to treat the same symptoms;

f. Failing to provide adequate instructions, guidelines, and safety precautions to those persons Defendants could reasonably foresee would use Zantac products;

g. Failing to disclose to Plaintiffs, users/consumers, healthcare providers and the general public that use of Zantac presented significant risks of cancer and other grave illnesses;

h. Failing to warn Plaintiffs, consumers, and the general public that the product's risk of harm was unreasonable and that there were safer and effective alternative medications available to Plaintiffs and other consumers;

i. Systematically suppressing or downplaying contrary evidence about the risks, incidence, and prevalence of the side effects of Zantac products;

j. Representing that their products were safe for their intended use when, in fact, Defendants knew or should have known the products were not safe for their intended purpose;

k. Declining to make or propose any changes to the products' labeling or other promotional materials that would alert consumers and the general public of the risks;

l. Advertising, marketing, and recommending the use of the products, while concealing and failing to disclose or warn of the dangers known (by Defendants) to be associated with or caused by the use of or exposure to NDMA in Zantac;

m. Continuing to disseminate information to their consumers, which indicate or imply that Defendants' products are not unsafe for regular consumer use;

n. Continuing the manufacture and sale of their products with the knowledge that the products were unreasonably unsafe and dangerous; and

o. Shipping, storing, and handling of Zantac in a manner that subjected it to heat and humidity so that it generated high levels of NDMA.

159. Defendants knew and/or should have known that foreseeable consumers, such as Plaintiffs, would suffer

injuries as a result of Defendants' failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution, storage, transport, and sale of Zantac.

160. Plaintiffs did not know the nature and extent of the injuries that could result from the intended use of and/or exposure to Zantac.

161. Defendants' negligence was the proximate cause of Plaintiffs' injuries, i.e., absent Defendants' negligence, Plaintiffs would not have developed cancer.

162. Defendants' conduct, as described above, was reckless and without regard for the safety of consumers including Plaintiffs herein. Defendants regularly risked the lives of consumers and users of their products, including Plaintiffs, with full knowledge of the dangers of their products. Defendants have made conscious decisions not to redesign, re-label, warn, or inform the unsuspecting public, including Plaintiffs of the risk of cancer from NDMA in Zantac, including warning or informing of appropriate conditions under which to store their products, the appropriate expiration dates, and the significant risks of seemingly harmless behavior such as storing ranitidine in a bathroom medicine cabinet where it would be regularly exposed to humidity.

163. Defendants' conduct as alleged herein was done with reckless disregard for human life, oppression, and malice. Defendants were fully aware of the safety risks of Zantac, particularly its carcinogenic potential as it transforms into NDMA within the chemical environment of the human body and/or during transport and/or storage. Nonetheless, Defendants deliberately crafted their label and marketing to mislead consumers. This was not done accidentally or through some justifiable negligence. Rather, Defendants knew they could profit by convincing

consumers that Zantac was harmless to humans, and that full disclosure of the true risks would limit the amount of money Defendants would make selling the drugs. Defendants' objective was accomplished not only through a misleading label, but through a comprehensive scheme of selective misleading research and testing, false advertising, and deceptive omissions as more fully alleged throughout this pleading. Plaintiffs were denied the right to make an informed decision about whether to purchase and use Zantac, knowing the full risks attendant to that use. Such conduct was done with conscious disregard of Plaintiffs' rights.

164. Defendants' conduct, as described above, was willful, wanton, malicious and conducted with reckless disregard for the health and safety of users of Zantac products, including Plaintiffs. Defendants' conduct warrants an award of punitive damages.

165. As a direct and proximate result of Defendants negligently placing defective Zantac products into the stream of commerce, Plaintiffs suffered significant, serious, and permanent injury and or death, and Plaintiffs sustained pecuniary loss and general damages in a sum exceeding the jurisdictional minimum of this Court.

166. As a proximate result of Defendants negligently placing defective Zantac products into the stream of commerce, as alleged herein, there was a measurable and significant interval of time during which Plaintiffs suffered great mental anguish, personal injury and/or death, and other damages.

167. As a proximate result of Defendants negligently placing defective Zantac products into the stream of commerce, as alleged herein, Plaintiffs sustained loss of income, and loss of earning capacity.

COUNT II: NEGLIGENCE – FAILURE TO WARN

168. Plaintiffs incorporate by reference each allegation set forth in preceding paragraphs as if fully stated herein.

169. Ranitidine leads to NDMA exposure in the following ways: (1) the NDMA levels in ranitidine increase as the drug breaks down in the human digestive system and interacts with various enzymes in the human body; (2) the ranitidine molecule internally degrades to form NDMA, and the NDMA levels in the drug substance and the drug product increase over time under normal storage conditions, but more so with exposure to heat or humidity.

170. NDMA is a potent carcinogen in humans. Higher exposure to NDMA over longer time periods leads to even higher risks of cancer.

171. To mitigate degradation of ranitidine into NDMA in the stomach, over time, and in the presence of heat or humidity, consumers could be warned:

a. To consume ranitidine shortly after manufacturing and to store it in a cool, dry place (e.g., not in a bathroom). No ranitidine containing product contained this warning.

b. To consume ranitidine for only short periods of time. No ranitidine-containing product warned that cancer could result from long-term ingestion of ranitidine.

c. Not to take ranitidine with or after meals or in combination with a high-nitrite diet. No ranitidine-containing product contained this warning.

d. To take ranitidine with Vitamin E or Vitamin C to inhibit nitrosation and the formation of NDMA in the

stomach. No ranitidine-containing product contained this warning.

172. To mitigate degradation of ranitidine into NDMA over time, and in the presence of heat or humidity, consumers should have been warned to consume ranitidine shortly after manufacturing. No ranitidine-containing product contained this warning.

173. In fact, ranitidine-containing products had expiration dating periods of one or two years allowing accumulation of more and more unsafe levels of NDMA. A much shorter period of a matter of months would have ensured that ranitidine contained far lower levels of NDMA when consumed.

174. In setting expiration and/or retest dates for their ranitidine-containing drugs, Defendants were required to take into consideration the real-world conditions the drugs would be exposed to, including the conditions under which the drugs would be stored and shipped. See 21 C.F.R. § 211.137.

175. A manufacturer has a duty of reasonable care to provide an adequate warning about known risks. The risk posed from NDMA in Zantac was known and/or knowable by Defendants. Defendants' duty of care owed to consumers and the general public included the duty to provide accurate, true, and correct information concerning the risks of using ranitidine-containing products and appropriate, complete, and accurate warnings concerning the potential adverse effects of ranitidine-containing products and, in particular, its ability to transform into the carcinogenic compound NDMA. Defendants had a continuing duty to provide appropriate and accurate warnings and precautions.

176. Defendants, as manufacturers and sellers of

pharmaceutical medication, are held to the knowledge of an expert in the field.

177. At all relevant times, Defendants negligently designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine-containing products, which are defective and unreasonably dangerous to consumers, including Plaintiffs, because they do not contain adequate warnings concerning the dangerous characteristics of Zantac and NDMA. These actions were under the ultimate control and supervision of Defendants.

178. At all relevant times, Defendants knew or, in the exercise of reasonable care, should have known of the hazards and dangers of ranitidine-containing products and, specifically, the carcinogenic properties of NDMA when ranitidine is ingested. Defendants knew or should have known about each of these risks in time to warn consumers.

179. Even though Defendants knew or should have known that Zantac posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to ranitidine-containing products. The dangerous propensities of ranitidine-containing products and the carcinogenic characteristics of NDMA, as described above, were known to Defendants, or scientifically knowable to Manufacturer Defendants through appropriate research and testing by known methods, at the time they manufactured, marketed, distributed, supplied, or sold the products, but were not known to end users and consumers, including Plaintiffs.

180. Defendants negligently failed to warn and have wrongfully concealed information concerning the dangerous level of NDMA in ranitidine-containing

products, and further, have made false and/or misleading statements concerning the safety of Zantac.

181. At the time of manufacture, Defendants could have provided warnings or instructions regarding the full and complete risks of Zantac because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products.

182. At various points in time, Defendants possessed new information or new analyses of existing information that empowered them unilaterally to change the warnings and precautions section of their ranitidine-containing products' label.

183. At all relevant times, Defendants negligently failed and deliberately refused to investigate, study, test, or promote the safety or to minimize the dangers to users and consumers of their products and to those who would foreseeably use or be harmed by Zantac.

184. Each Defendant breached this duty for the ranitidine-containing products it manufactured, marketed, and sold. The warnings included on each ranitidine-containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored or transported under humid conditions, when stored or transported under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture. Plaintiffs and/or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have ingested Zantac and would not have developed cancer or otherwise been harmed by exposure to NDMA in these products.

185. Despite this ability, Defendants failed to warn of the risks of NDMA in the warnings and precautions section of their ranitidine-containing products' label.

186. Plaintiffs were exposed to Defendants' ranitidine-containing products without knowledge of their dangerous characteristics. Plaintiffs could not have reasonably discovered the risks associated with ranitidine-containing products prior to or at the time Plaintiffs consumed the drugs. Plaintiffs and Plaintiffs' physicians relied upon the skill, superior knowledge, and judgment of Defendants to know about and disclose serious health risks associated with using Defendants' products.

187. At all relevant times, Plaintiffs used and/or were exposed to Defendants' ranitidine-containing products while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

188. Defendants knew or should have known that the minimal warnings disseminated with their ranitidine-containing products were inadequate, failed to communicate adequate information on the dangers and safe use/exposure, and failed to communicate warnings and instructions that were appropriate and adequate to render the products safe for their ordinary, intended and reasonably foreseeable uses. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs to avoid using the drug. Instead, Defendants disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of and/or exposure to ranitidine; continued to aggressively promote the efficacy of ranitidine- containing products, even after they knew or should have known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise

suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Zantac.

189. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their ranitidine-containing products on the warnings and precautions section of their products' labels, Plaintiffs could have avoided the risk of Plaintiffs developing cancer and could have obtained or used alternative medication. However, as a result of Defendants' concealment of the dangers posed by their ranitidine-containing products, Plaintiffs were not alerted, and so could not avert Plaintiffs' injuries.

190. Manufacturer Defendants' conduct, as described above, was reckless.

191. Manufacturer Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety problems associated with ranitidine-containing products, and suppressed this knowledge from the public. Defendants made conscious decisions not to warn or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

192. Defendants' lack of adequate warnings and instructions in the warnings and precautions section of their ranitidine-containing products' labels were a substantial factor in causing Plaintiffs' injuries.

193. As a direct and proximate result of Defendants' failure to provide an adequate warning of the risks of ranitidine-containing products, Plaintiffs suffered injuries and/or death, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to,

past and future medical expenses, lost income, funeral expenses, and other damages.

COUNT III: NEGLIGENT STORAGE AND TRANSPORTATION

194. Plaintiffs incorporate by reference each allegation set forth in preceding paragraphs as if fully stated herein.

195. As previously alleged, ranitidine degrades into NDMA more quickly at higher temperatures, at higher humidity levels, and under other poor storage or handling conditions.

196. Defendants were aware of the need to maintain sensitive pharmaceutical drugs under proper shipping and storage conditions, and that maintaining the highest safety techniques is best for the consumer. Pharmaceutical companies are well aware of the importance of precise temperature control down to the degree, and advertise on their ability to provide precise, quality service. More precise, colder transportation is, of course, more expensive than less precise, warmer transportation.

197. Testing of the quantity of NDMA in ranitidine performed to date has shown substantial variation among different batches. Some ranitidine has significantly more NDMA when tested.

198. NDMA forms due to chemical reactions in the human body, and also from degradation before consumption (principally heat, humidity, or time). Testing is performed before consumption and the age of the ranitidine is documented, so neither time nor degradation in the body should produce substantial variation. The best inference must be that substantial variation in heat and

humidity is causing differing amounts of NDMA to form.

199. Different ranitidine-containing products listed slightly different storage and transportation requirements.

200. Defendants systematically exposed ranitidine to excessive levels of heat and humidity that violated the instructions on the products' labels.

201. Defendants failed to implement rigorous policies to ensure substantial compliance with the heat and humidity requirements on product labels. This failure led to widespread noncompliance.

202. For example, Defendants shipped ranitidine-containing products through the mail. This method of transportation—whether through the United States Postal Service or large common carriers such as FedEx and UPS—does not guarantee controlled temperature or humidity. Because of Defendants' choice to use or allow this method of transportation, ranitidine-containing products shipped through the mail were systematically subject to excessive heat or humidity on days when the weather was hot or humid.

203. Defendants, directly or indirectly, transported, stored, handled, and/or sold ranitidine-containing products that were used by Plaintiffs.

204. At all relevant times, Defendants, had a duty to exercise reasonable care in the storage and transportation of ranitidine-containing products to ensure the products were not unreasonably dangerous to consumers and users.

205. Defendants breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products remained free from excessive heat and humidity, as required both by the duty of reasonable

care and the label.

206. At all relevant times, Defendants knew or should have known of the need for storing and transporting ranitidine-containing products within the labeled temperature range and at low humidity. Yet, Defendants ignored this risk. They did not ensure ranitidine-containing products were stored at low humidity or within the temperature range on the label. Instead, some ranitidine was subjected to excessive humidity and heat during storage, transportation, and shipping which caused the drug to degrade leading to the formation of excessive levels of NDMA.

207. Ignoring the risks of NDMA forming was unreasonable and reckless.

208. Plaintiffs did not know the nature and extent of the injuries that could result from the intended use of and/or exposure to ranitidine-containing products.

209. Defendants' negligence was a substantial factor in causing Plaintiffs' injuries.

210. As a direct and proximate result of Defendants' failure to store and transport ranitidine-containing products properly, Plaintiffs have suffered injuries and/or death, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, funeral expenses, and other damages.

211. As a direct and proximate result of these systematic failures, excessive levels of NDMA formed in the ranitidine-containing products the Defendants handled, stored and sold. These high levels of NDMA caused Plaintiffs' injuries and/or death.

COUNT VI: NEGLIGENT MISREPRESENTATION

212. Plaintiffs incorporate by reference each allegation set forth in preceding paragraphs as if fully stated herein.

213. The products complained of, Zantac Products, were designed, manufactured, advertised, marketed, distributed, and/or sold by the Defendants, which Plaintiffs regularly used and ingested.

214. At all relevant times, the Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold their Zantac Products, which are defective and unreasonably dangerous to consumers, including Plaintiff, because Zantac Products does not contain adequate warnings or instructions concerning the dangerous characteristics of ranitidine and NDMA. These actions were under the ultimate control and supervision of the Defendants.

215. Defendants represented to Plaintiffs via the media, advertising, website, social media, packaging, and promotions, among other misrepresentations described herein that:

a. the Zantac Products/ranitidine were both safe and effective for the lifetime of the product, when in fact, the drug contains unsafe levels of NDMA far in excess of the 96ng limit that increases at various points during the shipping, handling, storage, and consumption phases and as the product ages;

b. consumption of Zantac Products/ranitidine would not result in excessive amounts of NDMA being formed in their bodies;

c. the levels of NDMA in Zantac Products have no practical clinical significance; and

d. Zantac Products were safe for their intended use when, in fact, Defendants knew or should have known the products were not safe for their intended purpose.

216. These representations were false. Because of the unsafe levels of NDMA in Zantac Products, the drug presented an unacceptable risk of causing cancer. Zantac Products are so unsafe that the FDA was compelled to order the immediate withdrawal of all ranitidine-containing products on April 1, 2020.

217. Defendants knew that their Zantac Products would be used by their customers, such as Plaintiffs, without inspection for defects and that any such inspection would not have advised Plaintiffs of the fact that the Defendants' Zantac Products could cause the injuries which she suffered. Such facts made the Defendants' Zantac Products inherently and unreasonably dangerous in that Plaintiffs were not apprised of, could not and would not contemplate the danger and/or the extent of the danger of contracting colorectal and uterine cancer and the associated injuries and complications as a result of her exposure to the Defendants' Zantac Products and NDMA.

218. Defendants knew or should have known these representations were false and negligently made them without regard for their truth.

219. Defendants had a duty to accurately provide this information to Plaintiffs. In concealing this information from Plaintiffs, Defendants breached their duty. Defendants also gained financially from, and as a result of their breach.

220. Defendants intended for Plaintiffs and/or their physician(s) to rely on these representations.

221. Each of these misrepresentations were material

at the time they were made. In particular, each of the misrepresentations concerned material facts that were essential to the analysis undertaken by Plaintiffs as to whether to purchase or consume Zantac Products

222. Plaintiffs relied on the Defendants' statements regarding the Zantac Products by using and ingesting the Manufacturer Defendants' Zantac Products in the manner in which they were intended or reasonably foreseeable to the Defendants.

223. Plaintiffs would not have regularly used and ingested Zantac Products if Defendants did not make the foregoing misrepresentations.

224. Defendants' acts and omissions as described herein were committed in reckless disregard of Plaintiffs' rights, interests, and well-being to enrich Defendants.

225. Each of the Defendants owed a duty to Plaintiffs and the general public to make accurate and truthful representations regarding Zantac Products, and the Defendants breached their duty, thereby causing Plaintiffs to suffer harm.

226. Plaintiffs were exposed to the Defendants' products whenever they took Zantac Products. Each exposure to Defendants' Zantac Products caused Plaintiffs to be exposed to additional and accumulating NDMA, which then resulted in and directly caused Plaintiffs to suffer severe bodily injuries, specifically various types of cancer. Each exposure to Zantac Products was harmful and caused or contributed substantially to Plaintiffs' injuries and/or death.

227. As a direct and proximate result of the Defendants' negligent misrepresentations concerning their Zantac Products/ranitidine-containing products,

Plaintiffs have suffered injuries and/or death, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, funeral expenses, and other damages.

COUNT V: STRICT LIABILITY – DESIGN DEFECT

228. Plaintiffs incorporate by reference each allegation set forth in preceding paragraphs as if fully stated herein.

229. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and/or promoting ranitidine-containing products, which are defective and unreasonably dangerous to consumers, including Plaintiffs, thereby placing ranitidine-containing products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants.

230. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, stored, sold, and distributed the ranitidine-containing products used by Plaintiffs, as described herein.

231. At all relevant times, Defendants' ranitidine-containing products reached the intended consumers, handlers, and users or other persons coming into contact with these products within this State and throughout the United States, including Plaintiffs, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

232. Defendants' ranitidine-containing products, as researched, tested, developed, designed, licensed,

manufactured, packaged, labeled, distributed, sold, and/or marketed by Defendants were defective in design because they were unreasonably dangerous, and did not contain adequate warnings or instructions concerning the dangerous characteristics of ranitidine and NDMA. Defendants' ranitidine-containing products were therefore unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate.

233. At all relevant times, Defendants' ranitidine-containing products, as designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold by Defendants were defective in design and formulation, in one or more of the following ways:

a. Defendants' ranitidine-containing products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

b. Defendants' ranitidine-containing products were not reasonably safe when used in a reasonably anticipated or intended manner;

c. Defendants did not sufficiently test, investigate, or study their ranitidine-containing products and, specifically, the ability for ranitidine to transform into the carcinogenic compound NDMA within the human body;

d. Defendants did not sufficiently test, investigate, or study their ranitidine-containing products and, specifically, the stability of ranitidine and the ability for ranitidine- containing products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

e. Defendants failed to provide accurate expiration dates on the product label;

f. Defendants failed to package their ranitidine-containing products in a manner which would have preserved the safety, efficacy, quality, and purity of the product;

g. Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage of the drug;

h. Defendants knew or should have known at the time of marketing ranitidine- containing products that exposure to ranitidine could result in cancer and other severe illnesses and injuries;

i. Defendants did not conduct adequate post-marketing surveillance of their ranitidine-containing products;

j. Defendants did not conduct adequate stability testing of their product to ascertain shelf life, expiration, and proper storage, heat, and light specifications; and

k. Defendants could have employed safer alternative designs and formulations.

234. At all relevant times, Defendants knew or had reason to know that Zantac products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

235. At the time of manufacture, Defendants could have provided warnings or instructions regarding the full and complete risks of ranitidine because they knew or should have known of the unreasonable risks of harm

associated with the use of and/or exposure to such products. Despite this ability, Defendants failed to warn Plaintiffs of the risks of NDMA and in the warnings and precautions section of their ranitidine-containing products' label.

236. At various points in time, Defendants possessed new information or new analyses of existing information that empowered them unilaterally to change the warnings and precautions section of their ranitidine-containing products' label.

237. Plaintiffs used and were exposed to Defendants' ranitidine-containing products without knowledge of Zantac's dangerous characteristics.

238. At all times relevant to this litigation, Plaintiffs used and/or were exposed to the use of Defendants' ranitidine-containing products in an intended or reasonably foreseeable manner without knowledge of Zantac's dangerous characteristics.

239. Plaintiffs did not know and could not reasonably have discovered the defects and risks associated with ranitidine-containing products before or at the time of exposure due to the Defendants' suppression or obfuscation of scientific information linking Zantac to cancer.

240. The harm caused by Defendants' ranitidine-containing products far outweighed their benefit, rendering Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' ranitidine-containing products were and are more dangerous than alternative products, and Defendants could have designed ranitidine-containing products to make them less dangerous. Indeed, at the time Defendants designed ranitidine- containing products, the

state of the industry's scientific knowledge was such that a less risky design or formulation was attainable.

241. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their ranitidine-containing products on the warnings and precautions section of their products' labels, Plaintiffs could and would have avoided the risk of developing cancer and could and would have obtained alternative medication.

242. Defendants' defective design of ranitidine-containing products was willful, wanton, malicious, and conducted with reckless disregard for the health and safety of users of the Zantac products, including Plaintiffs. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety problems associated with ranitidine- containing products, and suppressed this knowledge from the general public. Defendants made conscious decisions not to warn or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

243. The defects in Defendants' ranitidine-containing products were substantial and contributing factors in causing Plaintiffs' injuries and/or death, and, but for Defendants' misconduct and omissions, Plaintiffs would not have sustained injuries and/or death.

244. As a direct and proximate result of Defendants placing their defective ranitidine- containing products into the stream of commerce, and the resulting injuries, Plaintiffs sustained personal injuries and/or death, mental anguish, loss of income, loss of earning capacity, pecuniary loss, funeral expenses, and other damages which exceeds the jurisdictional minimum of this Court.

COUNT VI: STRICT LIABILITY – FAILURE TO WARN

245. Plaintiffs incorporate by reference each allegation set forth in preceding paragraphs as if fully stated herein.

246. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and/or promoting ranitidine-containing products, which are defective and unreasonably dangerous to consumers; including Plaintiffs, because they do not contain adequate warnings or instructions concerning the proper expiration date of the product nor the dangerous characteristics of ranitidine and NDMA. These actions were under the ultimate control and supervision of Defendants.

247. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, stored, transported, sold, and/or otherwise released into the stream of commerce Zantac products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs, and therefore had a continuing duty to warn of the risks associated with the use of Zantac products.

248. Defendants also had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as the packaging, storage and handling or ranitidine.

249. Defendants, as a manufacturer and seller of pharmaceutical medications, are held to the knowledge of an expert in the field.

250. At the time of manufacture, Defendants could

have provided warnings or instructions regarding the full and complete risks of ranitidine-containing products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products.

251. At various points in time, Defendants possessed new information or new analyses of existing information that empowered them unilaterally to change the warnings and precautions section of their Zantac products' label.

252. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, promote the safety of, or minimize the dangers to users and consumers of their ranitidine-containing products and to those who would foreseeably use or be harmed by Defendants' ranitidine-containing products, including Plaintiffs.

253. Even though Defendants knew or should have known that ranitidine posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure. The dangerous propensities of their products and the carcinogenic characteristics of NDMA as produced within the human body as a result of ingesting ranitidine, as described above, were known to Defendants, or scientifically knowable to Defendants through appropriate research and testing by known methods, at the time they manufactured, distributed, supplied or sold the product, and were not known to end users and consumers, such as Plaintiffs.

254. To mitigate degradation of ranitidine into NDMA over time, and in the presence of heat or humidity, consumers should have been warned to consume ranitidine shortly after manufacturing. No ranitidine-

containing product contained this warning.

255. In fact, ranitidine-containing products had expiration dating periods of one or two years allowing accumulation of more and more unsafe levels of NDMA. A much shorter period of a matter of months would have ensured that ranitidine contained far lower levels of NDMA when consumed.

256. In setting expiration and/or retest dates for their ranitidine-containing drugs, Defendants were required to take into consideration the real-world conditions the drugs would be exposed to, including the conditions under which the drugs would be stored and shipped. See 21 C.F.R. § 211.137.

257. In setting expiration and/or retest dates for their ranitidine-containing drugs, Defendants were required to base those dates on stability testing, which in turn must account for storage conditions. 21 C.F.R. § 211.166.

258. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein, and Defendants failed to adequately warn consumers (i.e., the reasonably foreseeable users) of the risks of exposure to their products. Defendants have wrongfully concealed information concerning the dangerous nature of ranitidine-containing products, the potential for ingested ranitidine to transform into the carcinogenic NDMA compound, and further, have made false and/or misleading statements concerning the safety of ranitidine-containing products.

259. At all relevant times, Defendants' ranitidine-containing products reached the intended consumers, handlers, and users, or other persons coming into contact with these products within this State and throughout the United States, including Plaintiffs, without substantial

change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

260. Plaintiffs were exposed to Defendants' ranitidine-containing products without knowledge of their dangerous characteristics.

261. At all relevant times, Plaintiffs used Defendants' ranitidine-containing products for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

262. Plaintiffs and/or their personal representatives did not discover and could not have reasonably discovered the defects and risks associated with ranitidine-containing products prior to or at the time of Plaintiffs consuming them. Plaintiffs and/or their personal representatives relied upon the skill, superior knowledge, and judgment of Defendants to know about and disclose serious health risks associated with using Defendants' products.

263. Defendants knew or should have known that the minimal warnings disseminated with their ranitidine-containing products were inadequate, failed to communicate adequate information on the dangers and safe use/exposure, and failed to communicate warnings and instructions that were appropriate and adequate to render the products safe for their ordinary, intended, and reasonably foreseeable uses.

264. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs to utilize the products safely and with adequate protection. Instead, Defendants: disseminated information that was inaccurate, false, and misleading; failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of

injuries with use of and/or exposure to ranitidine; continued to aggressively promote the efficacy of their products, even after they knew or should have known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting ranitidine-containing products.

265. This alleged failure to warn is not limited to the information contained on ranitidine-containing products' labeling. The Defendants should have disclosed the known risks associated with Zantac and ranitidine-containing products through other non-labeling mediums (i.e., promotion, advertisements, public service announcements, and/or public information sources), but the Defendants did not disclose these known risks through any medium.

266. Defendants are liable to Plaintiffs for injuries caused by their negligent, willful or reckless conduct, as described above. Defendants risked the lives of consumers and users of their products, including Plaintiffs, by consciously deciding not to warn or inform physicians, patients and the public of known safety problems associated with ranitidine-containing products.

267. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their ranitidine-containing products, Plaintiffs could have avoided the risk of developing injuries and/or death and could have obtained or used alternative medication.

268. As a direct and proximate result of Defendants placing their defective ranitidine-containing products into the stream of commerce, and the resulting injuries,

Plaintiffs sustained personal injuries and/or death, mental anguish, loss of income, loss of earning capacity, pecuniary loss, funeral expenses, and other damages which exceeds the jurisdictional minimum of this Court.

COUNT VII: BREACH OF EXPRESS WARRANTIES

269. Plaintiffs incorporate by reference each allegation set forth in preceding paragraphs as if fully stated herein.

270. At all relevant times, Defendant engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and promoting ranitidine-containing products, which are defective and unreasonably dangerous to consumers, including Plaintiffs, thereby placing ranitidine-containing products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants.

271. Defendants had a duty to exercise reasonable care in the research, development, design, testing, packaging, manufacture, inspection, labeling, distributing, marketing, promotion, sale, and release of ranitidine-containing products, including ranitidine syrup, including a duty to:

a. ensure that their products did not cause the user unreasonably dangerous side effects;

b. warn of dangerous and potentially fatal side effects;

c. disclose adverse material facts, such as the true risks associated with the use of and exposure to ranitidine, when making representations to the FDA, consumers and the general public, including Plaintiff; and

d. set proper expiration dates and storage temperatures and disclose the adverse consequences should ranitidine not be stored properly.

272. As alleged throughout this pleading, the ability of Defendants to properly disclose those risks associated with its drugs are not limited to representations made on the labeling.

273. At all relevant times, Defendants expressly represented and warranted to the purchasers of their products, by and through statements made by Defendants in labels, publications, package inserts, and other written materials intended for consumers and the general public, that ranitidine-containing products were safe to human health and the environment, effective, fit, and proper for their intended use. Defendants advertised, labeled, marketed, and promoted its products, representing the quality to consumers and the public in such a way as to induce their purchase or use, thereby making an express warranty that its ranitidine-containing products would conform to the representations.

274. These express representations include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to ranitidine. Defendants knew and/or should have known that the risks expressly included in the warnings and labels did not and do not accurately or adequately set forth the risks of developing the serious injuries complained of herein. Nevertheless, Defendants expressly represented that its brand OTC ranitidine 150mg tablets were safe and effective, that it was safe and effective for use by individuals such as Plaintiffs, and/or that it was safe and effective as consumer medication.

275. The representations about brand OTC ranitidine 150mg tablets ranitidine, as set forth herein, contained, or constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, creating an express warranty that the goods would conform to the representations.

276. Defendants placed brand OTC ranitidine 150mg tablets into the stream of commerce for sale and recommended its use to consumers and the public without adequately warning of the true risks of developing the injuries associated with the ingestion of improperly stored ranitidine.

277. Defendants breached these warranties because, among other things, ranitidine products were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the warranties in the following ways:

a. Defendants represented through their labeling, advertising, and marketing materials that its products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with improper storage and handling of use ranitidine; and

b. Defendants represented that its products were safe for use and intentionally concealed information that demonstrated that ranitidine, by transforming into NDMA when improperly stored or handled, had carcinogenic properties, and that its products,

therefore, were not safer than alternatives available on the market.

278. Plaintiffs detrimentally relied on the express warranties and representations of Defendants concerning the safety and/or risk profile of ranitidine in deciding to purchase the product. Plaintiffs reasonably relied upon Defendants to disclose known defects, risks, dangers, and side effects of its products if not stored, shipped and handled properly. Plaintiffs would not have purchased brand OTC ranitidine tablets had Defendants properly disclosed the risks associated with the products, either through advertising, labeling, or any other form of disclosure.

279. Defendants had sole access to material facts concerning the nature of the risks associated with their products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in its warnings and labels were inadequate and inaccurate.

280. Plaintiffs had no knowledge of, and could not reasonably have discovered, the falsity or incompleteness of Defendants' statements and representations concerning ranitidine.

281. Plaintiffs used and/or were exposed to ranitidine as manufactured, tested, inspected, labeled, distributed, packaged, marketed, promoted, sold, or otherwise released into the stream of commerce by Defendants.

282. Had the labels, advertisements, or promotional material for its products accurately and adequately set forth the true risks associated with the use of such products, including Plaintiffs' injuries, rather than expressly excluding such information and warranting that

the products were safe for their intended use, Plaintiffs could have avoided the injuries complained of herein.

283. As a direct and proximate result of Defendants' breach of express warranty, Plaintiffs have sustained pecuniary loss and general damages in a sum exceeding the jurisdictional minimum of this Court.

284. As a proximate result of Defendants' breach of express warranty, as alleged herein, there was a measurable and significant interval of time during which Plaintiffs suffered great mental anguish and other personal injury and/or death, and damages.

285. As a proximate result of Defendants' breach of express warranty, as alleged herein, Plaintiffs sustained a loss of income and/or loss of earning capacity.

COUNT VII: FRAUD

286. Plaintiffs incorporate by reference every and every allegation of this Complaint as if fully stated herein.

287. Defendants intentionally and/or with reckless disregard for the truth misrepresented to Plaintiffs materials facts regarding the safety and effectiveness of ranitidine.

288. Defendants knew or recklessly disregarded the fact that these representations were false, yet made the deceitful representations to Plaintiffs.

289. Defendants actively concealed information about the defects and dangers of ranitidine with the absence of due care such that Plaintiffs and the consuming public would rely on such information, or the absence of information, in selecting ranitidine as a treatment.

290. The maker's knowledge of the falsity of the representation fundamentally supplies the element of

"fraudulent utterance" required to make a misrepresentation actionable.

291. Defendants made the misrepresentations alleged herein with the intent to induce consumers, like Plaintiffs, to take their ranitidine products.

292. As a result of these false and deceitful representations made by Defendants, which Defendants knew to be untrue or for which Defendants recklessly disregarded the truth, Plaintiffs purchased and ingested Defendants' ranitidine products causing the significant injuries and harm described herein.

293. As a direct and proximate result of the foregoing misrepresentations and deceitful intentions, Plaintiffs sustained serious injuries of a personal and pecuniary nature. Plaintiffs suffered serious injuries, including cancer and permanent disability and disfigurement. As a direct and proximate result of the foregoing misrepresentations and deceitful intentions, Plaintiffs require and/or will require more healthcare and services and did incur medical, health, incidental, and related expenses. Plaintiffs will also require additional medical and/or hospital care, attention, and services in the future.

JURY DEMAND

Plaintiff hereby demands a trial by jury of all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, each Plaintiff requests that the Court enter an order or judgment against the Defendants, including the following:

A. Actual or compensatory damages in such amount—and more than $15,000, exclusive of interest and costs—to be determined at trial and

as provided by applicable law;

B. Exemplary and punitive damages sufficient to punish and deter Defendants and others from future wrongful practices;

C. Costs, including reasonable attorneys' fees, court costs, and other litigation expenses; and

D. Such other and further relief as the Court deems just and proper.

Dated: July 29, 2022

Respectfully submitted,

By: /s/ Craig A. Raabe

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Attorneys for Plaintiff

RETURN DATE: AUGUST 30, 2022

BETH BACHER,	:	SUPERIOUR
PLAINTIFF	:	COURT
REPRESENTATIVE FOR	:	
PAUL BACHER	:	JUDICIAL
(DECEASED); ASHA	:	DISRICT OF
ATKINS; ANTHONY	:	DANBURY
BALDWIN; LASHAUNNA	:	
DENISE BANKS; NIEMA	:	
BAPTISTA; CALANTHE	:	JULY 29, 2022
BATISTE; JASON	:	
BEHRENS; CHASITY	:	
BELLARD; JESSE BLAKE;	:	
WILLIAM BLOCK;	:	
JEFFREY BOLEN;	:	
CHRISTOPHER BROPHY,	:	
SR.; KENISHIA BUNDAGE;	:	
MAURICE CALHOUN;	:	
SONJA CHAMBERLAIN;	:	
STEPHEN CHAMPINE;	:	
LINDSEY CHARLES;	:	
DOUGLAS CHOUINARD;	:	
BILLIE JO CLEM; RON	:	
MAZUN COLLINS;	:	
CHAUNCEY CONWAY;	:	
FLORENCE COUCHIE;	:	
TRINA DAU; KENNETH	:	
DAVIS; ROGER ALLAN	:	
DEFRANG; RUSTY	:	
DELANEY; RANDY	:	
DERCKS; ALVESTER	:	
DONES; CHASTITY	:	
DOTSON; HORACE DOTY;	:	
TEDDY DOUCET; DETRIC	:	

DREWERY; CONNIE :
DUGDALE; HARRIS :
DUGGER; TANTASHA :
DUTYE; LAURA :
EDWARDS; LORI A :
EISCHEN; CINDY :
EKLUND; LAURA ELLIS; :
DARELL ENLOE; LILLIE :
EVANS; AUSTIN :
FERGUSON; DOLLIE :
FIELDS; WILLIAM LYNN :
FISHER; KEVIN :
HERBERT KAY :
FIVECOAIT; PAUL :
FLUESMEIER; EDWARD :
L FORREST; LEAH :
FRANCIS; VIOLA :
FRANCIS; MARK :
FRANKLIN; TAMARA :
FREDERICK; CELESTE :
FREEMAN; ROBERT :
FROMMER; TERRANCE :
GAINES; TRAVEON :
GAINES; LADORIS :
GALBERT; ROBERT :
GARDNER; LINDA GILL; :
MICHAEL GLIDDEN; :
JOHN GOINGS; JASON :
GOLDEN; ROY GOODMAN; :
JUSTIN GORHAM; DALE :
GRAHAM; CALANDRA :
GREY; MARIO :
GUALTIERI; ARNOLDO :
GUTIERREZ; MILDRED :
HAGGERTY; BRYTTNY :

HALL; DELLA HAMM; TREMIAN HAMPTON; ZACK HANSANA; BRIDGETTE HARDY; ROBERT HARMAN

JOANN ADAMS, PLAINTIFF REPRESENTATIVE FOR ROBERT EUGENE ADAMS (DECEASED);

JOHN BAGACO, PLAINTIFF REPRESENTATIVE FOR JOAO BAGACO, (DECEASED);

ILENE BARAJAS, PLAINTIFF REPRESENTATIVE FOR MARTIN BARAJAS, (DECEASED);

RICKY DOYLE, PLAINTIFF REPRESENTATIVE FOR ANITA BENNETE (DECEASED);

MARK BLEUER, PLAINTIFF REPRESENTATIVE FOR KAREN BLEUER (DECEASED);

JULIE RUDOLPH, PLAINTIFF

REPRESENTATIVE FOR ANDREW BOISVERT (DECEASED);

DARLA BOOKER, PLAINTIFF REPRESENTATIVE FOR DOUGLAS LYDELL BOOKER (DECEASED);

JOSEPH BUCCERI, PLAINTIFF REPRESENTATIVE FOR BARBARA BUCCERI (DECEASED);

ROBBIE CAHOON, PLAINTIFF REPRESENTATIVE FOR DUSTY CAHOON (DECEASED);

SHERMECKA DUBOSE, PLAINTIFF REPRESENTATIVE FOR PATRICIA COBB (DECEASED);

TERESA GHOSIO, PLAINTIFF REPRESENTATIVE FOR SUSAN CALLARI (DECEASED);

TRACIE CATO, PLAINTIFF REPRESENTATIVE FOR

SANDRA CATO (DECEASED);

FORESTINE CLARK, PLAINTIFF REPRESENTATIVE FOR EDWARD CLARK (DECEASED);

SONJA CONTRERAS, PLAINTIFF REPRESENTATIVE FOR ENRIQUE CONTRERAS (DECEASED);

JAQUELINE CORTEZ-BATEMAN, PLAINTIFF REPRESENTATIVE FOR WILLIAM CORTEZ (DECEASED);

NICHOLAS CRISTINO, PLAINTIFF REPRESENTATIVE FOR FRANCIS CRISTINO (DECEASED);

AARON CURRIE, PLAINTIFF REPRESENTATIVE FOR BONITA CURRIE (DECEASED);

SUSAN VERBACK, PLAINTIFF REPRESENTATIVE FOR VIRGINA CWIAKALA (DECEASED);

DIANE DAHL, PLAINTIFF REPRESENTATIVE FOR MICHAEL A. DAHL SR. (DECEASED);

DIANA DASENT, PLAINTIFF REPRESENTATIVE FOR MARY DASENT (DECEASED);

JOANNE YOBAK, PLAINTIFF REPRESENTATIVE FOR RITA JANE DONOHUE (DECEASED);

THOMAS ECCLES, PLAINTIFF REPRESENTATIVE FOR PATRICIA ECCLES (DECEASED);

DANA DUGAS, PLAINTIFF REPRESENTATIVE FOR BONNIE EDWARDS (DECEASED);

LILLIAN FEARS, PLAINTIFF REPRESENTATIVE FOR WAYNE FEARS (DECEASED);

LISA RICHIE, PLAINTIFF REPRESENTATIVE FOR

DANIEL MOLZ (DECEASED);	:
Plaintiffs,	:
v.	:
BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; BOEHRINGER INGELHEIM CORPORATION; BOEHRINGER INGELHEIM USA CORPORATION; GLAXOSMITHKLINE, LLC; GLAXOSMITHKLINE HOLDINGS (AMERICAS), INC.; PFIZER, INC.; SANOFI-AVENTIS U.S. LLC; SANOFI U.S. SERVICES, INC.	:
Defendants.	:

STATEMENT OF AMOUNT IN DEMAND

Each Plaintiff demands an amount in excess of $15,000, exclusive of interest and costs.

Dated: July 29, 2022

Respectfully submitted,

By: /s/ Craig A. Raabe
Craig A. Raabe
Robert A. Izard

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Attorneys for Plaintiff

APPENDIX G

[FILED: NOVEMBER 10, 2022]

DOCKET NO. DBD-CV-22-6043738-S

BETH BACHER, Plaintiff Representative For Paul Bacher (Deceased), *et al.*, *Plaintiffs*, -v.- BOEHRINGER INGELHEIM PHARMACEUTICALS, INC. *et al.*, *Defendants*.	: : : : : : : : : : : :	SUPERIOR COURT JUDICICAL DISTRICT OF DANBURY AT DANBURY NOVEMBER 2, 2022

PLAINTIFFS' MOTION TO CONSOLIDATE

Pursuant to Conn. Prac. Book § 9-5, Plaintiffs in this action move to consolidate it with the following actions:

DBD-CV-22-6043741-S
Ramos v Boehringer Ingelheim Pharmaceuticals, Inc

DBD-CV-22-6043749-S
Sullivan v Boehringer Ingelheim Pharmaceuticals, Inc

DBD-CV-22-6043759-S
Yost v. Boehringer Ingelheim Pharmaceuticals, Inc

DBD-CV-22-6044009-S
Berkowitz v Boehringer Ingelheim Pharmaceuticals, Inc

DBD-CV-22-6044174-S
Cassidy v Boehringer Ingelheim Pharmaceuticals, Inc

DBD-CV-22-6044175-S
Rolon v Boehringer Ingelheim Pharmaceuticals, Inc

DBD-CV-22-6044206-S
Corwin v Boehringer Ingelheim Pharmaceuticals, Inc

DBD-CV-22-6044212-S
Vazzano v. Boehringer Ingelheim Pharmaceuticals, Inc

In support of this motion, Plaintiffs state the following:

1. These actions are all against the same Defendants.

2. All of the actions involve the same legal claims sounding in product liability related to the heartburn medication Zantac.

3. It is likely that issues raised in any one of the cases could impact the other cases.

4. Consolidating these actions will allow for the court to manage all of them in an orderly and efficient manner.

5. Plaintiffs are filing similar consolidation motions in each of the above-listed actions.

6. All Defendants consent to this proposed consolidation.

WHEREFORE, Plaintiffs move that this action be consolidated with the above-listed actions.

Dated: November 2, 2022

Respectfully submitted,

By: /s/ Craig A. Raabe
Craig A. Raabe
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ATTORNEYS FOR PLAINTIFFS

CERTIFICATION

Pursuant to Practice Book § 10-14, I hereby certify that a copy of the above was mailed or electronically delivered on November 2, 2022 to all counsel and pro se parties of record.

BOEHRINGER INGELHEIM
PHARMACEUTICALS, INC. BOEHRINGER
INGELHEIM CORPORATION BOEHRINGER
INGELHEIM USA CORPORATION
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GLAXOSMITHKLINE, LLC
GLAXOSMITHKLINE HOLDINGS
(AMERICAS), INC.
Robert R. Simpson
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PFIZER, INC.
James I. Glasser
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P.O. Box 1832, New Haven, CT 06508
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SANOFI-AVENTIS U.S. LLC
SANOFI U.S. SERVICES, INC.
Joseph W. Martini
Janna D. Eastwood
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jmartini@spearsmanning.com
jeastwood@spearsmanning.com

/s/ Craig A. Raabe
Craig A. Raabe

APPENDIX H

[FILED: NOVEMBER 17, 2022]

From: Craig Raabe
Sent: Wednesday, October 26, 2022 10:56 AM
To: Glasser, James
Subject: RE: Zantac

Yup--I got arm-twisted into leading the Federal Practice Section with Allison Near ….

From: Glasser, James <JGlasser@wiggin.com>
Sent: Wednesday, October 26, 2022 10:51 AM
To: Craig Raabe <craabe@ikrlaw.com>
Subject: RE: Zantac

CAUTION: External email

I am. You? I got a call saying attendance was thin and to encourage folks to attend. I hope to see you there.

Jim

From: Craig Raabe <craabe@ikrlaw.com>
Sent: Wednesday, October 26, 2022 10:47 AM
To: Glasser, James <JGlasser@wiggin.com>
Subject: RE: Zantac

Thanks, Jim. We'll prepare the consolidation motion and CLD application. You going to the bench/bar gig tomorrow?

From: Glasser, James <JGlasser@wiggin.com>
Sent: Wednesday, October 26, 2022 10:45 AM
To: Craig Raabe <craabe@ikrlaw.com>
Subject: RE: Zantac

CAUTION: External email

Craig--
It appears all defendants are comfortable with recommending: 1) Hartford and 2) Stamford under CLD.

Sorry for the delay.

Best,
Jim

From: Craig Raabe <craabe@ikrlaw.com>
Sent: Wednesday, October 26, 2022 10:03 AM
To: Glasser, James <JGlasser@wiggin.com>
Subject: RE: Zantac

Hey Jim,
My guys are anxious to file the consolidation motions/CLD application. Any progress on your end?

Craig

From: Glasser, James <JGlasser@wiggin.com>
Sent: Friday, October 21, 2022 12:30 PM

To: Craig Raabe <craabe@ikrlaw.com>
Subject: Zantac

CAUTION: External email

Craig--

Before I start making my calls, I want to make sure my notes are accurate. Plaintiffs want all cases consolidated in the same court and as far as CLD designation, would like to designate: 1) Hartford, 2) Stamford. If I have that right, I will start making calls today and hopefully get back to you early next week.

Enjoy the weekend.

Jim

James I Glasser
Wiggin and Dana LLP
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New Haven, Connecticut 06508-1832
Direct: 203.498.4313 jglasser@wiggin.com

New York Office
437 Madison Avenue, 35th Floor
New York, New York 10022

APPENDIX I

[FILED: DECEMBER 8, 2022]

AFFIDAVIT OF JAMES I. GLASSER

I, James I. Glasser, being duly sworn do hereby depose and state:

1. I am over the age of eighteen and understand the obligations of an oath.

2. I am an attorney and partner of Wiggin and Dana LLP.

3. The facts set forth herein are based upon my personal knowledge.

4. I represent Defendant Pfizer Inc. in the instant matter.

5. I participated in a telephone call and exchange of e-mails with Plaintiffs' counsel, Craig Raabe, about the Zantac cases that were filed in the Connecticut State Court.

6. Plaintiffs' counsel approached Defendants' counsel in September 2022 about consenting to an application to transfer all Zantac cases filed in Connecticut to Connecticut's Complex Litigation Docket ("CLD").

7. At no point did Plaintiffs' counsel reference Connecticut Practice Book Section 9-5.

8. I conferred with counsel for Defendants Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, Boehringer Ingelheim USA Corporation, GlaxoSmithKline LLC, GlaxoSmithKline Holdings (Americas) Inc., Sanofi-Aventis U.S. LLC, and Sanofi US Services Inc. Defendants agreed to consent to Plaintiffs' application to transfer all cases to the CLD so long as the parties agreed to indicate a joint preference

for: (1) the Judicial District of Hartford, or (2) the Judicial District of Stamford.

9. I communicated that consent to Plaintiffs' counsel in an email dated October 26, 2022. *(See, e.g., Bacher, et al. v. Boehringer Ingelheim Pharms., Inc., et al.*, 3:22-cv-01432-JAM (D. Ct. Nov. 17, 2022) D.E. 30-2.) I neither indicated nor intended to indicate consent or agreement on behalf of Defendants to consolidation of the cases for trial pursuant to Section 9-5, or otherwise. Indeed, when I later made inquiry of Plaintiff's counsel into the status of the planned motion, my inquiry addressed the motion for transfer to the CLD only. *(See, e.g., id.*, D.E. 30-3.)

10. Counsel for Plaintiffs never further inquired about consent to consolidation or shared a draft of a motion for consolidation for my review or approval before filing.

Pursuant to Title 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on this the 8th day of December, 2022, at New York, New York.

/s/ James I. Glasser, Esq.
James I. Glasser, Esq.