

No. _____

In the Supreme Court of the United States

MARILYN COUDRAIN, AS ADMINISTRATOR OF THE ESTATE
OF ELLEN SMITH, ET AL.,

Petitioners,

v.

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., ET AL.,
Respondents.

ON PETITION FOR WRIT OF CERTIORARI
TO THE APPELLATE COURT OF ILLINOIS
FOR THE FIRST DISTRICT

APPENDIX

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AUGUST MMXXVI

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Appendix A

2026 IL App (1st) 250614-U

FIFTH DIVISION

February 20, 2026

No. 1-25-0614

NOTICE: This order was filed under Supreme Court Rule 23 and is not precedent except in the limited circumstances allowed under Rule 23(e)(1).

IN THE
APPELLATE COURT OF ILLINOIS
FIRST DISTRICT

MARILYN COUDRAIN, as	)	Appeal from the
Administrator of the Estate of	)	Circuit Court of
Ellen Smith, <i>et al.</i> ,	)	Cook County.
	)	
Plaintiff-Appellant,	)	No. 23 L 3569
	)	
v.	)	Honorable
	)	Daniel Trevino,
WALGREEN CO.;	)	Judge Presiding.
WALGREENS BOOTS ALLI-	)	
ANCE, INC.; GLAX-	)	
OSMITHKLINE, LLC; GLAX-	)	
OSMITHKLINE HOLDINGS	)	
(AMERICAS), INC.; PFIZER,	)	
INC.; BOEHRINGER INGEL-	)	
HEIM PHARMACEUTICALS,	)	
INC.; BOEHRINGER INGEL-	)	
HEIM USA CORPORATION;	)	
BOEHRINGER INGELHEIM	)	

CORPORATION; SANOFI-)
AVENTIS U.S. LLC; and)
SANOFI US SERVICES,)
INC.,)
)
Defendants,)
)
(Boehringer Ingelheim Phar-)
maceuticals, Inc.; Boehringer)
Ingelheim USA Corporation;)
Boehringer Ingelheim Corpo-)
ration; Sanofi-Aventis U.S.)
LLC; and Sanofi U.S. Ser-)
vices, Inc., Defendants-Appel-)
lees).)
)

JUSTICE MIKVA delivered the judgment of the court. Presiding Justice Mitchell and Justice Wilson concurred in the judgment.

ORDER

¶1 *Held:* The circuit court did not err in dismissing nonresident plaintiffs' claims for lack of personal jurisdiction where those claims did not relate to defendants' contacts with Illinois.

¶2 The question before us is whether the claims of these nonresident plaintiffs, who were not injured in Illinois, can proceed in the Illinois courts against these defendants. It is undisputed that the medication that is alleged to have injured these plaintiffs was not manufactured in Illinois, but plaintiffs point to the fact that defendants utilized certain third-party companies in Illinois to repackage, inspect, and distribute

products for nationwide distribution and to sell this same product to other people in Illinois. We hold that our courts do not have jurisdiction over these claims against these defendants for the reasons outlined below and affirm the dismissal of these claims by the circuit court.

¶3 I. BACKGROUND

¶4 The cases in which these appeals are brought are among thousands of individual lawsuits filed in federal and various state courts against the manufacturers and marketers of Zantac, a brand of heartburn medication with the active ingredient of ranitidine. Between August 22, 2022, and September 26, 2022, five lawsuits with over 300 plaintiffs residing in 39 states were filed in Madison County, Illinois. These cases were filed against numerous defendants, some of whom have had the claims against them dismissed or have settled.

¶5 The defendants who are parties to this appeal are Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation (collectively, Boehringer), and Sanofi-Aventis U. S. LLC and Sanofi US Services Inc. (collectively, Sanofi). The plaintiffs alleged in their complaint strict product liability, failure to warn, negligent transportation and storage, negligent misrepresentation, fraud, and breach of express and implied warranties—all stemming from their use of Zantac, which was manufactured, marketed, and sold by these defendants and which the plaintiffs alleged caused them cancer. On October 25, 2022, the Illinois Supreme Court consolidated these actions with several other Illinois cases alleging

similar ranitidine-related injuries in Cook County. All multi-plaintiff actions were administratively dismissed, and plaintiffs were instructed to refile individual complaints. This appeal concerns 180 out-of-state plaintiffs, including the first named plaintiff, Marilyn Coudrain, as administrator of the estate of Ellen Smith, who refiled individual actions in Cook County.

¶6 On October 25, 2023, Boehringer, Sanofi, and other defendants who are not parties to this appeal, filed a joint motion under section 2–301 of the Code of Civil Procedure (735 ILCS 5/2–301 (West 2022)) to dismiss all non-Illinois plaintiffs’ claims for lack of general and specific jurisdiction. Boehringer and Sanofi argued that the court had no general jurisdiction over them because neither their headquarters nor their principal places of business were in Illinois. They argued that they were not subject to the court’s specific jurisdiction because the plaintiffs were not residents of Illinois, had not purchased or consumed Zantac in Illinois, and were not injured in Illinois.

¶7 After jurisdictional discovery, plaintiffs filed their response on January 10, 2025. They argued that Boehringer and Sanofi “purposefully reached into Illinois with respect to the development, marketing, and sales of their Zantac products.” The plaintiffs pointed to the fact that Boehringer and Sanofi intentionally sought out and contracted with Walgreens and other Illinois corporations for product sales and distribution, and that each plaintiff bought their Zantac from a Walgreens store. The gist of their argument was that Boehringer utilized several Illinois companies to help it “market, promote, and enter into contracts for

selling Zantac to Walgreens, an Illinois company, for sales nationally.”

¶8 The plaintiffs pointed out that Boehringer also contracted with two Illinois companies to repackage Zantac for nationwide sales. The first company, Mechanical Servants, was based in Melrose Park, Illinois. As part of this agreement, Boehringer would ship Zantac to Mechanical Servants in Illinois, which would then put the medication into its final packaging with the appropriate labels and package inserts. The agreement specifically noted that Mechanical Servants was to include in its final packages the “FDA Drug Facts Labeling for the Products,” which, according to plaintiffs, was defective and failed to warn consumers that Zantac contained NDMA, a known carcinogen. The agreement also specified that Boehringer was to provide Mechanical Servants samples of this FDA label as well as all “necessary Intellectual Property, Storage Specifications and IP Specifications including all artwork, copy, or other material relating to the Products,” which Mechanical Servants could not alter. Boehringer entered into an identical repackaging agreement with Modern Aids, another Illinois corporation based in Elk Grove.

¶9 Boehringer also entered into an agreement with Rand Diversified Companies, LLC (Rand) to provide quality assurance testing. Although Rand was headquartered in New Jersey, a substantial part of this agreement was to be performed at its facility in Edwardsville, Illinois. Additionally, Boehringer retained a Texas-based broker, Crossmark, Inc., to help it market and sell Zantac, including to Walgreens, for nationwide sales.

¶10 According to plaintiffs, Sanofi earned \$465,486,873.15 in revenue from the products it sold in Illinois between 2017 and 2023. This figure included \$14,652,126.54 worth of Zantac sold to Illinois companies, nearly \$5,000,000 of which was sold and shipped to Walgreens in Illinois for national distribution. Like Boehringer, Sanofi also had agreements with Modern Aids and Mechanical Servants to provide repackaging services in Illinois. Additionally, Sanofi contracted with other companies with ties to Illinois to help it sell Zantac. For example, Sanofi contracted with AmerisourceBergen to sell its products. Although AmerisourceBergen is based in Orlando, Florida, its largest shareholder is Walgreens. Through AmerisourceBergen, Sanofi sold millions of dollars of Zantac to retailers and distribution hubs in Illinois for Amazon, Sam's Club, Supervalu, McKesson, Costco, and Walgreens. The plaintiffs highlighted the fact that their failure-to-warn claim stemmed from the defective label that did not warn consumers that Zantac contained a known carcinogen and that that label was inserted into Zantac packages in Illinois.

¶11 Plaintiffs also argued that the court had general jurisdiction over *Boehringer and Sanofi under Mallory v. Norfolk Southern Railway Co.*, 600 U. S. 122 (2023), because some of the entities were, or had recently been, foreign corporations registered to do business in Illinois. Plaintiffs contended that it would be reasonable to exercise personal jurisdiction over these defendants because similar claims of Illinois residents were continuing in Cook County, rendering the resolution of these claims little additional burden on the state and because Illinois had significant contacts with these companies.

¶12 The circuit court heard argument on January 23, 2025. *The court asked the plaintiffs to address Bristol-Myers Squibb Co. v. Superior Court*, 582 U. S. 255 (2017), in which the United States Supreme Court had held that a defendant’s relationship with a third party, standing alone, is an insufficient basis for jurisdiction. The plaintiffs argued that unlike in that case, where sales agents had broad discretion over where and how they sold medication, Boehringer and Sanofi specifically directed these third parties to sell Zantac to Walgreens. In rebuttal, Boehringer and Sanofi stressed that Bristol-Myers should control, and pointed out that the purportedly defective labels were not drafted or created in Illinois and no plaintiff could definitively trace their pills as having passed through Illinois.

¶13 The court granted Boehringer and Sanofi’s motion to dismiss. It reasoned that the nonresident plaintiffs’ claims did not arise out of or relate to any of Boehringer or Sanofi’s activities in Illinois and that their contacts with third-party companies to distribute, market, and package Zantac were not a sufficient basis for jurisdiction.

¶14 This appeal followed.

¶15 II. JURISDICTION

¶16 The circuit court granted Boehringer and Sanofi’s motion to dismiss for lack of personal jurisdiction in orders entered between March 5, 2025, and March 24, 2025, in the nonresident plaintiffs’ cases, and plaintiffs timely filed a notice of appeal on April 3, 2025. We have jurisdiction under Illinois Supreme Court Rule 301 (eff. Feb. 1, 1994) and Rule 303 (eff.

July 1, 2017), which govern appeals from final judgments entered by the circuit court in civil cases.

¶17 III. ANALYSIS

¶18 The Illinois long-arm statute governs the exercise of personal jurisdiction by an Illinois court over a nonresident defendant. 735 ILCS 5/2-209 (West 2022); *Russell v. SNFA*, 2013 IL 113909, ¶ 29. The statute permits the exercise of personal jurisdiction over a nonresident defendant to the extent that it is permitted by the Illinois Constitution and the Constitution of the United States. *Russell*, 2013 IL 113909, ¶ 29. Since the Illinois long-arm statute is co-extensive with the limits of due process, we must determine whether due process permits the exercise of personal jurisdiction over these defendants on the claims of these out-of-state plaintiffs. *Id.* ¶ 30.

¶19 Due process requires that a defendant have such “contacts” with the forum State that “the maintenance of the suit” is “reasonable, in the context of our federal system of government,” and “does not offend traditional notions of fair play and substantial justice.” *Ford Motor Company v. Montana Eighth Judicial District Court*, 592 U.S. 351, 358 (2021). In Illinois, the “threshold issue” is often referred to as “the ‘minimum contacts’ test.” *Russell*, 2013 IL 113909, ¶ 36. The contacts necessary to satisfy this test will depend on whether the plaintiff is asserting that the court has general or specific personal jurisdiction over a defendant. *Rios*, 2020 IL 125020, ¶ 19. Plaintiffs here assert that the court had both general and specific jurisdiction over Boehringer and Sanofi.

¶20 General jurisdiction exists where a corporate defendant “has engaged in continuous and substantial

business activity within the forum,” and allows them to be sued for any claim, regardless of where the conduct took place, because they are essentially “at home” in the forum state. *Id.* Specific jurisdiction, on the other hand, requires a showing that (1) “the defendant purposefully directed its activities at the forum state” and (2) “the cause of action arose out of or relates to the defendant’s contacts with the forum state.” Russell, 2013 IL 113909, ¶ 40. Even where these first two criteria are met, specific jurisdiction also includes a “reasonableness” prong. Rios, 2020 IL 125020, ¶ 30. ¶21 It was the plaintiffs’ burden to “establish a prima facie basis for exercising personal jurisdiction over a nonresident defendant.” *Rios v. Bayer Corp.*, 2020 IL 125020, ¶ 16. When, as here, the circuit court based its determination of jurisdiction solely on documentary evidence, our review is de novo. *Id.* We consider plaintiffs’ claims for specific and then for general jurisdiction over these defendants on these claims.

¶22 A. Specific Jurisdiction

¶23 Plaintiffs point out that, to satisfy the first requirement of specific jurisdiction, they only need show that Boehringer and Sanofi purposely directed activities into Illinois and that this is not an exacting standard. *Kothawala v. Whole Leaf, LLC*, 2023 IL App (1st) 210972, ¶ 29. These activities “need not be causally or even indirectly related to the claims plaintiff raises in the lawsuit; that deeper dive into the facts of the lawsuit occurs in the second prong regarding causation or relatedness.” *Id.* Boehringer and Sanofi sold millions of dollars of Zantac in Illinois. Both also utilized Illinois companies to market and

repackage Zantac for nationwide distribution as well as to perform quality assurance work, functions which were all, at least partially performed at various locations throughout Illinois. Thus, it appears that defendants did direct activities into Illinois.

¶24 Plaintiffs also spend a great deal of their briefs discussing the reasonableness requirement. They rely on the fact that defendants engaged in direct-to-consumer marketing efforts through a major distributor, Walgreens, an Illinois company, and that defective and insufficient labeling took place in Illinois. All of this, according to plaintiffs, makes it “reasonable for this Court to exercise personal jurisdiction over the Defendants” in this case.

¶25 However, even if we agree that plaintiffs meet the first prong, and that the exercise of jurisdiction would be reasonable, plaintiffs clearly fail to meet the second prong of the test for specific personal jurisdiction, which requires that the cause of action “arose out of or relates to” Boehringer and Sanofi’s contacts with Illinois.

¶26 Plaintiffs argue that their claims “relate to” Boehringer and Sanofi’s activities in Illinois because “those activities were intentionally directed into Illinois for the purpose of getting consumers in every state, like Plaintiffs, to believe their claims and buy their Zantac at their local Walgreens.” Plaintiffs point to the facts cited above in their reasonableness argument regarding nationwide marketing and repackaging in Illinois and to their allegation that each of these out-of-state plaintiffs purchased their Zantac at a Walgreens.

¶27 According to plaintiffs, the circuit court misconstrued the meaning of “relate to,” a requirement that

they insist “is flexible, lenient, and does not require a showing of causation.” Plaintiffs contend that the circuit court improperly relied on *Rios* and *Bristol-Myers* and that the reach of these cases must be reconsidered in light of the more expansive understanding of specific personal jurisdiction articulated by the United States Supreme Court in *Ford Motor Company v. Montana Eighth Judicial District Court*, 592 U. S. 351 (2021).

¶28 Plaintiffs’ reliance on the analysis in *Ford* is misplaced. That analysis did not fundamentally change the requirements for specific personal jurisdiction in the way plaintiffs suggest. That case does not address cases where, as here, the plaintiffs are not residents of the forum state and the injury did not occur in that state. The jurisdictional limitations set forth in *Bristol-Myers* and *Rios* for claims brought by nonresident plaintiffs who suffered an injury outside the state remain in place and are directly applicable to the facts of this case.

¶29 In *Ford*, the U.S. Supreme Court concluded that two different states could exercise personal jurisdiction over Ford Motor Company where, in each instance, a resident of that state was injured in that state by an allegedly defective Ford vehicle. *Id.* at 354–55. The two specific vehicles at issue were not actually sold to the plaintiffs by Ford in the forum states. *Id.* at 355. Rather, they were resold to the plaintiffs in those states by the prior owners. *Id.* at 357. The Supreme Court rejected Ford’s argument that the courts could not exercise personal jurisdiction over it, as a nonresident defendant, unless the company had designed, manufactured, or sold the car in the forum state. Ford’s argument, which the

Supreme Court rejected, was that the conduct of Ford in the forum state must be what “gave rise to the plaintiff’s claims.” *Id.* at 361. The court read its prior precedent as not requiring a “strict causal relationship” between a defendant’s in-state activities and the plaintiff’s injury. *Id.* at 362. Rather, the plaintiff’s suit must “arise out of or *relate to* the defendant’s contacts with the forum.” (Emphasis in original.) *Id.* (quoting *Bristol-Myers Squibb Co.*, 582 U. S. 255, 262 (2017)). In *Ford* the court found this relationship in the fact that the car accidents took place in the forum states, the defective Ford vehicles caused the crashes and resulting harm in the forum states, and Ford had advertised, sold, and serviced those two car models in the forum states for many years. *Id.* at 365. As the court concluded, “Ford had systematically served a market in [the forum states] for the very vehicles that the plaintiffs allege malfunctioned and injured them in those States.” *Id.*

¶30 Plaintiffs argue that *Ford*’s relaxation of the causal requirement means that they need only show that defendants marketed and sold other units of Zantac in Illinois and utilized Illinois as part of their nationwide distribution efforts. Their claim is that this fact and the defendants’ other activities involving Illinois companies, like repackaging and quality assurance, are sufficient to vest Illinois courts with jurisdiction over these defendants for claims involving nonresident plaintiffs and injuries.

¶31 Plaintiffs’ argument significantly overstates the holding in *Ford*. Citing to *Bristol-Myers*, the court in *Ford* explained, “That does not mean anything goes. In the sphere of specific jurisdiction, the phrase ‘relate to’ incorporates real limits, as it must to

adequately protect defendants foreign to a forum.” *Id.* at 362. In *Ford* the necessary relationship between the injury and the forum states was present because the plaintiffs were residents of the forum states, the accidents that injured them took place in the forum states, *and* Ford had systematically served a market for those vehicles in those states. *Id.* at 365. While Ford relaxed the necessary causal relationship between defendant’s conduct in the forum state for those cases in which a claim is brought by a resident of the forum state for an injury that occurred in that state, nothing in that case suggests that the Court was announcing a new rule for cases like this one where there is no tie to the forum state by way of the plaintiff’s residency or the alleged injury. *Id.* at 365–67.

¶32 *Bristol-Myers* and *Rios*, relied on by the circuit court, are both applicable here, and the analysis of the court in each of those cases is not impacted by *Ford*. In *Bristol-Myers*, the plaintiffs sued a pharmaceutical manufacturer in California for injuries allegedly caused by one of its prescription drugs, Plavix. *Bristol-Myers Squibb Co.*, 582 U. S. 255, 260 (2017). The plaintiffs were not residents of, injured in, or treated in California and the drug was not purchased there. *Id.* Plaintiffs argued that the company’s “wide ranging” business activities in the state, which included a distribution agreement with a California company and sales in the state that led to similar claims by residents, were enough connection to the forum state. *Id.* at 255. The Supreme Court explained that these activities were insufficient to establish specific personal jurisdiction:

“[A] defendant’s relationship with a . . . third party, standing alone, is an insufficient basis for jurisdiction. This remains true even when third parties (here, the plaintiffs who reside in California) can bring claims similar to those brought by the nonresidents. *** What is needed—and what is missing here—is a connection between the forum and the specific claims at issue.” *Id.* at 265. (Internal citations and quotation marks omitted).

¶33 Similarly, in *Rios*, nonresident plaintiffs brought an action in Illinois against an out-of-state company for injuries suffered outside of Illinois caused by a device manufactured outside of Illinois. *Rios*, 2020 IL 125020, ¶ 1. The company, Bayer, had conducted clinical trials in Illinois (and other states), held a physician training program for the harmful device in Illinois, and coordinated a marketing strategy in Illinois, all of which the Illinois Supreme Court found did not sufficiently relate to the claims brought by the plaintiffs. *Id.* ¶ 24. Most relevant here was the failure-to-warn allegation against Bayer, which the supreme court noted failed because “plaintiffs fail[ed] to allege that either they or their physicians received that false information in Illinois, and as noted, th[o]se plaintiffs and their physicians d[id] not reside in th[e] forum.” *Id.* ¶ 26. In short, “nothing in their complaints link[ed] Bayer’s alleged failure to warn the nonresidents and their physicians to any activities that occurred or should have occurred in Illinois.” *Id.*

¶34 Plaintiffs attempt to distinguish *Rios* on the basis that Boehringer and Sanofi utilized Illinois

companies to repackage Zantac with defective warning labels. However, as defendants point out, there was no evidence that any of these out-of-state plaintiffs purchased a Zantac product packaged or distributed by those Illinois companies or that there was any connection between the conduct of these Illinois companies and the injury to these nonresident plaintiffs.

¶35 Plaintiffs attempt to distinguish *Bristol-Myers* by arguing that Boehringer and Sanofi “reached into Illinois to create a marketing, distribution, and sales plan with Walgreens, the largest retail pharmacy in the United States,” and that plaintiffs allege in their complaints that they purchased their Zantac from a Walgreens store. Plaintiffs contrast these facts with those in *Bristol-Myers*, where the third-party distributor was a resident of the forum state but, as the Court noted, could not necessarily be proven to be the distributor to the pharmacies where the nonresident plaintiffs purchased Plavix. *Bristol-Myers Squibb Co.*, 582 U. S. 255, 268 (2017).

¶36 However, this distinction is not significant. Walgreens is still a third party, and the fact that Illinois courts could have jurisdiction over a claim against them does not give rise to derivative jurisdiction over the defendants in this case. As the court made clear in *Bristol-Myers*, the plaintiffs must have jurisdiction over each of the defendants and a relationship between a defendant and a third party, over whom the court could exercise jurisdiction, is simply not sufficient. *Id.* at 268.

¶37 B. General Jurisdiction

¶38 Plaintiffs also argue that Illinois can exercise general jurisdiction. They contend this jurisdiction

exists over Boehringer because it is registered to do business in Illinois and over Sanofi because one of its companies was registered to do business in Illinois from 2006 until 2017.

¶39 General jurisdiction is “all-purpose” and allows the defendant to be sued for any claim, regardless of where the plaintiff was injured or resides or where the conduct took place, because the defendant is essentially “at home” in the forum state. *Aspen American Insurance Co. v. Interstate Warehousing, Inc.*, 2017 IL 121281, ¶ 14. Plaintiffs claim that Boehringer and Sanofi should be subject to general jurisdiction “based on their foreign corporate registration under 735 ILCS 5/2–209 and the U.S. Supreme Court’s holding in *Mallory*.”

¶40 *Mallory* answered the narrow question of whether the federal due process clause prohibits a State from requiring an out-of-state corporation to consent to personal jurisdiction to do business there. *Mallory*, 600 U. S. at 127. The defendant corporation in that case had registered to do business in Pennsylvania for over 20 years and understood that, pursuant to Pennsylvania law, it would be amenable to suit there on any claim. *Id.* at 135. The court found that these facts and Pennsylvania law—which it noted “is explicit that qualification as a foreign corporation shall permit state courts to exercise general personal jurisdiction over a registered foreign corporation”—made the exercise of general jurisdiction permissible. (Internal quotation marks omitted.) *Id.* at 134. The court specifically noted that this holding was limited, explaining, “To decide this case, we need not speculate whether any other statutory scheme and set of facts would suffice to establish consent to suit.” *Id.* at 135.

¶41 Plaintiffs overstate the impact of *Mallory*, which in no way undermined the clear pronouncement of our own supreme court in *Aspen* that: “[T]he fact that a foreign corporation has registered to do business under the Act does not mean that the corporation has thereby consented to general jurisdiction” of the Illinois courts. *Aspen*, 2017 IL 121281, ¶ 22. As our supreme court recognized in *Aspen*, neither the Illinois long-arm statute (735 ILCS 5/2–209 (West 2012)) nor the Business Corporation Act (805 ILCS 5/1.01 et seq. (West 2012)) have any provision, like the Pennsylvania provision at issue in *Mallory*, that would support a claim that by registering to do business, an out-of-state corporation consents to general personal jurisdiction. While *Aspen* predates *Mallory*, the analysis of our supreme court regarding the relevant Illinois statutes makes it clear that the rule in Pennsylvania simply has no application in Illinois. See *Franco v. Chobani, LLC*, 789 F.Supp. 3d 584, 602 (N.D. Ill. 2025) (“Nothing in *Mallory* demands a different result or upsets this [*Aspen*] conclusion, which is based squarely on statutory interpretation.”)

¶42 IV. CONCLUSION

¶43 The circuit court did not err in granting Boehringer and Sanofi’s motion to dismiss the nonresident plaintiffs’ claims, where no specific or general personal jurisdiction exists. We affirm the circuit court’s dismissal.

¶44 Affirmed.

¶45 V. APPENDIX

¶46 Plaintiffs-Appellants

Plaintiff	Cook County Circuit Court Case Number
Ellen Smith (LEAD CASE)	2023L003569
Olivia Adams	2023L003324
Deanna Adelman	2023L004069
Anthony Anderson	2023L003624
Susan Austin	2023L003631
Janardanan Ayyappan	2023L003327
Cynthia Ballou	2023L003653
Rita Banks (for Estate of Wilbert Banks)	2023L003659
Shirley Barney	2023L003341
Venissa Barquet	2023L003675
Mary Barrett	2023L003425
Linwood Battle	2023L003673
Norene Beard	2023L003431
Jimetta Beasley	2023L003426
Barbara Belcher	2023L003430
Mary Betts	2023L003684
Michael Borookhim	2023L003957
Anthony Bouchard	2023L003697
Sybil Bouse	2023L004044
Anna Brandtjen (Estate of Anthony Brandtjen)	2023L004013
Douglas Brenton	2023L003961
Janet Brett	2023L003730

Plaintiff	Cook County Circuit Court Case Number
Sandra Brogan	2023L003438
Elvira Brown	2023L003735
Erin Brown	2023L004043
Shelley Bullock	2023L003463
Owen Burdge	2023L004039
Jimmy Burnside	2023L003761
Boyd Cain	2023L003700
Charles Caldwell	2023L004046
Matt Callahan	2023L003762
Alfredo Canizalez	2023L003766
Serenia Carnegie	2023L004048
Nancy Carnes (Estate of Mark Carnes)	2023L004094
Missouri Carstaffney	2023L003767
Allen Carter	2023L003667
Norma Cetuk	2023L003768
Helen Chow	2023L003704
Richard Christoffersen	2023L003988
Nicole Christopher	2023L003707
John Clare	2023L004104
Dorothy Collins	2023L003791
Gerald Combs	2023L004050
Eddie Cooper	2023L004054
Marilyn Coudrain	2023L003569

Plaintiff	Cook County Circuit Court Case Number
Carolyn Coughlin	2023L003712
Cynthia Covington	2023L003433
Candace Crone	2023L003785
Patricia Crouch	2023L004012
Christine Currie	2023L003432
Anthny Czerwein	2023L003440
Daisy Damian	2023L003779
Gemayel Davis	2023L003789
Michael Davis	2023L004015
Roncindra Davis	2023L003797
Jeffrey Todd Davis	2023L003795
Heidi DeClue	2023L003970
Sharmayne Dicks	2023L003787
Deborah Dodd	2023L003807
Ruth Dorrance	2023L003815
Deborah Drew	2023L003442
Nanci Drury	2023L003444
Richard Dusch	2023L003817
Roland Eaglin	2023L003820
Gary D. Eckrich	2023L003819
Cathy Evans	2023L003842
Jeanette Evans	2023L003847
Georgia Ezeilo	2023L003434
Pearl R. Fields	2023L003443

Plaintiff	Cook County Circuit Court Case Number
William Fleming	2023L004011
George Flint	2023L003454
Robert Florkey	2023L003845
Aaron J. Foster	2023L004093
Dennis Fox	2023L003680
Emilio Franco	2023L003848
Katrina Frazier	2023L003852
Ronald Fulmer	2023L003854
Richard Gaiti	2023L004097
Dinah George	2023L003879
Larry German	2023L004102
Jeffrey Gill	2023L003455
Khaliefe Glover	2023L003763
Emmanuel Goldstein	2023L003467
Greg Gover	2023L003738
Michael Hall	2023L003865
Shayne (Shane) M. Hall	2023L003868
Lashonda Hampton	2023L003858
Minnie Harris	2023L003871
Douglas Harrison	2023L003869
Joshua Hawkins	2023L003873
Tina Herrin	2023L003874
Tomasa Hill	2023L003876
Lois Hinkle	2023L003464

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Plaintiff	Cook County Circuit Court Case Number
Sandra Holmes	2023L003739
Willie Holmes	2023L003731
John Holstein	2023L003465
Dawn Hurr	2023L003447
Earl Johnson	2023L003466
Lisha Johnson	2023L003467
Maria Johnson	2023L003469
Gary Johnston	2023L003470
Gilbert Joines	2023L003705
Kenya Knezevich	2023L003733
Joan Knoph	2023L003890
Leonard J. Lee	2023L003908
Carol Lorenz	2023L004100
Betty Lu bar	2023L004061
Lawrence Luckey	2023L003905
David William Lundblom	2023L003907
Carlos Maldonado	2023L003923
David Mann	2023L003504
Vicki McCall	2023L003930
David McClelland	2023L003932
Jean McDonnell	2023L003523
Curtis McPherson	2023L003744
Mark Meyer	2023L003529
Micheal Miller	2023L003920

Plaintiff	Cook County Circuit Court Case Number
Richard B. Moffitt	2023L004062
Kerrie L. Moran.	2023L003919
Deborah Morgan	2023L004066
Freedom Murray	2023L003915
Azmi Mustafa	2023L004005
Garard Naff	2023L003974
Albert Nevarez, Jr.	2023L004004
Robert Newman	2023L004077
Marilyn Denise Oreoluwa	2023L004127
Joshua Owens	2023L003533
Gloria Y. Pacley	2023L003535
Shanna Palmour	2023L003996
Dina Peller	2023L003750
Renita Perez	2023L004090
Kaysandra Peyton	2023L003769
Michele Dawn Piacquadio	2023L003538
Franco Polizzi	2023L003992
Marlon Pucket	2023L003984
Vadalina Quinones	2023L003542
David Long Quintero	2023L004107
Sharon Renfro	2023L003951
Patricia Rhem	2023L003939
Danica Riley	2023L003752
Vernon Risby	2023L003969

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Plaintiff	Cook County Circuit Court Case Number
Craig Rodkin	2023L004001
Elvir Sabanovic	2023L003991
Marco Antonio Sandoval	2023L003976
Kimberly Sayles	2023L003941
Louise Scott	2023L003567
Sammy Shah	2023L003943
Patricia Siebert	2023L003568
Joseph T. Silva	2023L003916
Pamela Smith	2023L003812
Rebecca Smith	2023L003574
Talton Smith	2023L003575
Donna Snyder {Estate of Ronald Lee Snyder)	2023L003782
Melisa Sobota	2023L003579
Rose A. South	2023L003986
Christian Spining	2023L003813
Olivia Sutton	2023L003841
Jeffrey Tantleff	2023L003826
Johnnie Tarver	2023L004032
Tinisha Thomas	2023L003582
David Thureau	2023L003827
Shane Tomczak	2023L004086
Elizabeth Francy Torres Vieira	2023L003833
Timmy Trahan	2023L003583

Plaintiff	Cook County Circuit Court Case Number
Courtney Turner	2023L003830
Detlef Vance	2023L004110
Tina Ayers Vick	2023L003713
Nate Vortherms	2023L003893
Kyla Voss	2023L003990
Cynthia M. Ward	2023L003882
Christopher Warren	2023L003664
Karleythia Washington	2023L003793
Stephen Weidenhamer	2023L004106
Mary Jane White	2023L003584
Kazuko Williams	2023L004052
Paul Williams	2023L003586
Quincy Carl Williams	2023L003834
Rory Williams	2023L003587
Myisha Wright	2023L003832
Allen Wronko	2023L003831
Robert Yasick	2023L003592
Sheila Furr	2023L003858
Daryle Peters	2023L003990
Cassandra Day	2023L003447
Danielle Barney	2023L003664
Marilyn Holland	2023L003463

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Appendix B

[Filed: Apr. 25, 2025]

**IN THE CIRCUIT COURT OF COOK COUNTY,
ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION**

ELLEN SMITH,
Plaintiff,

v.

WALGREEN CO., *et al.*,
Defendants.

**ORDER OF
DISMISSAL WITH
PREJUDICE**

Case No. 2023L003569

Judge Daniel A. Trevino

**[PROPOSED] ORDER OF DISMISSAL WITH
PREJUDICE**

THIS CAUSE coming before the Court on Brand Defendants' Joint Motion Under 735 ILCS 5/2-301 to Dismiss All Non-Illinois Plaintiffs' Claims, and the Court being fully advised in the premises, IT IS HEREBY ORDERED THAT:

1. Brand Defendants' motion is GRANTED over Plaintiffs' objection for the reasons stated on the record at the Court's January 23, 2025 Case Management Conference in *Banna v. Walgreen Co., et al.*, No. 2020-L-004916, under which this action is consolidated for pretrial purposes.
2. The above-captioned lawsuit, Circuit Court of Cook County, Case No. 2023L003569, is dismissed with prejudice as to all Defendants.
3. Plaintiff and Defendants shall bear their own attorneys' fees and costs.

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Dated: March _____, 2025

/s/ Daniel A. Trevino

Honorable Daniel A. Trevino

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Appendix C

STATE OF ILLINOIS)
) SS:
COUNTY OF COOK)

IN THE CIRCUIT COURT OF COOK COUNTY,
ILLINOIS
COUNTY DEPARTMENT – LAW DIVISION

GEORGE BANNA,)
)
 Plaintiff,)
)
 –v.–) No. 20-L-004916
)
WALGREEN CO., et al.,)
)
 Defendants.)

RECORD OF PROCEEDINGS held in the above-entitled cause before the Honorable DANIEL A. TREVINO, Judge of said Court, via videoconference, at approximately 10:49 a.m. on January 23, 2025.

Reported By Beth Radtke, RPR, CRR
License No. 084-004561

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PARAFINCZUK WOLF
By Mr. John Bruegger

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Appeared on behalf of Defendant Patheon.

THE COURT: As I mentioned in my e-mail, I know—we're going to go on the record.

This is the Banna versus Walgreens matter 2020-L-4916 consolidated case. This case has—was set for hearing on January 23rd. The Court was aware of the 23rd date; however, I wrote it in my bench calendar for tomorrow. I apologize. I sincerely apologize. The last thing the Court would want to do is waste anyone's time. In all my years on the bench, I don't think this has ever happened like this, so I am sorry. And Ms. Zousmer kindly sent an e-mail; I was

actually going through—finishing going through the materials here and was not checking my e-mails since earlier this morning, and then Mr. Bayman kindly actually was in the building because of another trial, and advised my clerk.

So that's why we're late. It's a mis-diary on my part, but I am in receipt of all of the courtesy copies specifically relating to the personal jurisdiction motion which is set for hearing today. The Court has reviewed all those materials, and is prepared to move forward, first and foremost, on that motion.

So, Counsels, we will wait until the end of the hearing to put your specific appearances on the record; however, if you are arguing an aspect of the motion before the Court or are the first person to—or are speaking, please feel free to identify yourself first and foremost by your name and who you represent.

So at this time, we are going to move into the brand defendants' 5/2-301 motion to dismiss the non-Illinois plaintiffs' claims based on—pursuant to the motion, lack of personal jurisdiction.

Attached as Appendix A to the motion is a list of cases and I just want to confirm that Appendix A has been—so I'll ask movant this question first, just from an administrative standpoint: Has Exhibit A—strike that. Has Appendix A also been filed with the Court?

MS. SHARPE: Good morning, your Honor this is Paige Sharpe on behalf of the Sanofi defendants. I'll be taking the lead on arguing the personal jurisdiction motion for the brands this morning.

I believe Appendix A was filed with the Court when the motion was filed back in October of 2023; however, there have been significant changes to the docket since then. I think when we filed the motion, there

were 543 pending cases, and now there are 423. There were 263 plaintiffs that were subject to the motion previously, and I believe that number is down to 182.

So my proposal would be that if your Honor grants the motion that we confer with plaintiffs' counsel to update and submit a revised Attachment A that reflects the current cases that would be subject to the motion.

THE COURT: The reason I'm asking that question, I think you've touched on some of it, is so that there is a record on what the non-Illinois cases are, and I know this is referenced in the briefs that the—this Court's requirement that all the plaintiffs file individual cases has happened, and this Court understands that each plaintiff has their individual case, but I just want to make sure that the record is clear on which, of all the filed cases, are non-Illinois versus Illinois. And I think you answered my question.

Okay, then, Counsel for plaintiffs, do you have anything to add, just based on that specific question that I asked about Appendix A and the non-Illinois cases?

MR. SNIDOW: Your Honor, just for clarity, I don't believe that I represent any non-Illinois plaintiffs in Illinois.

Of course if there is an exhibit, we'll confirm that none of my cases are on there, but I believe it's not a motion that affects the cases that we've filed, so I'd defer to Mr. Bruegger.

MR. BRUEGGER: Thanks J.J.

Your Honor, we agree, we will confer after the hearing, if need be, to discuss which cases this applies to, get a file list.

THE COURT: Understood. Thank you, Mr. Bruegger and Mr. Snidow.

Ms. Sharpe, you may proceed with your argument, and as I have already mentioned, I have gone through the materials.

You may proceed, Counsel.

MS. SHARPE: Thank you, your Honor. Again, this is Paige Sharpe. I represent the Sanofi defendants, but arguing the motion to dismiss today on behalf of defendants Boehringer Ingelheim and Pfizer as well.

And, your Honor, I just want to start with a reset on the facts that gave rise to our motion, none of which is in dispute.

First of all, all of the brand defendants are residents of states other than Illinois. They are all incorporated in other states, and the principal places of business are in other states.

Second, none of the plaintiffs who are subject to the motion are residents of Illinois.

Third, each of these plaintiffs is claiming to have purchased either Zantac or generic ranitidine in states outside of Illinois, more specifically their respective home states.

Finally, your Honor, none of these plaintiffs are claiming to have suffered any injury in the State of Illinois.

These are all facts that are set forth in the plaintiffs' complaints, and there is clear and binding case law from both the U. S. Supreme Court and the Illinois Supreme Court that applies to these facts, and that case law forecloses jurisdiction here.

I'm going to start with general jurisdiction, which as I'm sure your Honor knows, is jurisdiction for all purposes, and under the U. S. Supreme Court case of Daimler AG v. Bauman, general jurisdiction is, with very limited exception, limited to two places for

corporations: One is their principal place of business, the other is their state of incorporation.

Plaintiffs here are not claiming an exception to that rule from *Daimler*. They say nothing in their opposition brief about an exception.

Instead, plaintiffs are relying on a more recent ruling from the U. S. Supreme Court, and that's the *Mallory v. Norfolk Southern* case. There, the Supreme Court did recognize that an out-of-state defendant might be subject to jurisdiction by consent when it registers to do business in the state. But that's where the registration statute explicitly states that registration gives rise to jurisdiction. In *Mallory*, the Supreme Court decided that question only with respect to the statute before it, which was that of Pennsylvania.

But, your Honor, the Court does not even need to grapple with *Mallory* here, and that's because the Illinois Supreme Court in the *Aspen American* case answered the direct question of whether the Illinois Registration Statute gives rise to general jurisdiction, and the Court in *Aspen* held that it does not, and that ruling was unequivocal, and I just want to read you the holding from the *Aspen* case.

The fact that a foreign corporation has registered to do business under the Act does not mean that the corporation has thereby consented to general jurisdiction over all causes of action. That's the *Aspen* case at paragraph 27.

And, your Honor, the Court is bound to follow *Aspen* as the law of the land in Illinois.

Other states' interpretation of their own registration statutes just have no relevance to the analysis of what happens in Illinois.

I do, however, want to say a brief word about the cases involving the registration statutes of other states the plaintiffs cite, just to explain how those cases actually support the defendants' position here.

So plaintiffs rely on a case involving an interpretation of the Missouri Registration Statute by an Illinois Federal Court. That case is *Donaldson v. Mead Johnson*. It's cited at page 23 of their opposition brief.

But the Court in that case actually reconsidered and vacated that ruling. It went back and did an analysis of what the Missouri Supreme Court had done with respect to analyzing the Missouri statute, and the Missouri Supreme Court previously held that the Missouri statute did not give rise to consent jurisdiction.

So the—the Court, the federal court, the Illinois federal court ultimately vacated that ruling, and the citation to the decision vacating the ruling is *In Re: Abbott Labs*, 2023, 852 7415.

That's exactly the case here, your Honor, where the Illinois Supreme Court already has spoken, already has interpreted the Illinois Registration Statute and held that there's no general jurisdiction under that statute.

I also want to address the recent decision plaintiffs cite from a Connecticut court that also involved *Zantac* litigation that's pending there.

The court in the Connecticut case relied on a pre-Mallory Connecticut appellate case that found that the Connecticut statute did in fact give rise to general jurisdiction, and that was the dispositive fact for the Connecticut court deciding the matter in the *Zantac* case.

Specifically, that court noted that a finding by general—of general jurisdiction by consent is appropriate only if that condition is explicit in the registration statute, or the state courts have interpreted the statute as imposing that condition.

That quote is from the slip opinion at 22, and the opinion is attached as Exhibit 40 to plaintiffs' opposition brief.

So that's the opposite situation of what you have here, your Honor, where the Illinois Supreme Court has already held that the Illinois Registration does not confer jurisdiction.

So Mallory simply does not apply here, given the controlling case from the Illinois Supreme Court, the Aspen case.

But there is an additional reason why the argument fails as to my client, Sanofi, and that's because Sanofi was actually not registered to do business in Illinois at the time these cases were first filed.

There is uniform case law that general jurisdiction is decided at the time that the complaint is filed. We cited cases in our opposition to the personal jurisdiction motion to that effect. To give you one cite, the *Baton v. Ledger* case, 2021 WL-5226315 from the Northern District of California makes that clear.

The first complaints filed in this litigation for these plaintiffs were filed in 2022. As plaintiffs note in their opposition brief, Sanofi was registered to do business in Illinois only from 2006 to 2017. That's in their opposition at 24, and the documentary support for that is attached as Exhibit 38 to their brief.

So because Sanofi was not registered to do business in Illinois at the time the first complaints were filed,

there can be no jurisdiction under this registration theory as to Sanofi.

I'm going to turn, your Honor, now to specific jurisdiction.

With respect to specific jurisdiction, plaintiffs point to a hodgepodge of random facts about each defendant's activities in Illinois. But none of these facts is relevant under the governing cases on specific jurisdiction, and those cases are, first, the Bristol-Myers Squibb v. Superior Court of California case from the U.S. Supreme Court, and second, the Rios v. Bayer corporation from the Illinois Supreme Court.

Those cases both hold that there's no specific jurisdiction over claims brought by an out-of-state plaintiff against an out-of-state defendant for activities and injuries that occurred out of state, which is the exact fact pattern that we have here. The test for specific jurisdiction is whether there is an affiliation between the forum and the underlying controversy. That's set forth in Bristol-Myers Squibb at 262.

In applying that test, the courts in both Bristol-Myers and Rios considered and rejected the very types of evidence that plaintiffs cite in support of specific jurisdiction here.

Product sales, even sizable and regularly occurring product sales, do not justify jurisdiction. That's Bristol-Myers Squibb at 264.

Employing individuals in the forum is insufficient. That's Bristol-Myers at 258 to 259.

Conducting clinical trials in the forum, coordinating a marketing strategy in the forum, holding a physician training program in the forum, all of those contacts are insufficient, and that's stated in the Rios case at paragraph 24.

The court in Bristol-Myers Squibb also considered and rejected an additional argument that plaintiffs make here, that contracting with an in-state third party for nationwide sales gives a sufficient basis for jurisdiction. And in Bristol-Myers Squibb, the Supreme Court referred to that as a last-ditch contention.

Here, plaintiffs make a similar last-ditch argument that the brand defendants' contracts with Walgreens, an in-state retailer that sold Zantac nationwide, gave rise to specific jurisdiction.

For Boehringer Ingelheim in particular, plaintiffs fail to establish the evidence of a contract between these entities whatsoever, because Boehringer employed a third-party sales broker to manage its sales to Walgreens. That's at page 17 of the opposition.

But in any event, this entire premise runs directly afoul of Bristol-Myers Squibb and the cases that precede it, which makes clear that personal jurisdiction has to be established as each individual defendant on their own. You can't impute one company's contacts with a forum to establish jurisdiction over a completely separate company.

That position that plaintiffs are staking out here also violates the fundamental principle underlying specific jurisdiction, that there has to be this link between the activities at issue and the underlying controversy.

The controversy here is whether Zantac failed—whether the defendants failed to warn about the risks of Zantac or negligently stored or transported Zantac, and those claims have nothing to do with the retailer from which plaintiffs bought their Zantac, it has nothing to do with these defendants' contracts with

Walmart—with Walgreens, and plaintiffs can point to no facts to show that any of the defendants made relevant decisions about Zantac labeling or supply chain logistics that are relevant to any of plaintiffs' claims in Illinois.

The claims are exactly the same for plaintiffs who bought Zantac from Target or Walmart or anywhere else, so these contracts with Walgreens are incidental to the claims and they don't have anything to do with the underlying controversy.

Plaintiffs, tellingly, cite no case law to support their position.

But I do want to talk briefly about the cases that the plaintiffs do cite.

All but one of these cases shares a critical distinction that makes them completely irrelevant to the analysis here. They involved claims brought by a plaintiff—brought by plaintiffs living in the forum and claiming to have suffered in-state injuries.

So these are the cases cited in the specific jurisdiction of plaintiffs' brief at pages 12 to 22: There's *Kothawala v. Whole Leaf*. That case involved a plaintiff who was an Illinois resident who purchased a vape pen in Illinois, used the vape pen in Illinois, and was injured when the vape pen exploded in Illinois.

Russell v. SNFA, the plaintiff decedent there was living and working in Illinois for an Illinois company and was killed in a helicopter crash that occurred in Illinois.

Clarke Mosquito Control Products v. Lee Container Iowa, the plaintiff there was also an Illinois resident, an Illinois company that alleged defective containers were shipped to its facility in Illinois.

And finally, your Honor, the Ford Motor Company case from the U.S. Supreme Court, that involved plaintiffs who were residents of Montana and Minnesota whose suits arose from car accidents that occurred in those states and who sought to bring their claims in those states' courts.

The Supreme Court in Ford Motor couldn't have been clearer. This was the holding of that case: When a company like Ford serves a market for a product in a state and that product causes injury in the state to one of its residents, the state's courts may entertain the resulting suit. That's Ford Motor at 355.

But, your Honor, that has nothing to do with the fact pattern here which involves claims by out-of-state plaintiffs suffering out-of-state injuries.

Now beyond these cases, plaintiffs do rely extensively on one case where a court did find jurisdiction over out-of-state residents' claims based on a company's activities in Illinois, and that's the case of M.M. v. GlaxoSmithKline that's cited at pages 16 to 17 of the opposition brief.

But that case was decided before Bristol-Myers Squibb and is no longer good law, and that's clearly stated in Rios, the Illinois Supreme Court case that actually does control here.

Here's what the Illinois Supreme Court said about the M.M. case in Rios: M.M. does not reflect the law in Illinois and should no longer be relied upon. That's Rios at paragraph 32.

So, your Honor, I just have one final point, again from the Rios case to close. As the court said there in dismissing the out-of-state plaintiffs' claims, Illinois has no particular interest in resolving claims that did

not arise out of or relate to activities that occurred here. That's Rios at paragraph 31.

The same is true here, your Honor. Illinois has no interest in these out-of-state plaintiffs' claims. These plaintiffs could have filed suit in multiple other forums where jurisdiction would have been proper. They could have filed in their home states, they could have filed their cases in the federal multidistrict litigation, or they could have joined tens of thousands of other plaintiffs who brought suit in Delaware, where all of these brand defendants are incorporated and where jurisdiction would be proper.

These plaintiffs' choice to forego those forums does not make jurisdiction in Illinois proper or give this Court a basis to hear their claims.

Your Honor, that is the sum and substance of my affirmative presentation. I'll reserve for rebuttal, unless the Court has questions, but otherwise, I'll cede the floor.

THE COURT: Thank you, Counsel. No questions at this time, and I also want to let everyone know on the Zoom that there's no one else in my chambers, other than myself.

Counsel who was in the courtroom, who I identified in the e-mail, Mr. Bayman, he is not here; he had to go to his trial or wherever he is, but he's not in chambers. I just wanted everyone to know that there's no one else other than me and there has not been anyone else other than me.

Counsel for plaintiff?

You're on mute, Mr. Bruegger.

MR. BRUEGGER: Thank you, your Honor. John Bruegger from Parafinczuk Wolf on behalf of some of the plaintiffs here.

Your Honor, I just want to start by stating a few things that defense counsel said, and it seems to me, and I don't want it put words in her mouth, but there's no dispute as to the facts here. There are numerous facts, based on numerous documents that are now part of the record that plaintiffs have cited to establish the facts under the Illinois test for specific jurisdiction. Those facts are undisputed. They're uncontroverted.

So really what we are discussing today is what is the legal impact of those connections that each of the defendants has with Illinois in this case.

So they're making a categorical argument, your Honor. They're making an argument that they made originally in their motion, that they've made in numerous responses to motions to compel on the personal jurisdiction discovery, that there's no set of facts in Illinois that would ever allow an Illinois court to exercise jurisdiction over the claims of a non-resident against a non-resident defendant.

I don't think that's the law in Illinois, and I think that completely goes against not only Illinois cases law, but the United States Supreme Court case law on the subject.

Your Honor, with that said, I want to get into what the actual test is here. There's a lot of discussion so far about glossing over these tests, and these connections and the residence of the plaintiffs, but we have to follow the Illinois Supreme Court and apply the test and the standard that they have given us to determine if jurisdiction is appropriate.

The standard here, even though this is defendants' motion, the plaintiffs have the burden to establish a prima facie case for jurisdiction over the defendants,

and once we establish a prima facie case and the burden shifts to the defendants, to overcome that prima facie case through uncontradicted evidence. That's the test from the Russell case.

Courts have held that this standard is lenient and flexible, and in the—and the First District has stated that the plaintiffs, at this stage, need not prove their case but only meet the low threshold that is a prima facie showing.

Now, your Honor, as defense counsel pointed out, Illinois recognizes two types of jurisdiction: General jurisdiction and specific jurisdiction. And, your Honor, the plaintiffs would like to stand on their brief with regard to general jurisdiction and preserve those arguments, with the exception of just pointing out that the Aspen Insurance case and the Rios case were both cases decided by the Illinois Supreme Court when there was no United States Supreme Court Federal Constitutional due process mechanism for imposing personal jurisdiction over a foreign corporation based on foreign registration.

So, your Honor, to the extent that the Mallory case has now changed the jurisdictional analysis on the federal level, I would say that it's ripe for the Illinois courts to reexamine the doctrines in Aspen Insurance and Rios on that basis.

Leaving that aside, your Honor, what I really want to talk to you about today is specific jurisdiction, and I think specific jurisdiction is the crux of this case.

Again, in Illinois, there is a very clearly defined test that the Court has to apply to determine whether specific jurisdiction exists. The plaintiff, in order to make its prima facie case, must show that the defendants purposely availed themselves of doing business

of Illinois, that the current cases either arise out of or relate to those Illinois contacts, and that this Court's exercise of jurisdiction would be reasonable in these circumstances.

So those are the different prongs of specific jurisdiction that the plaintiffs have to meet to make their prima facie case.

I want to talk about personal availment first. As we know from the U. S. Supreme Court's Burger King decision, and has been repeated in numerous cases in Illinois, purposeful availment only means that a defendant has to take some act to avail itself of the privilege of conducting activities in Illinois. But these acts don't necessarily have to be related to the case in hand. The Kothawala case in the First District has stated that there has to be some act, but not that the acts have to be connected to the underlying case. This is only to show purposeful availment.

Your Honor, with respect to each of the defendants here, and I don't think the defendants could disagree on the documents, we can show purposeful availment for each one.

With regard to Pfizer, Pfizer undertook development—Pfizer co-developed over-the-counter Zantac with GlaxoSmithKline in a joint venture, and they conducted clinical trials in Illinois by retaining the University of Illinois College of Medicine in Rockford for clinical trials. That's at Exhibit 25.

Zantac, as controlled by Pfizer, was marketed by their division called the Pfizer Consumer Healthcare Division. This division acted to develop, market, and test and sell Zantac all over the country. We learned this from two corporate rep depositions: The Warner

deposition and the MacNeal deposition. Those are Exhibits 2 and 4 to our response.

Now, questions about Zantac were handled by these Pfizer consumer healthcare employees in Geneva, Illinois, including questions between Pfizer Consumer Healthcare in Geneva, and questions from the corporate headquarters for Walgreens in Deerfield, Illinois. There are several e-mails to this effect, which we cite at Exhibits 5, 6, 7, 8, and 9 to our response.

In addition to these employees, despite the fact that Pfizer has said in their responses to requests for admission that they only know about one employee in Illinois, Pfizer's own documents, which we cite at Exhibit 10, show they had hundreds of employees throughout Illinois, and these are employees working in divisions like research and development, biopharma, and global health, global supply, and essential health.

So they have a substantial presence in Illinois.

Additionally, Pfizer reached in to Illinois deliberately and entered into a contract with a company called Fitzpatrick Company in Elmhurst, Illinois, specifically to explore testing of equipment for suitability for the production of ranitidine HCL, the active ingredient in Zantac.

This is not the only contract that Pfizer entered into with respect to Zantac in Illinois. Pfizer specifically targeted an Illinois company, Walgreens, the largest retail pharmacy in the United States, for nationwide sales and marketing. They were not contacting Walgreens to ask about how they could sell Zantac within the State of Illinois, they were contacting Walgreens to create a national marketing and sale plan for all of Walgreens stores around the entire

country. And this is evidenced by not only the e-mails that I have already cited, but the employees that Pfizer Consumer Healthcare in Geneva, talking about shipping Zantac 150 kits, and these are marketing kits, to all Walgreens stores, including Puerto Rico. So the contacts to Walgreens in Illinois had national implications.

Pfizer also had a dedicated Walgreens team that communicated with Illinois employees regarding nationwide marketing and sales of Zantac to Walgreens, and that's Exhibit 17.

Finally, your Honor, Pfizer sold and shipped not just generally products into Illinois, they sold and shipped, over the time that they controlled over-the-counter Zantac, \$194 million worth of Zantac into Illinois to the Walgreens warehouse and distribution center in Mount Vernon, Illinois for redistribution and sales to Walgreens stores throughout the entire country.

This is not some sort of tenuous one-time connection, this is a systematic, consistent contact that occurred over many years.

We think that shows purposeful availment as to Pfizer.

With regard to Boehringer Ingelheim, Boehringer Ingelheim admits that they sold all kinds of products, including Zantac, to retailers, distributors, and wholesalers around the country, including into Illinois between 2007 and 2016.

Boehringer Ingelheim hired an agent, and not just any agent as was the case possibly in Bristol-Myers Squibb to just go sell Zantac anywhere. They hired Crossmark, an agent, to go market and sell Zantac to Walgreens. They gave them responsibility for the

Walgreens national account and gave them two products to focus on: Zantac and Dulcolax.

So they retained an agent specifically to reach into Walgreens, not a case where they didn't know what they were—what Crossmark was going to do or they didn't know Crossmark was going to contact Walgreens. They told them, go after Walgreens. This is shown in the documents we attach at Exhibits 27 and 28.

Boehringer Ingelheim also retained and entered into contracts with two other Illinois companies in Illinois, one is Mechanical Servants in Melrose Park, and the other one is Modern Aids in Elk Grove, to repackage its Zantac for nationwide retail sales. And this is very significant. You can see this at Exhibits 31, 32, and 44 of our response.

How these contracts worked, your Honor, is Boehringer Ingelheim shipped Zantac to these companies in Illinois for repackaging, so they would send them the Zantac product, these companies would then put the product into the final consumer-facing retail packaging that the consumers would then see on the shelves and purchase.

If that wasn't enough, your Honor, specifically as you can see in Exhibit 30, these contracts required these repackaging companies to include certain information in the packaging, including, and I quote: "FDA drug facts labeling for the products for use by the repackager in preparing repackaging materials."

So Boehringer Ingelheim told these repackagers, box up the Zantac into retail packaging, put the FDA drug label on it, here's what you have to have on the label.

So the defective label, which forms the basis of a lot of these cases, as Ms. Sharpe has indicated, these failure to warn cases, a failure to warn based on the defective label, the defective label was put on the retail consumer packaging in the State of Illinois. And not just sold in Illinois, your Honor, then redistributed and shipped throughout the country, including to the Walgreens where these plaintiffs purchased their Zantac.

One more fact about BI, your Honor: They contracted with a company called Rand Diversified Companies for quality assurance and packaging controls. Now, while Rand is a New Jersey company, the contract specifically identified the work to be done in two facilities: One in New Jersey and the other one in Edwardsville, Illinois, and they named several key executives who signed the agreement and were in charge of the contract in Edwardsville, Illinois.

We think that that more than establishes personal availment against BI.

Your Honor, the Sanofi facts are very similar. Sanofi admits that, between 2017 and 2023, they sold—they earned \$465 million of revenue for all of their products sold in Illinois, and between 2017 and ‘19 when they controlled Zantac, they sold \$15 million of Zantac into Illinois to Illinois companies.

Now Sanofi contracted with AmerisourceBergen, which is a company who distributes medications. They’re primarily owned by Walgreens, and they contracted them for the sales of Walgreens, shipped Zantac to AmerisourceBergen in Romeoville, Illinois.

Sanofi also sold and shipped millions of dollars of Zantac to distribution centers to Walgreens, the same one that Pfizer did and the same ones that BI did.

These drugs—this Zantac went to the Walgreens facility, distribution facility, in Mount Vernon and others.

In addition to that, your Honor, they sold millions of dollars of Zantac, shipped it to the distribution centers in Illinois for Walmart, Sam's, Costco, SuperValu, Amazon, and McKesson, and other companies.

Now this was for the sale of Zantac in the state of Illinois only. These are for distribution throughout the country to all of these retail outlets. Contacted and shipped to an Illinois company for that Illinois company to sell in their stores nationwide, and then they sent it also to other Illinois facilities for other companies for sale in those stores nationwide.

Now Sanofi took over the NDA for over-the-counter Zantac from Boehringer Ingelheim. When they did so, they adopted the agreement, the repackaging agreement, they had with Mechanical Servants in Melrose Park and Modern Aids in Elk Grove.

So again, Sanofi also, as BI did, shipped the Zantac product to these companies for repackaging, including putting the defective label that did not have the proper warnings, as plaintiffs allege, on the retail packaging for distribution and sale around the country.

Then finally, your Honor, with regard to Sanofi, Sanofi sold millions and millions of dollars of Zantac into Illinois to Walgreens, to these repackagers, to other companies for distribution throughout the United States.

So we believe that this shows, more than just some act as required by Burger King, this shows a purposeful avilment of the Illinois privileges and protections

for doing business in Illinois with regard to Zantac specifically, not even counting their general business.

So, your Honor, once we show—once we make a prima facie case and show that we have purposeful availment, we now move on to the next test.

The next test prior to the Ford case in 2021, this prong was considered as one piece of the puzzle, and it was—whether the disputes at hand arise out of or relate to the contacts with Illinois.

Again, prior to 2021 and the Ford case, that was generally handled as one piece of the puzzle, arise out of or—or relate to. We see that in the Russell case.

But with the Ford case in 2021, which postdates Bristol-Myers and which postdates Rios, these are two separate things, either one of which if the plaintiff proves, could prima facie case for jurisdiction am.

Now here each of these plaintiff's disputes, each of these non-resident plaintiff's disputes are specifically tied to the defendants' contracts in Illinois.

First, every one of these plaintiffs, your Honor, that our firm has filed in Illinois bought their drugs at Walgreens. They bought their over-the-counter Zantac, they went to Walgreens and bought their Zantac.

That's relevant, your Honor, because, as we said, Walgreens is based in Illinois, it's incorporated in Illinois, its principal place of business in Illinois, and it has stores, retail stores, throughout the country.

So every plaintiff here, their dispute touches and concerns the State of Illinois because of the prominence of Walgreens. Walgreens was such a critical part of the national marketing and sales campaign for all three of these companies, as it would be, being the largest retail pharmacy in America.

All of these decisions to sell where the plaintiffs bought it touched Illinois.

In addition, every single one of these plaintiffs, your Honor, and you know this from having tried some of these cases, every single one of these plaintiffs have brought counts for failure to warn, that the label was defective because it didn't warn of the contamination with NDMA and it didn't warn of the risk of cancer.

Now whether any other claims survive, your Honor, you know that going through trial, these—the failure to warn claims have been surviving and going to trial, going to the juries.

So the two critical facts here are the defendants reached in to Illinois to contract with Walgreens to have these defective labels put on their drugs in Illinois by Illinois companies for redistribution to Walgreens everywhere. The plaintiffs bought at Walgreens, and the labels put on by the Illinois companies in Illinois form the basis of the failure to warn defective labeling that forms the basis of these lawsuits.

And, your Honor, this applies to each of the defendants: Pfizer aggressively marketed to Walgreens, shipped product into Illinois to Walgreens for redistribution around the country. BI and Sanofi aggressively marketed to Walgreens through their authorized agent. They put the Zantac in the final defective packaging in Illinois for distribution throughout the country, and this is the packaging that the plaintiffs picked up on their local Walgreens shelf, and did not have the proper warnings on it.

So, your Honor, to the extent that this arise out of prong, even as a causal requirement or there has to be a direct link, as defendants seem to be implying here,

we can meet that in this case. Their connections to Illinois specifically relate to these plaintiffs who purchased from Walgreens and have failure to warn claims in Illinois.

Now even if there is no causal link, even if the Court finds that there was not a direct connection to these plaintiffs' claims, that's not the only standard. Under the Ford case, and under the Kothawala case, we've seen that even if we can't show that they arise out of the contacts, we can still show that the contacts with Illinois are related to the disputes that the plaintiffs are bringing here.

This is a very flexible standard, this relate to standard.

Now defendants are arguing, based on Bristol-Myers Squibb, which is old law, and in Rios, which is based on old law, and they're implying to the Court that there has to be a direct connection here, that the connections to Illinois have to be directly connected to the disputes for the non-residents. But that's not what the Supreme Court said and that's not what the Illinois courts now recognize.

The relate to standard is not a cause to complain. Ford made this exact argument in this case, and it was rejected by the Supreme Court.

Relate to does not require a causal link between the activities in Illinois and the plaintiffs' claims.

So here, we have targeted, direct, substantial ongoing efforts to contract with Illinois companies for the repackaging with defective labeling, the nationwide market and sales, the distribution efforts of Zantac all over the country.

Each of these plaintiffs bought Zantac at Walgreens. Each of these plaintiffs are alleging

failure to warn. Each of these plaintiffs are the direct victims of the plaintiffs' efforts to reach into Illinois and target Walgreens and put the defective labeling on in Illinois, and then distribute this defective Zantac around the country where the plaintiffs have ingested it.

So if the Court finds we cannot prove there is a direct connection based on the arise out of prong of Ford, we posit that we can certainly show a prima facie case, and at least these claims relate to all of these substantial Zantac connections in Illinois.

And, your Honor, the last thing we have to show to make our prima facie case is that it would be reasonable for this Court to exercise jurisdiction over these defendants.

These are not defendants who have some sort of tenuous connection to the state of Illinois.

Now in the Bristol-Myers Squibb case, we've see that those were non-residents versus non-residents, but if you look at the facts of that case, you can see that California was one of 50 states where the drug was sold, seemingly chosen at random for the plaintiffs to bring their cases. This is not the case at all with Illinois.

So in order to show reasonableness, we have to show that the burden—the Court has to consider the burden of proof that's imposed on the defendant, the forum state's interest in adjudicating the dispute and the plaintiffs' interest in obtaining convenient and effective relief, and then finally, the judicial system's interest in obtaining the most efficient resolution of the controversy. That comes right from the Rios case.

Burden on the defendant. Now these defendants at issue here have all been litigating these cases for

well over two years in Cook County. If the Court grants these—the motion to dismiss, the cases that are being litigated in Cook County will not disappear. Every trial that’s gone forward so far, every trial that’s currently set for this year and into 2026, when those get set, involved Illinois plaintiffs.

This Court and these defendants are still going to have a busy trial schedule and still have to litigate these cases in the State of Illinois.

Now what they’re doing that these cases—if the non-residents get dismissed and have to get re-filed in their home jurisdictions, all that does is increase the burden on everybody. It increases the burden on defendants, because now they are going to have to litigate in dozens and dozens of more jurisdictions, it increases on plaintiffs, who are going to have to do the same, plaintiffs’ counsel will have to litigate in dozens and dozens of jurisdictions, and then the different court systems, now instead of having the Cook County court system addressing these cases, we are going to have dozens of different random county courts around the country who have to, for the first time, pick up these cases and look at them and try to understand the issues.

So the burden would actually be eased on defendants, would be lighter on defendants, if we keep the cases in Illinois.

Now Illinois does not have a tenuous connection to these cases. Illinois has a very strong interest in adjudicating this dispute. Why? Because Illinois was a key critical part of the nationwide marketing and sales plan.

Pfizer took development efforts by doing clinical trials in Illinois. Everybody aggressively marketed

towards Illinois as part of their nationwide sales and marketing plan. Everybody had contracts with Walgreens, either directly or through an authorized agent that they retained, to sell across the country, and BI and Sanofi shipped the Zantac into Illinois for Illinois companies to put the defective label on and then sell across the country.

This is not like California in the Bristol-Myers Squibb case where it was a random connection, where yeah, they had employees there and yeah, they also sold some of this drug there, and you know, they didn't take any different action in California than they did in any of the other 50 states.

Here, Illinois stands apart from the other states because of this. The plaintiff also has a strong interest in obtaining convenient and effective relief.

Now from the plaintiffs' perspectives, these plaintiffs have had their cases on file for over two years. These cases have been stalled for two years while we litigate this issue.

We have gone through the round of motions to dismiss on the pleadings from the master complaint, and then we have been litigating this personal jurisdiction motion for well over a year.

So the plaintiffs, if they have to get—if the case gets dismissed, they have to go to their home county or home forum to re-file the case, they're getting to the back of the line, not counting any statutes of limitation or repose issues that the defendants will likely raise. The plaintiffs are going to have to go home, get to the back of the line, and that means starting all over from scratch with a new court, a new judge, a new system, and taking another year, two years, to get to trial from that point. So it would be much more efficient to

have these cases heard in Cook County where they are already pending.

Then finally, your Honor, principles of judicial efficiency and economy support keeping the cases in Illinois.

As I said, the Illinois courts are already very familiar with these cases. Your Honor has been handling the pretrial matters in these cases for over two years. Several of these cases have gone to trial in Cook County. Your Honor is familiar with the legal and factual issues with regard to these cases. So to engage—you know, we have a cohort trial system that was established setting cases for trials throughout 2025 and likely into 2026, so your Honor, we have that versus each of these cases being scattered around the country for individual judges to learn all of this information, to consider all of these experts, to make all of these decisions, to make all of these rulings that your Honor has already made, with regard to experts and evidence and jury instructions and everything else. Now we're going to have dozens and dozens of dozens of judges around the country starting from scratch to do that themselves.

So not only are we engaging in Cook County still, now we're going to be engaging a whole scattershot approach of courts around the country.

So, your Honor, we feel the reasonableness prong here is clearly met.

So with that, your Honor, we have established our prima facie case to show that each of these defendants have purposely availed themselves or are doing business in Illinois, that these cases arise out of or relate to either standard in Illinois because of the direct connections, because each plaintiff bought from

Walgreens, each plaintiff alleges failure to warn, and those activities directly occurred in Illinois.

And, your Honor, just to discuss a couple of the cases that Ms. Sharpe had raised, the Ford Motor Company case, your Honor, I don't know if it was mentioned at all, or maybe this was barely mentioned by Ms. Sharpe, but that changed the analysis here. This is not just the Bristol-Myers case where we are talking about California having zero connection or no better connection than any of the other 50 states to a case. We're talking about whether Illinois can either meet the arise out of and having a direct connection to the case, or this relate to standard.

Bristol-Myers, the plaintiffs have been championing this case for over a year, that this seals the deal. This is the categorical argument, that, no matter what the evidence shows, Bristol-Myers Squibb is controlling, and that's not the case. This is a Plavix case, a drug case where non-residents sued non-resident defendants in California.

There is a clear difference here, your Honor. Every one of our plaintiffs brought their case in Illinois because they bought their drugs, their defective Zantac from a Walgreens store, and as your Honor may remember, they named Walgreens in the original complaints. Every one of these cases.

So unlike Bristol-Myers, where California was one of 50 states where they sold Plavix and took some marketing activities, in Bristol-Myers, at page 255 of the court's opinion, there were three facts that the court found, that—that are critical to the distinction here. The Court, the Supreme Court found that Bristol-Myers did not develop Plavix in California, it did not create a marketing strategy for Plavix in

California, and they did not manufacture, label, or package Plavix in California. Those are clearly different than the activities these brand defendants have taken in Illinois.

As we have seen, Pfizer undertook development activities in Illinois by conducting clinical trials in Illinois. We see that all three of them had Walgreens as the critical national sales marketing component of their campaigns because Walgreens is the largest national retail pharmacy.

They—Pfizer had Pfizer Consumer Healthcare employees dealing with Walgreens in Illinois. BI and Sanofi retained an agent specifically to target the national sales of Walgreens in Illinois.

So—and then they sold to Walgreens hundreds of millions of dollars of Zantac, which they shipped into Illinois for distribution all over the country.

Finally, we can see that the labeling in this case with regard to Boehringer Ingelheim and Sanofi, the defective labeling that forms the heart of this case, your Honor, occurred in Illinois. They reached into Illinois to ask these Illinois companies to put the final retail packaging on that consumers would see, and—including with that the defective label.

Now the Plavix cases were prescription drug cases where they had to talk about whether they trained the doctors, whether they—whether they warned the doctors in Illinois, whether the doctors had misinformation in Illinois. None of that is relevant here.

What we have here is three facts of the Bristol-Myers case, which showed no connection to California and those same factors show a direct connection to these cases in Illinois.

And, your Honor, finally, with regard to the Rios case, your Honor, Rios, again, was decided before Ford. So what Rios found in that case didn't close the door on all non-resident plaintiffs bringing claims against all non-resident defendants per se, end of story.

Rios relied on three facts in that decision. The plaintiffs claimed a manufacturing defect that Essure was not manufactured in Illinois. Plaintiffs alleged failure to warn that their prescribing physicians weren't warned of the side effects, but they did not link any connection to Illinois that the—that the prescribing physicians were warned or not warned or inadequately warned in Illinois, and, as Ms. Sharpe said, Bayer undertook a physician training program in Illinois to—and Essure is a birth control implant, your Honor, and so what Bayer did is undertook a program in Illinois to teach doctors how to use Essure, and the allegation there was, well, none of the plaintiffs' physicians underwent that training in Illinois.

So that's why Rios is fundamentally different on the facts here, your Honor, because in our case, we have, as I said, each plaintiff bought from Walgreens, each plaintiff picked up that retail packaging of Zantac at their Walgreens, looked at it, and relied on what was on that packaging. And that, those packages, Zantac was shipped to Walgreens in Illinois when these deals were made with Walgreens in Illinois, they were sent to Walgreens for distribution nationwide to where the plaintiffs would buy them, and the defective warning labels were placed on the packages in Illinois for then distribution around the country.

This is a direct connection to Illinois that was not present in the Essure case and Rios.

So, your Honor, just to reiterate, the Supreme Court in the Keeton case has shown that a state can exercise jurisdiction over a non-resident accused by a non-resident causing injuries, most of which activity took place outside of the foreign state. That's Keeton vs. Hustler Magazine, 465 U. S. 770.

In this case, your Honor, that's exactly what we have. The plaintiffs took the drug outside of Illinois, but all the steps leading up to that to convince the plaintiffs to take it, to market it, to prepare it for sale, to put it in the position where the plaintiffs can pick it up off the shelf, read the packaging and ingest the defective drug, those decisions occurred in Illinois.

As for that, your Honor, I want to say we have met our prima facie burden to show purposeful availment, cases arise out of or relate to the dispute here in the connections with Illinois. It would be reasonable for the Court to exercise jurisdiction here, and the defendants have not met their burden now to show uncontradicted evidence to contradict our evidence that we have shown that there is no jurisdiction here.

If your Honor has any questions, I'd be happy to entertain those.

THE COURT: I do have one question for you, Mr. Bruegger.

In the Ford Motor Company versus Montana Eighth Judicial District Court, Supreme Court of the United States matter which you have argued here in the hearing and is referenced in your brief, one of the holdings of that court was that defendants demand for an exclusively causal connection test was inconsistent with the court's precedence under which specific jurisdiction attached when a company started to market in the foreign state and the product malfunctioned there.

Do you recognize that that's part of the holding there? And I'm specifically referring to the product having malfunctioned in the forum state.

MR. BRUEGGER: Yes, your Honor, and we can say that, with regard to the Ford case, yes, while Ford says there doesn't have to be a causal connection between the foreign state and the underlying cases, yes, the—in this case, these defendants sold defective Zantac in Illinois. The Zantac they sold in Illinois was defective in the same way it was defective around the country; it had the same problems, it had the same failure to warn, and it had—you know, it caused the same problems, these various cancer injuries.

So, your Honor, without creating a causal connection to say that these particular cases, the context—you know, these cases arise out of those contacts with Illinois, these cases certainly relate to those contacts in Illinois. It's the same case, the same injury, it's the same product, it's the same failure to warn.

THE COURT: And one other question—I know I said I have one question. I actually have a second one I would like you to address.

It's out of the Bristol-Myers decision where that court talked about how it's difficult to trace, you know, a pill. How are you able to trace a pill or any of the Zantac at issue here from anything that was allegedly—let's go with plaintiffs' argument about the repackaging in Illinois and distributed from Illinois.

How do you reconcile that, where that court—and I can give you have the cite. Just one moment.

What do you have in the record here that shows how any of the product that was allegedly distributed by Walgreens ended up in a specific pharmacy or retailer

or place where your client, your out-of-Illinois client actually took those pills?

MR. BRUEGGER: Well, your Honor, what we have here is we have obviously the Walgreens headquarters are in Illinois, major distribution centers in Illinois. So the marketing efforts directed towards Walgreens in Illinois are relevant to all of these cases.

In addition, your Honor, we have multiple spreadsheets from the defendants showing the list of all of their shipments into Illinois and to these Walgreens facilities, as well as other facilities for other retailers.

So, your Honor, the Walgreens stores are corporate owned; these are not—you know, in Bristol-Myers, the concern was that Bristol-Myers sold Plavix to a middleman, the middleman then went and struck deals and sold Plavix to retailers around the country, and Bristol-Myers is saying, you know, it's unfair for us to be held into any of these courts because the third-party middleman was running around reselling Plavix to all the retailers.

Here, we don't have that issue. You know, even with BI and Sanofi, they didn't retain a middleman and sell the Zantac to the middleman and it was out of their hands and they didn't care after that.

In this case, we have these defendants specifically targeting Walgreens in Illinois, shipping hundreds of millions of dollars of product to Walgreens in Illinois. Walgreens distributes that around the country, which is—sorry, your Honor, let me just...

So, you know, this is what we've learned in the documents in the spreadsheets that we have that show that these were sent to Walgreens with the address, these addresses in Illinois, and these—we have the plaintiffs who have alleged in their complaints that

they bought from Walgreens, you know, as a result of these distribution efforts, and that they failed to warn.

So, your Honor, I don't think there's any allegation here, the defendants certainly haven't raised any facts that the packaging for some Walgreens was different than other Walgreens, the packaging for some retailers was different than other retailers and contained better warnings. This all funneled through Illinois, and all contained the same defective warnings.

So we have, your Honor, is the contracts with Illinois, the contacts through the e-mails with Illinois, the spreadsheets showing hundreds of millions of dollars of Zantac being shipped into Illinois for redistribution.

THE COURT: Okay. And one final question, Mr. Bruegger.

MR. BRUEGGER: Yes, sir.

THE COURT: I want you to address—this was brought up by defendants in their argument, initial argument, but it's also in the Bristol-Myers Squibb Supreme Court of the United States decision that talks about a third—the involvement of a third party and how a defendant's relationship with a third party standing alone is an insufficient basis for jurisdiction, third party being Walgreens at this point in this litigation and/or some of the other entities that you've mentioned as part of your argument.

MR. BRUEGGER: Yes, sir.

THE COURT: So how—how do you—what's plaintiffs' position on how this is different from Bristol-Myers Squibb?

MR. BRUEGGER: Sure. Bristol-Myers, in that case, they hired a third party, they sold the drugs to a

third-party wholesaler, and then the wholesaler went around and struck deals with the pharmacies and the retailers and sold it that way.

So that is a—that is a very large step removed, you know, in this case, one, we have direct connection between Pfizer and Walgreens, so there's no third party there, in addition to all the other contacts that Pfizer has with Illinois.

With BI and Sanofi, yes, they retained a sales agent, a sales broker, but they didn't just say, here, we're going to sell you all of our Zantac and you go out and do whatever you want with it, you can throw it in the river, you can burn it, you can sell it to Walgreens, I don't care.

What you saw there in those contracts, and we cite those contracts as exhibits, is that you are responsible for this territory, responsible to sell Zantac according to our marketing plan, you are responsible for the national account for Walgreens, to sell Zantac to Walgreens.

So that is wholly different. These companies, BI, Pfizer, and Sanofi, are not caught off guard here; they're not surprised that some of their product ended up in Walgreens stores. That was a critical part of the marketing and sales strategy, as you can see in all of the documents we have cited.

It's completely different from what happened in Bristol-Myers.

THE COURT: Thank you, Counsel.

Any reply or rebuttal?

MS. SHARPE: Yes, your Honor, I have a few points to make, and then I think that Counsel for BI and Pfizer have also turned on their cameras, so they might have additional points to make as well.

Your Honor, first of all, our argument is based on the set of facts before the Court, that there is no jurisdiction based on these particular facts and the binding case law.

Secondly, I think I heard Counsel concede that the Aspen case controls the general jurisdiction inquiry here, and unless and until the Supreme Court revisits that decision, that's binding law on this court, and there is no general jurisdiction.

Then, your Honor, I just wanted to address a couple of points related to the specific jurisdiction argument that plaintiffs' counsel made.

First of all, Bristol-Myers Squibb and Rios are good, current, and binding case law, and they address this exact fact pattern where you have out-of-state plaintiffs bringing claims against out-of-state defendants for out-of-state injuries and out-of-state purchases.

The courts in both of those cases rejected the exact types of connections that plaintiffs are alleging here to try to make their specific jurisdiction argument.

For example, you heard Mr. Bruegger speak a lot about the volume of the defendants' sales in Illinois and how much business they did in the state. That is flatly irrelevant under Bristol-Myers Squibb and Rios; they rejected that very contention. In Bristol-Myers Squibb, they said even regularly occurring sales of a product in a state do not exercise—do not justify the exercise of jurisdiction over a claim unrelated to those sales. That's the decision at 264.

And, your Honor, the same thing is true with these additional types of connections. In Rios, the plaintiffs made the same types of arguments, they tried to throw up a lot of noise about all of the activities that the Bayer defendant did there. The court said those

activities are not jurisdictionally relevant when they're not connected to the underlying controversy or the plaintiffs' particular claims. That's exactly the case we have here.

No court in the country, your Honor, no court ever since Bristol-Myers Squibb has—has accepted an argument that purchases out of state can give rise to claims against an out-of-state defendant. No court has done that. That is exactly what plaintiffs are asking you to do.

To the contrary, Bristol-Myers Squibb addressed the very types of arguments that the plaintiffs' counsel is making here, that ties to a third party that's in state are very sufficient. The court said, no, you have to assess claims based on a—on an individual defendant basis.

And there, as here—and your Honor asked just the right question, there's no way these plaintiffs can say that they took any particular Zantac pill that passed through Illinois. Illinois was not the only place that—where these pills were distributed from, and there's no way that these plaintiffs, who none of them purchased their product in Illinois can trace their pill back to the state of Illinois.

With respect to the labeling, it was not created or drafted in Illinois. The failure to warn that plaintiffs allege did not arise from Illinois.

The Ford case that we heard so much talk about, again, your Honor is exactly right, a fundamental part of the holding of Ford related to the fact that the plaintiffs were in-state residents and the injuries they suffered were in-state as well.

With respect to the reasonableness argument that Mr. Bruegger spent a lot of time on, you don't get to

reasonableness without a basis for jurisdiction, and the Court has no basis for jurisdiction here.

The courts in VMS and Rios, again, the plaintiffs there made those exact reasonableness arguments; they said you've already got jurisdiction because there's also in-state residents who are also plaintiffs here. It didn't matter; you cannot glom on to claims of out-of-state residents to those of in state residents who are properly before the Court.

And, you know, just to close with this Walgreens argument, it's clear that Illinois residents have claims against, you know, the companies in Illinois. We're not disputing that. It's clear that Walgreens would be subject to jurisdiction in Illinois. We are not disputing that.

The question is whether that gives rise to jurisdiction against out-of-state defendants who have never been incorporated or had their principal places of business in Illinois, and the case law is very clear that the Court does not have jurisdiction, and as in Bristol-Myers Squibb, there's no allegation that these defendants were acting in concert or through a conspiracy with Walgreens. They are separate corporate entities, and you cannot use one entity's contacts with Illinois to bootstrap jurisdiction on to these other set of defendants. You just can't do that under binding case law, your Honor.

With that, I would cede to Mr. Ruehlmann or Mr. Adams who I see have come on camera.

THE COURT: To the extent Mr. Ruehlmann or Mr. Adams are going to say anything—actually, plaintiff, because they are going to say something now, plaintiff will have an opportunity to respond to their arguments, if any, so I'm just making you aware of that.

MR. RUEHLMANN: Understood, your Honor. I want to make sure you can hear me okay?

THE COURT: I can.

MR. RUEHLMANN: Very good, thank you.

I'll keep my comments brief as it relates to Boehringer, because I think Ms. Sharpe has very forcefully set forth why the facts that we expected plaintiffs' counsel to put forth here do not matter, and why your Honor would be the first judge anywhere in Illinois to find specific jurisdiction on such threadbare facts, or indeed nationally after the VMS decision.

Your Honor asked how plaintiffs' counsel would ever be able to trace any of these facts to pills purchased by these plaintiffs. We heard a lot of words, but it all came down to plaintiffs' counsel cannot do so, and I want to hit on BI specific points here.

First, plaintiffs' counsel conceded that Boehringer had no contract with Walgreens, and so the idea that we aggressively marketed to Walgreens because a third-party broker negotiated a contract, that fact amounts to nothing.

There are two Illinois companies: Mechanical Servants and Modern Aids plaintiffs counsel referenced for purposes of repackaging certain Zantac, and he asserted this was for nationwide sales, and that was also cited in plaintiffs' opposition brief. There is zero evidence on this record, your Honor, of national sales involving either of those companies. Zero.

Similarly, with the Rand Company that plaintiffs' counsel referenced, that is a New Jersey corporation, as plaintiff acknowledged. There is no evidence at all of any purchase by plaintiff of this speciality packaging product that Rand had anything to do with.

I would just echo this idea about defective labeling. Your Honor, there is no claim here from any of these plaintiffs that the label was defectively affixed to a packaging box. The label wasn't controlled or drafted in Illinois. Walgreens had no control over any aspect of the label.

The only other point I would mention is just we heard a lot about dozens of jurisdictions from plaintiffs' counsel. We are several years into this litigation, and that has not happened and it's been no challenge to plaintiffs in any other law firm with these claims to file in Delaware, a state that I did not even hear acknowledged in plaintiffs' arguments.

So the idea that this would require dozens of states is—is absurd on its face, and there's no judicial economy here for plaintiffs.

So I'll leave it there. Thank you.

THE COURT: Thank you, Counsel.

Anyone else?

MR. ADAMS: Your Honor, after Ms. Sharpe and Mr. Ruehlmann's arguments, we don't have anything to add.

THE COURT: Thank you, Counsel.

Mr. Bruegger, anything on what Ms. Sharpe argued or Mr. Ruehlmann argued? But please keep in mind that movant will have the last word, so to speak.

MR. BRUEGGER: Understood, your Honor.

Your Honor, I just want to reiterate that we have to look at what the Illinois test is here, what the burden of proof is here to establish jurisdiction.

Illinois law is clear that in the Kothawala case in the First District and other cases, that the plaintiffs don't have to prove all the elements of their case at

this stage, we just have to make a prima facie showing that jurisdiction lies.

So to say that we have to—we can't say that this particular lot of Zantac that was manufactured was sent to this place and sent to this place and sent to this place and sent to the retail, and then that particular box was purchased by this particular plaintiff, those are all—this case hasn't started yet; these are all facts that have to occur in discovery in this case, and I don't even think in that case it would be relevant to jurisdiction.

What we have done here, your Honor, is we have met the Illinois burden to show that there is a prima facie case for jurisdiction, and they have not shown that those connections that are clear connections, now they are trying to construe differently after the fact based on their own documents, doesn't give rise to jurisdiction.

So what they say here, your Honor, is the Bristol-Myers case—you know, Ms. Sharpe said no amount of sales, even substantial sales in jurisdiction, can give rise to jurisdiction in cases that are unconnected.

Well, your Honor, we don't have that here. What we have here is all of these sales into Illinois, and all of this activity with regard to thesis repackagers with regard to these repackagers, with regard to the aggressive sales and marketing to Walgreens itself. All of that occurred in Illinois, and all of that touches each one of those cases, so that's not even a concern here.

And, your Honor, you know, Ms. Sharpe is trying to argue that, you know, there are multiple distribution centers and there's no evidence of what distribution center sent to what store, and, your Honor, there's no evidence, they have not produced any evidence at all

to that. What they are doing is trying to change the meaning of the documents that they have produced in this litigation to sworn discovery responses, to now say that, well, those documents don't mean what they—what they say they mean, or we want to explain that they mean something else now. That's not the level of evidence here to refute their prima facie case.

Your Honor, with regard to the Rios case, you know, it was clear that Illinois courts—this is not just based on Illinois law, it's based on the Supreme Court's holding in the Keeton case, that non-resident plaintiffs can bring claims against non-resident defendants in a state even if most of the activities occurred outside of the state.

Now, you know, the quote that Ms. Sharpe gave from the Rios case, that it is not good law because Rios—or because M.M. was decided before Bristol-Myers Squibb. Well, that ignores the elephant in the room, your Honor, that Rios itself was decided before the Ford case. So what would the Supreme Court then say about Rios?

We don't have to get to that, your Honor; we are not asking the Court to—to be the only—I guess the argument was nobody in the history of the common law system has ever held on these facts that there was jurisdiction, which I think is a little bit bombastic and overstated. Clearly, Illinois courts have held this. Clearly, the U. S. Supreme Court in the Keeton case has held this. This is not a stretch. This is not the Court—we're not asking the Court to stick its neck out.

All we are asking the Court to do is just follow clear Illinois precedent. We've met the prima facie burden of proof, we have shown that the exercise of

jurisdiction is reasonable here. We have shown under existing U. S. Supreme Court precedent under the Ford case, under the subsequent cases in Illinois, that jurisdiction is proper here, and so these cases should move forward.

THE COURT: Thank you, Counsel.

And I should have asked this earlier in the hearing just for the record. Are there any other defendants left in these cases at this juncture?

MR. BRUEGGER: No, your Honor. With the Court's dismissal of the Walgreens defendant, we have just these—well, and, you know, the settlement in progress for the GlaxoSmithKline defendant, we have just have the BI entities, Pfizer, and the Sanofi entities.

THE COURT: Counsel, Ms. Sharpe, summarized the pending claims as failure to warn, negligent storage, and negligent transportation. Are those the claims that remain at this time?

MR. BRUEGGER: Your Honor, so the claim—technically the claims that remain at this time are the claims that have not been dismissed by your Honor in the master complaint. I believe that's correct, but as your Honor knows, as these cases move forward, the failure to warn claims are the prominent claims in this case that survive summary judgment and get to the jury.

As your Honor knows, in previous cases, including our own cases, the negligent transportation and storage claims have been dropped.

So yes, your Honor, technically that's true but these are primarily failure to warn cases.

THE COURT: And isn't it also true that, under the law, for the most part, the failure to warn really applies to the NDA holder? Am I oversimplifying it?

MR. BRUEGGER: I believe that's true, your Honor. I mean, in this case, the—these three NDA holders controlled the warnings and then required that the warnings be marketed to Walgreens or required that these defective warnings be put on the packaging by these repackagers.

THE COURT: The reason I ask that question is then what facts would there be, and not that plaintiff has to take this all the way to what they would put on for trial or even perhaps for a summary judgment motion, but what facts in the failure to warn context could plaintiff put forward that's applicable to this point, which is the *prima facie*, the burden to show *prima facie*, meet its *prima facie* burden with respect to specific jurisdiction as to what, if anything, Walgreens or any other distributors would ever have to do with what's contained in the label?

MR. BRUEGGER: Sure, your Honor, and I think that's a bit of a red herring. I don't think that's what we need to show here, what we have to show here.

We are not saying that Walgreens did something wrong, and therefore, these NDA holders are on the hook. You know, that was part of the original allegations. The Walgreens defendants have been dismissed.

What we are saying here is that these NDA holders reached into Illinois and used Walgreens, an Illinois company and used Illinois laws and Illinois facilities and Illinois warehouses and all of these contacts with Illinois as a conduit to sell their Zantac to these

plaintiffs around the country. That's the connection with Illinois.

So this doesn't turn on, well, Walgreens couldn't control the warning. No, we've seen from the documents, we've seen from the sales agreements, and we've seen from the repackaging agreements, that these Illinois companies were told by these NDA holders what to include. You include these warnings, and then those get sold around the country.

So it's these NDA holders, not Walgreens, who are using Illinois, using Illinois companies, using Illinois resources, to sell their product around the country, and it's defective.

THE COURT: Thank you, Counsel.

MR. BRUEGGER: Thank you, your Honor.

THE COURT: Movant, anything in final reply?

MS. SHARPE: Your Honor, I would just say these are out-of-state plaintiffs bringing claims against out-of-state defendants for product they brought out of state and injuries they suffered out of state. There's clear and binding case law from Bristol-Myers Squibb and Rios that governs this exact fact pattern and holds that there is no jurisdiction here. That's the end of the story.

THE COURT: Does anyone else wish to say anything at this time?

Okay, hearing none, the Court now having conducted a full hearing on the brand defendants' joint motion under 735 ILCS 5/2-301 to dismiss all non-Illinois plaintiffs' claims, and what that really is and clarified by a couple of the questions I asked, it's a motion to dismiss all the non-Illinois plaintiffs' cases that have been consolidated into this Banna matter pursuant to the orders of the Illinois Supreme Court and

any other orders entered through the Circuit Court of Cook County.

The Court had the opportunity to review all the briefing and the materials that were submitted in advance. The Court also additionally reviewed and re-reviewed several of the cases cited by the parties here and also specifically argued this morning, including but not limited to the Ford versus Montana Eighth Judicial District Court, Supreme Court of the United States decision 592 U. S. 351, Bristol-Myers Squibb versus Superior Court, Supreme Court of the United States decision 582 U. S. 255, the Rios versus Bayer Corp. decision, Supreme Court of Illinois, 2020 IL 125020, the Court now being fully advised.

The parties have articulated what the—what the personal jurisdiction requirements are and what are considered both in the framework of the United States Supreme Court and, importantly, the Illinois Supreme Court's decisions in this matter, and there are two categories of personal jurisdiction: General, or all-purpose jurisdiction, and specific or case-linked jurisdiction.

There was an argument contained in plaintiffs' response brief that general jurisdiction should be conferred in this matter and referred to the Mallory versus Norfolk Southern Railway, United States Supreme Court decision 600 U. S. 122, and while defendants referred to the Aspen Illinois Supreme Court decision, 2017 IL 121281 in support of their position.

This Court's review of the applicable and binding case law here is that no Illinois court has determined that the Pennsylvania statute at issue in the Mallory decision is equivalent to the Illinois Registration Statute. As a result, this Court finds that the Aspen

decision is binding, and—which recognizes the fact that a foreign corporation is registered to do business in the state does not mean that there is jurisdiction—general jurisdiction.

So to the extent that—so general jurisdiction, this Court is not going to decide this on general jurisdiction or lack thereof. The Court finds that the question here is a question of specific jurisdiction.

Here, the relevant plaintiffs, who are not Illinois residents and do not claim to have suffered harm in Illinois, and that's important, because the Ford United States Supreme Court decision, which plaintiffs cited as—as an exception of sorts, or perhaps a reason for this Court to not rely entirely on the Rios case or the Bristol-Myers Squibb case. There, the injuries happened in the forum states, which is something that actually is highlighted in Bristol-Myers Squibb multiple times in that decision, where the relevant plaintiffs in Bristol-Myers Squibb were not California residents and do not claim to have suffered harm in the state. That's something that came up a number of times in Bristol-Myers Squibb.

This Court finds as binding the Supreme Court of Illinois case Rios versus Bayer Corp. and the Bristol-Myers Squibb case.

The Rios versus Bayer Corp. case exhaustively went through and relied on Bristol-Myers Squibb, and I will note that there are more parallels with the Bristol-Myers Squibb case to this current litigation that this Court is dealing with factually, and the facts sort of speak for themselves on what's required for this Court to review in the context of this motion.

In Rios, the Illinois Supreme Court recognized that specific jurisdiction is very different. A state may

assert specific personal jurisdiction over an out-of-state defendant only if the defendant has purposefully directed its activities as resident of the forum, and if the litigation results in alleged injuries that arise out of or relate to those activities.

The Court relied on *Bristol-Myers* where the non-resident plaintiffs in *Bristol-Myers* did not allege that they obtained a drug from California physicians. Those plaintiffs did not claim that they were injured by the drug in California or treated for their injuries in California, and the Supreme Court rejected—strike that.

The United States Supreme Court reiterated that a non-resident defendant's general connection with a forum do not provide a basis for state courts to assert specific personal jurisdiction. The Court chided the State Supreme Court for permitting the exercise of specific personal jurisdiction without identifying an adequate link between the state and the non-residents' claims. That's out of the *Rios* case.

As was true in *Bristol-Myers* and in *Rios*, in this case, the *Banna* litigation relating to the non-Illinois defendants—or non-Illinois plaintiffs, rather, defendants do not dispute that they purposefully directed activities towards Illinois. That was a big part of plaintiffs' argument.

There are a number of things that show activities conducted by the brand defendants here in Illinois; however, here, as in *Rios*, the question is whether the non-resident plaintiffs' claims arise out of or relate to those activities in any meaningful sense of the terms.

Following *Rios*, this Court finds that they do not. The Court has considered plaintiffs' arguments that the brand defendants conducted activities relating to

the distribution, clinical trials, aggressive marketing efforts, repackaging, et cetera. Those are all part of the record, and part of the briefs, and Mr. Bruegger provided a very detailed account of those types of facts for this Court to consider.

But this Court finds, similar to and following Bristol-Myers Squibb, that defendants' relationship with a third party or other parties is an insufficient basis for jurisdiction, specifically in light of the claims that remain pending, and this Court asked the parties, you know, what are the claims that remain pending.

In summary—strike that. Not in summary, but further, in this case, Banna, related to the non-Illinois plaintiffs' cases, the plaintiffs have identified no jurisdictionally relevant links between their claims and Illinois from a specific jurisdiction standpoint.

For these reasons, this Court finds that the non-Illinois plaintiffs have failed to meet their burden of establishing a prima facie basis to exercise specific personal jurisdiction over defendants as to the non-resident plaintiffs' claims here in Illinois. As a result, the brand defendants' 735 ILCS 5/203-1 motion to dismiss the non-Illinois plaintiffs' claims and cases is granted.

And obviously, this is over objection of the non-Illinois plaintiffs.

Counsels, you will have to confer to—if this disposes of those non-Illinois cases, meaning you are—there were no other defendants, this is a dismissal with prejudice, then that means that those cases will need the requisite order, and as to those cases, I will need a specific order as to each one, because it is a final and appealable order.

MR. BRUEGGER: Thank you, your Honor. I appreciate the clarification.

We will work with defense counsel to identify the specific cases at issue. Is this an order that your Honor would like to have entered prior to our deadline under 306(a) to file a petition for appeal?

THE COURT: Well, I want you to have a good handle—I do not—this Court, under no circumstances, do I wish to abridge any rights under the rules or shorten any timeframes at all, okay?

So usually plaintiffs are the ones that want the final and appealable, but I don't even really need to say that, because this is unique, because each of these are individual cases, so once you have a motion to dismiss that's granted with prejudice as to a case, that in and of itself is a final and appealable order.

So that's why we have to be careful that these are their own cases. Yes, they are consolidated for pre-trial and discovery under the Banna umbrella. Each of these are specific court cases, so each of these are afforded the same rights under the rules.

So I don't know if that addresses your question fully.

MR. BRUEGGER: Your Honor, just purely for logistical clarification, I understand the Court is making this ruling today but that we'll have to submit, assuming not today, a list of cases that we agree that this applies to, and so for purposes of 306(a) and the 30-day deadline to file an interlocutory appeal, your Honor, would the 30 days start running from the time the written order was entered with the correct number of cases, or from today's date where your Honor is making this ruling?

THE COURT: I understand your question.

In this situation, it would go from—and let me know if someone has—if anyone has an objection. It should be off of the date that the order is entered. That's how I would interpret that.

MR. BRUEGGER: For purpose of your Honor's ruling today, this ruling takes effect the date that the written order is entered with those cases.

THE COURT: Yes, because I'm looking at Rule 306. It says from an order of the Circuit Court, et cetera. Yes, this is an order, we're on the record, but an order is the written order that goes in the docket. That's the date that would govern.

By the same token, not that anyone here would do that, because I know you counsels and I know the high level of professionalism that I see every time I convene a hearing with you, that no one's going wait a month to send me the order. So time is of the essence. The way I envision it is, there should be an order under the Banna court number identifying the cases, and I think that's the first order of business, and I'll need one for each of the cases. And if you need to, you know, deliver, you know, a package, that might be the most—even in 2025, that might be the most efficient thing, is to just drop off those orders so I can physically sign them and have them entered, might be easier.

But does anyone have any questions on that? Any logistical questions? Or objections as to what I just said about Rule 306?

MS. SHARPE: No, your Honor and we'll work with plaintiffs, again, to agree on that list and get the order submitted. Thank you.

THE COURT: All right. Ms. Zousmer had sent an agenda.

What else is on the agenda? I don't know if Ms. Zousmer is still here or if someone else wants to take the lead.

MR. SNIDOW: I spoke with Ms. Zousmer. This is J.J. Snidow on behalf of the Keller Postman plaintiffs.

I think the other remaining items are going to be a lot more straightforward.

First, we submitted to the Court yesterday an agreed-to scheduling order that lays out final deadlines for the Fiduccia trial, which is coming up in March. I'm happy to answer any questions the Court has on it, but there is one thing to flag that we probably need the Court's input on, which is scheduling of the hearing for motions for summary judgment and Frye.

THE COURT: Sure. Oh, go ahead, Counsel.

MR. SNIDOW: I was going to say, we put in a placeholder date of March 5th, but realize that the Court's schedule takes precedence, and any time during that week I think we can work out.

THE COURT: I'm grabbing my court calendar, which failed me this morning, and I only have myself to blame.

MR. SNIDOW: And just so the Court knows, those motions will be fully briefed on February the 25th, so I think we chose the next week, but that's when it's fully briefed.

THE COURT: March 5th works. What's your trial date on that again?

MR. SNIDOW: The 13th is when we go to 2005.

THE COURT: So March 5th for Fiduccia, 9:00 a.m., Zoom is fine unless you want to come in person, but...

MR. SNIDOW: I think we have been doing those—

THE COURT: You have been, yeah. You want to keep it the same way?

MR. SNIDOW: Might be easier, yes.

THE COURT: So it will be in person, Fiduccia CMC and Frye motions. Sorry, MSJ and Frye. Are there Frye motions in that one as well?

MR. SNIDOW: Yes, your Honor.

MR. CHRISTIAN: Your Honor, may I address the Court on that?

THE COURT: Yes.

MR. CHRISTIAN: This is my first time before you, your Honor. Randall Christian on behalf of Patheon Manufacturing Services. We are a defendant in the Fiduccia matter, and this would be our first case to proceed at—for this juncture, and we do have a pending motion for summary judgment, and one of the things that we were hoping to get maybe an earlier decision from your Honor, because it's very consistent with what you've already ruled before. I think you hesitated on our motion to dismiss because it was alleged that we were an NDA holder, and now that the record is closed, we are—it is clear we are not an NDA holder so we could not have changed the warning.

So for us to be spending the next few weeks getting ready for our first trial when, consistent with your rulings, we anticipate that you'll grant our motion for summary judgment with the record closed on that issue, we're hoping if there's anyway we could speed up with respect to our motion because I think it's uncontested.

THE COURT: If it's uncontested, that's—

MR. SNIDOW: Well, it's not uncontested, Judge. We have until February the 11th to respond to the

summary judgment motion, and as I alluded to, briefing won't close until the 25th.

THE COURT: I'm looking—sorry. I'm looking at that on the proposed order. I see that briefing.

Mr. Snidow, you anticipated my next question, and I see that the briefing is going until the reply to summary judgment are due.

So, Mr. Christian, so I see replies due February 25th. This looks like, for the most part, it's a joint order.

So I can move it up a little bit.

MR. SNIDOW: We're happy to do it a little earlier, I just would flag I have not discussed with the other defendants their availability. I know they are available for March 5th, which is why we used that as the placeholder, but...

THE COURT: You know what, Counsel, Mr. Christian, I understand where you're coming from. I'm looking at the calendar. February 25th to March 5th is actually only a little over a week. So we're going to keep March 5th.

MR. CHRISTIAN: Thank you, your Honor.

THE COURT: So, Counsels, I see that's in there, March 5th. Can you send me a separate order setting the MSJ specific? I'll have this order entered today, the Fiduccia order you sent yesterday. I think it was yesterday. Yes, it was.

But just send a specific MSJ scheduling order, 9:00 a.m., March 5th, room 2606, the Daley Center here in Chicago.

MR. SNIDOW: Thanks, your Honor.

THE COURT: There was another item on the agenda. Did it relate to a 304(a) hearing?

MR. SNIDOW: Yes, your Honor. That is our motion under 304(a) to have the Court certify—"certify" is probably the wrong word. Enter judgment that would allow us to appeal the Court's ruling on the generic motions to dismiss.

THE COURT: And is this opposed?

MR. GUGERTY: Yes, your Honor. This is Sean Gugerty, counsel for Perrigo, one of the generic defendants.

Speaking on behalf of the generic defendants, collectively, yes, it is opposed. An opposition was filed yesterday.

MR. SNIDOW: We're just looking for a hearing date.

THE COURT: Understood. Thank you.

The Court's practice has been just motion and response.

Let's schedule that for a week from today at 9:30, please.

MR. GUGERTY: Your Honor, just to clarify, I presume that's by Zoom?

THE COURT: It will be by Zoom. I had a trial off of our pick five scheduling system slated to start the 27th. I did receive an e-mail saying they have resolved the case. I don't have the dismissal order yet, so I'm operating that their case has settled. If we need to change the date, I will let you know. But that's why I'm giving you such a quick date, because it just literally opened up this morning.

MR. SNIDOW: Judge, my apologies, I have a conflict that day, one that I potentially could move, but if the Court has availability on either Thursday or Friday next week, the 30th or the 31st, I thought I would at least ask.

THE COURT: What did I say?

MR. SNIDOW: I think you said the 29th.

THE COURT: The 30th, yeah, I was looking—the 9:30 is fine. The 30th at 9:30 is fine.

MR. SNIDOW: Thank you.

THE COURT: Is there anything else that was on the agenda?

MR. SNIDOW: I don't think so, your Honor.

THE COURT: Then let's also set the next full CMC.

MR. GUGERTY: Your Honor, there is not another item on the agenda; however, the—we did submit a motion yesterday on behalf of the generic defendants.

At the last—on December 13th, your Honor granted an order to supplement the record in the Valadez case, and that order has been entered, but while we have been moving forward on supplementation, the record was very extensive, and so we have submitted an order to modify your Honor's prior order to submit a more narrow supplementation, and that order, I raise it only—it is not on the agenda, but we did confer with plaintiffs' counsel and that motion is unopposed.

MR. SNIDOW: That's correct.

THE COURT: Okay, so is this an e-mail that was sent by Mr. Browning, a James Browning?

MR. GUGERTY: Yes, your Honor. Mr. Browning is counsel for Teva, one of the generic defendants.

THE COURT: So it's unopposed. That will be granted.

Can you please send me the proposed order as a standalone PDF? Because I see it's all attached together with the motion.

MR. GUGERTY: Yes, your Honor, we can do that.

THE COURT: Administratively it helps us process it if it's its own PDF. That motion is granted. The order will be entered.

The next CMC will be set for February 27th at 9:00 a.m. by Zoom. Thursday February 27, 9:00 a.m. zoom.

I should ask, I heard a reference a couple times to a settlement having been reached. Are there—are you working on orders that I will eventually have to deal with?

MR. SNIDOW: Yes, with respect to individual cases as they come up, if they are—if they're eligible for the settlement and the client accepts and signs release, then we've moved to dismiss them with the Court.

That process will speed up, we hope, and we'll have more, and of course try to batch them together for the Court when possible.

But right now, you know, to put it plainly, as these get close to trial and end up settling and of course if the client signs a release, then we do dismiss them.

THE COURT: Okay, understood.

It sounds like you are staying on top of that. I just wanted to let you know that as soon as those orders are ready, don't—do not hesitate, submit them, but add it as an agenda item for February 27th, just to keep them on track, okay?

MS. ZOUSMER: Your Honor, this, is Julia Zousmer. I'm sorry I can't be on camera.

We have a hearing set before Judge Flanagan on February 27th that the order sets for 10:00 a.m., so I think that might pose a conflict with the 9:00 a.m. start time that your Honor just proposed for the CMC.

THE COURT: Understood. Thank you for letting me know.

The next CMC, I cannot do it the next week. Well, we could do it the next day, Friday the 31st, same time. I'm sorry, looking at the wrong month.

The next day would be February 28th.

MS. ZOUSMER: That works for us, your Honor.

THE COURT: Oh, no, you know what? Sorry, Counsels, I have a pretrial at 8:30 that day.

I like to keep—we usually do these on Thursdays. The next CMC will be March 13th then.

MR. SNIDOW: Sorry, Judge, that is the day we go to 2005 for the Fiduccia trial.

THE COURT: All right. So let's—we're going to go off the record for a moment. We're off the record to address scheduling.

(A brief discussion was had off the record.)

THE COURT: The next Banna CMC will be on March 4th, 9:00 a.m. by zoom.

MS. ZOUSMER: Thank you, your Honor.

THE COURT: Thank you, Counsel. Thank you again for your patience this morning.

Is there anything else that needs to be addressed with the court?

MR. BROWN-HARKINS: Just quickly, I know you received several e-mails last night. I sent one regarding the Steven Casten matter. It's a signed HIPAA order that's needed to secure a healthcare treater deposition. It's the—the form version, so it shouldn't cause any dispute, but we just need to get that submitted so we can secure this to stay on our deadline for fact discovery.

THE COURT: What case? Oh, Casten I see it here. That will be—the Court will sign that order. That will be entered.

MR. BROWN-HARKINS: Thank you, your Honor.

THE COURT: Counsel, I'm just trying to get a good sense in case I have to make any corrections here administratively.

My practice is, as soon as you get an e-mail from me saying that I have granted a motion entering an order, for example, I walk those orders down and ask that they be entered immediately.

Are you seeing a delay from the—like I'm talking about more than a day. Are you seeing a delay that's between the time I say it's being entered and when you see it on system?

MR. BRUEGGER: I don't think so.

THE COURT: Like a week or something exorbitant?

MR. SNIDOW: I don't think so.

THE COURT: Okay, I just wanted to make sure.

Do not hesitate, just based on the volume of e-mails that I get, do not hesitate to send any follow up e-mail or reminder. I don't consider it anything other than people needing to get their business concluded. I don't take any offense to it. Do not hesitate to send something like that, an inquiry about an order, that sort of thing. Hopefully you don't have to, but I just want to let you know that's appropriate. Okay?

Anything else that needs to be addressed with the Court at this time?

Okay. Hearing none then, if anyone wants to let our court reporter know that you are here, I know our court reporter normally has a very efficient system on getting making sure everyone is on the record, but please take that opportunity, I'll leave the zoom up for a couple minutes to let everyone put their appearances if you have not done so already, otherwise court is adjourned.

(Court was adjourned at 12:42 p.m.)

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Appendix D



SUPREME COURT OF ILLINOIS
SUPREME COURT BUILDING
200 EAST CAPITOL AVENUE
SPRINGFIELD, ILLINOIS 62701-1721
(217) 782-2035

FIRST DISTRICT OFFICE
160 North LaSalle Street, 20th Floor
Chicago, IL 60601-3103
(312) 793-1332
TDD: (312) 793-6185

May 27, 2026

In re: Marilyn Coudrain, etc., et al., petitioners,
v. Walgreen Co. et al. (Boehringer Ingel-
heim Pharmaceuticals, Inc., et al., re-
spondents). Leave to appeal, Appellate
Court, First District. 132993

The Supreme Court today DENIED the Petition for
Leave to Appeal in the above entitled cause.

The mandate of this Court will issue to the Appel-
late Court on 07/01/2026.

Very truly yours,

/s/ Cynthia A. Grant
Clerk of the Supreme Court

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Appendix E

[Filed: Apr. 12, 2023]

**IN THE CIRCUIT COURT OF COOK COUNTY
STATE OF ILLINOIS**

ELLEN J. SMITH,
Plaintiff,

Case No.:
2023L003569

v.

**JURY TRIAL
DEMANDED
ON ALL
COUNTS**

WALGREEN CO.;
WALGREENS BOOTS
ALLIANCE, INC.;
GLAXOSMITHKLINE, LLC;
GLAXOSMITHKLINE
HOLDINGS (AMERICAS), INC.;
and
JOHN DOES 1-100 INCLUSIVE,
Defendants.

**PERSONAL
INJURY**

COMPLAINT

COMES NOW, Plaintiff, Ellen J. Smith, through the undersigned counsel, and brings this action for personal injuries against Defendants, and alleges as follows:

INTRODUCTION

1. Zantac is the branded name for ranitidine, a “blockbuster” drug that was sold as a safe and effective antacid. But ranitidine transforms over time and under particular conditions into high levels of N-Nitrosodimethylamine (“NDMA”), a carcinogen that is

as potent as it is dangerous. After almost four decades and billions of dollars of sales, ranitidine consumption has caused scores of consumers to develop cancer. Plaintiff brings this action for personal injuries resulting from Defendants' design, testing, marketing, labeling, packaging, handling, distribution, storage and/or sale of brand-name Zantac products.

2. Until its 2020 recall by the Food and Drug Administration ("FDA"), ranitidine was a popular heartburn drug consumed by millions of people every day. Recent scientific studies, however, confirm what drug companies knew or should have known decades earlier: ingesting ranitidine exposes the consumer to unsafe and excessive amounts of NDMA.

3. NDMA is a well-known potent carcinogen. It was first discovered in the early 1900s as a byproduct of manufacturing rocket fuel. Today, its only use is to induce cancerous tumors in animals as part of laboratory experiments. Its only function is to cause cancer. It has no medicinal purpose whatsoever.

4. NDMA is not akin to other compounds that have a salutary effect at low levels and a negative effect with greater exposure. There is no recommended daily dose of NDMA. The ideal level of exposure is zero. Nonetheless, the FDA previously set an allowable daily limit of NDMA of 96 nanograms (ng) to minimize the risks posed by this dangerous molecule. Yet a single pill of ranitidine can contain quantities of NDMA that are hundreds, if not thousands, of times higher than the allowable limit.

5. Those recent revelations by the scientific community have caused widespread recalls of

ranitidine both domestically and internationally. In fact, after numerous voluntary recalls, 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.

6. The high levels of NDMA observed in ranitidine-containing products are a function of various factors. The ranitidine molecule internally degrades to form NDMA. The degradation of ranitidine into NDMA can increase over time under normal storage conditions, but more so with exposure to heat and/or humidity. Once in the body, ranitidine continues to degrade and can yield increasing levels of NDMA in the human digestive system.

7. Zantac wreaked such widespread harm in large part because Defendant GlaxoSmithKline—the inventor of ranitidine through its predecessors—succumbed to a temptation that is all too familiar to pharmaceutical innovators: maximizing the profits of an incredibly lucrative, government-conferred monopoly.

8. To encourage pharmaceutical companies to invest in research and development (“R&D”), the U.S. legal and regulatory system offers drug companies who invent “new chemical entities” two powerful inducements. First, innovators obtain patent protection for their pharmaceutical compounds. Second, approved new drugs enjoy FDA exclusivity, irrespective of whether the molecule is protected by one or more issued patents. Taken together, these policies assure that a pharmaceutical innovator will receive the exclusive right, for a limited period of time, to sell its drug to the American public.

9. As a result, branded drug manufacturers have a strong—and too often perverse—incentive to sell as much product as they can during their exclusivity window. That is why brand-name manufacturers spend billions of dollars per year in sales and marketing efforts to push incremental sales of a brand-name drug. Where every \$1 in new sales can produce upwards of \$.90 in gross profit, staggering sales and marketing budgets are a very profitable investment. But while it makes sense for brand-name manufacturers to spend vast sums of money to develop and promote FDA-approved drugs, they have no economic or regulatory incentive to uncover and investigate developing risks posed by their products.

10. That problem is especially acute for bestselling, blockbuster drugs. Zantac is the brand that gave meaning to the term blockbuster pharmaceutical product, becoming the first drug ever to generate over \$1 billion in annual sales. Zantac's success catapulted Glaxo ahead of its previously larger rivals, fueling the market capitalization and corporate combinations that gave the company its current name: GlaxoSmithKline. It is little wonder Glaxo spared no expense to both get Zantac to market and to aggressively promote it to millions of consumers. Yet Glaxo did not part with a comparative pittance to investigate the obvious cancer risk posed by ranitidine. Turning a blind eye was far more profitable.

11. Ultimately, the law holds corporate entities responsible for the personal injuries caused by unsafe products, and in pharmaceutical liability actions, the entities that are responsible for developing,

marketing, selling, packaging, distributing, and labeling the drugs. The civil justice system is the first, last, and only line of defense against the unchecked avarice that is a byproduct of a regulatory regime with the well-intentioned aim of bringing safe and effective medicines to market. Plaintiff seeks redress both for compensation for the horrific losses Plaintiff has suffered in the past and to strongly deter future misconduct.

THE PLAINTIFF'S CLAIM

12. From approximately 1987 through 2020, Plaintiff Ellen J. Smith purchased and ingested prescription name brand Zantac (hereinafter referred to as “Zantac”) which was manufactured by GlaxoSmithKline to treat Plaintiff's symptoms of heartburn, acid indigestion, and other gastrointestinal conditions.

13. From approximately 1987 through 2020, Plaintiff purchased this Zantac from Walgreens.

14. The Zantac that Plaintiff purchased and ingested contained dangerous levels of the chemical ranitidine and N-Nitrosodimethylamine (“NDMA”) and after ingestion some of the ranitidine created more NDMA in Plaintiff's body. The Zantac that Plaintiff purchased and ingested caused Plaintiff to develop colorectal cancer, which was diagnosed on or about 8/1/2015.

15. Plaintiff purchased Zantac at Walgreens in such quantities and with such frequency that the amount of Zantac that Plaintiff purchased at Walgreens was a substantial contributing cause of Plaintiff's cancer and the injuries alleged herein.

16. Plaintiff purchased and ingested Zantac that was manufactured by GlaxoSmithKline in such quantities and with such frequency that the amount of Zantac was a substantial contributing cause of Plaintiff's cancer and the injuries alleged herein.

17. The Zantac that Plaintiff purchased and ingested that was manufactured by GlaxoSmithKline and sold to Plaintiff by Walgreens was a direct and legal proximate cause of Plaintiff's cancer and the injuries alleged herein.

PARTIES

PLAINTIFF

18. Plaintiff is an individual and resident of Texas.

19. Plaintiff began using Zantac in 1987 and continued to use it through 2020. Plaintiff obtained these prescriptions for Zantac at Walgreens pharmacies owned and operated by Defendants Walgreens Co. and Walgreens Boots Alliance, Inc.

20. During this time, Plaintiff was not aware that ingesting ranitidine-containing Zantac led to exposure to NDMA, or that ranitidine caused cancer.

21. Plaintiff was diagnosed with colorectal cancer on or about 8/1/2015 related to Plaintiff's ingestion of ranitidine-containing products. As a result of Plaintiff's cancer and subsequent treatment, Plaintiff has suffered significant bodily injury, pain and suffering, mental anguish, disfigurement, embarrassment, inconvenience, loss of earnings and earning capacity, and have and will incur past and future medical expenses.

22. Based on prevailing scientific evidence, exposure to NDMA caused by consuming ranitidine can cause Plaintiff's type of cancer in humans.

23. Plaintiff's cancer was caused by ingesting Zantac Plaintiff obtained from Defendants Walgreens Co. and Walgreens Boots Alliance, Inc.'s pharmacies and stores.

DEFENDANTS

24. Defendants are entities that designed, manufactured, marketed, distributed, labeled, packaged, handled, stored, and/or sold ranitidine-containing Zantac.

Walgreens

25. Walgreen Co. and Walgreens Boots Alliance, Inc. derived substantial revenue from marketing, handling, distributing, storing, and selling Zantac products within each of the States and Territories of the United States, including in Cook County, Illinois.

26. Defendant Walgreen Co. is an Illinois corporation with its principal place of business located at 108 Wilmot Road, Deerfield, Illinois 60015. Walgreen Co. is a citizen of Illinois.

27. Defendant Walgreens Boots Alliance, Inc. is a Delaware corporation with its principal place of business located at 108 Wilmot Road, Deerfield, Illinois 60015. Walgreens Boots Alliance, Inc. is a citizen of Delaware and Illinois.

28. Walgreen Co. is a subsidiary of Walgreens Boots Alliance, Inc. Collectively, Walgreen Co. and Walgreens Boots Alliance, Inc. shall be referred to as

“Walgreens” or “Walgreens Defendants.”

29. Walgreens operates and derives substantial revenue from operating in excess of 100 retail pharmacies in Cook County, Illinois.

GlaxoSmithKline

30. Defendant GlaxoSmithKline LLC (also referred to herein as “GSK”) is a Delaware limited liability company with its principal place of business located at Five Crescent Drive, Philadelphia, Pennsylvania, 19112. Defendant GlaxoSmithKline LLC’s sole member is GlaxoSmithKline Holdings (Americas) Inc., a Delaware corporation with its principal place of business in that state. GlaxoSmithKline LLC is a citizen of Delaware.

31. Defendant GlaxoSmithKline LLC is a subsidiary of GlaxoSmithKline plc.

JURISDICTION & VENUE

32. This Court has subject matter jurisdiction pursuant to 735 ILCS 5/2-209(b)(3-4), (c).

33. This Court has personal jurisdiction over Defendants insofar as Defendants are authorized and licensed to conduct business in Illinois, maintain and carry on systematic and continuous contacts in Illinois, and regularly transact business within Illinois.

34. Additionally, Defendants caused injury by acts and omissions in Illinois and caused injury in Illinois by acts and omissions outside Illinois while regularly doing and soliciting business, engaging in a persistent course of conduct, and receiving financial

benefit and profits from goods used or consumed in Illinois.

35. At all relevant times, Defendants were present and doing business in Illinois, and should have expected that their acts would have consequences within the state of Illinois.

36. Walgreens is “at home” in Illinois because its principal place of business is located in Deerfield, Illinois.

37. Defendant GSK marketed and sold their various ranitidine-containing products throughout the United States, including in Illinois. Plaintiff ingested the various ranitidine-containing Zantac products manufactured, distributed, marketed, and sold by the Defendants, including in Illinois.

38. Venue is proper in Cook County because Walgreens operates and derives substantial revenue from operating in excess of 100 retail pharmacies in Cook County, and therefore is “doing business” in Cook County. 735 ILCS § 2-102(a); *Quigg v. Walgreen Co.*, 388 Ill.App.3d 696 (Ill. App. 2nd Dist. 2009). Further, venue is proper in Cook County because all Defendants conduct business within this County. 735 ILCS 5/2-101.

THE DEFECTIVE ZANTAC PRODUCT

39. At all relevant times during which Plaintiff purchased and ingested Zantac, the Zantac that Plaintiff purchased and ingested was manufactured and/or distributed and/or sold by GSK.

40. GSK owed a duty to Plaintiff and the public in general to assure that Zantac remained safe and free from any defects and/or unreasonable risks of

danger to the consumers such as Plaintiff who would purchase and ingest Zantac. GSK breached their duties to Plaintiff and the public in general.

41. At all times relevant hereto each of the Defendants knew or should have known—as further explained in detail—that Zantac contained the active ingredient ranitidine. A derivative compound of ranitidine is N-Nitrosodimethylamine (“NDMA”), a well-known and dangerous carcinogen. As further explained herein, certain amounts of NDMA are inherent in the manufacture of Zantac, and then, once ranitidine is ingested, additional NDMA is created in greater amounts and in greater dangerous quantities in the stomach and intestines and in other parts of the human body. Hence, Zantac itself is a cancer-causing substance when used as intended by consumers such as Plaintiff.

42. At all relevant times hereto, the cancer-causing properties of Zantac were known to GSK and Walgreens.

43. At all relevant times hereto, the cancer-causing properties of Zantac were unknown by ordinary consumers such as Plaintiff and were far beyond the reasonable expectations of the ordinary consumer such as Plaintiff. Zantac was at all relevant times hereto a defective product.

FACTUAL ALLEGATIONS

I. THE CREATION OF RANITIDINE-CONTAINING PRODUCTS AND THEIR INTRODUCTION TO THE MARKET

44. GSK designed, manufactured, tested,

marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine under the brand name Zantac by prescription.

45. Ranitidine belongs to a class of medications called histamine H₂-receptor antagonists (or H₂ blockers), which decrease the amount of acid produced by cells in the lining of the stomach. Other drugs within this class include cimetidine (branded Tagamet), famotidine (Pepcid), and nizatidine (Axid).

46. GSK-predecessor Smith, Kline & French discovered and developed Tagamet, the first H₂ blocker and the prototypical histamine H₂ receptor antagonist from which the later members of the class were developed.

47. GSK¹ developed Zantac specifically in response to the success of cimetidine.

Recognizing the extraordinary potential of having its own H₂ blocker in the burgeoning anti-ulcer market, GSK was all too willing to ensure its drug succeeded at all costs.

48. Allen & Hanburys Ltd., a then-subsidiary of Glaxo Laboratories Ltd., is credited with developing ranitidine and was awarded Patent No. 4,128,658 by the U.S. Patent and Trademark Office in December 1978, which covered the ranitidine molecule.

49. In 1983, the FDA granted 505(b) approval to Glaxo to sell Zantac, pursuant to the New Drug

¹ GSK, as it's 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.

Application (“NDA”) No. 18-703, and it quickly became GSK’s most successful product—a “blockbuster.” Indeed, Zantac became the first prescription drug in history to reach \$1 billion in sales.

50. To accomplish this feat, GSK entered into a joint promotion agreement with Hoffmann-LaRoche, Inc. More salespersons drove more sales and blockbuster profits for GSK. GSK engaged in a multi-million-dollar promotional campaign throughout the United States, including in Cook County, Illinois.

51. In June of 1986, the FDA approved Zantac for maintenance therapy of duodenal ulcers and for treatment of patients with gastroesophageal reflux disease (GERD).

52. Between 1983 and 1994, GSK sought and obtained 505(b) approval for additional NDAs representing additional formulations of Zantac. These NDAs include 19-675, 20-095, and 20-251.

53. At all relevant times, GSK retained the right to exclusive use of the Zantac name for any prescription ranitidine-containing product in the United States.

54. GSK continued marketing prescription Zantac in the United States until 2017 and still holds the NDAs for several prescription formulations of Zantac. GSK continued to maintain manufacturing and supply agreements relating to various formulations of prescription Zantac. According to its recent annual report, GSK claims to have “discontinued making and selling prescription Zantac tablets in 2017 . . . in the U.S.”²

² GlaxoSmithKline, plc, *Annual Report* 37 (2019),

II. NDMA IS A CARCINOGEN WHOSE DANGEROUS PROPERTIES ARE WELL ESTABLISHED.

55. According to the Environmental Protection Agency (“EPA”), “NDMA is a semivolatile organic chemical that forms in both industrial and natural processes.”³ It is one of the simplest members of a class of N-nitrosamines, a family of potent carcinogens. Scientists have long recognized the dangers that NDMA poses to human health. A 1979 news article noted that “NDMA has caused cancer in nearly every laboratory animal tested so far.”⁴ NDMA is no longer produced or commercially used in the United States except for research. Its only use today is to cause cancer in laboratory animals.

<https://www.gsk.com/media/5894/annual-report.pdf>.

³ U.S. Environmental Protection Agency, *Technical Fact Sheet – N-Nitroso-dimethylamine (NDMA)* (Nov. 2017), https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

⁴ Jane Brody, *Bottoms Up: Alcohol in Moderation Can Extend Life*, *The Globe & Mail* (CANADA) (Oct. 11, 1979); see Rudy Platiel, *Anger Grows as Officials Unable to Trace Poison in Reserve’s Water*, *The Globe & 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 byproduct chemical that has been linked to cancer”); Kyrtopoulos et al, *DNA Adducts in Humans After Exposure to Methylating Agents*, 405 *Mut. Res.* 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”).

56. Both the EPA and the International Agency for Research on Cancer (“IARC”) classify NDMA as a probable human carcinogen.⁵

57. The American Conference of Governmental Industrial Hygienists classifies NDMA as a confirmed animal carcinogen.⁶

58. 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

59. The FDA considers NDMA a carcinogenic impurity and chemical that “could cause cancer” in humans.⁹ The FDA recognizes that NDMA is “known to be toxic.”¹⁰

60. The World Health Organization states that

⁵ See EPA Technical Fact Sheet, *supra* note 6; Int’l Agency for Research on Cancer (IARC), *Summaries & Evaluations, N-NITROSODIMETHYLAMINE* (1978), <http://www.inchem.org/documents/iarc/vol17/n-nitrosodimethylamine.html>.

⁶ See EPA Technical Fact Sheet, *supra* note 6.

⁷ *Id.* at 3.

⁸ *Id.*

⁹ FDA Statement, Janet Woodcock, Director – Ctr. for Drug Evaluation & Research, *Statement Alerting Patients and Health Care Professionals of NDMA Found in Samples of Ranitidine* (Sept. 13, 2019), <https://www.fda.gov/news-events/press-announcements/statement-alerting-patients-and-health-care-professionals-ndma-found-samples-ranitidine>.

¹⁰ Amneal_prod 1 _ 0000002938.

there is “conclusive evidence that NDMA is a potent carcinogen” and that there is “clear evidence of carcinogenicity.”¹¹ NDMA belongs to the so-called “cohort of concern” which is a group of highly potent mutagenic carcinogens that have been classified as probable human carcinogens.¹²

61. The EMA has referred to NDMA as “highly carcinogenic.” It recommended that “primary attention with respect to risk for patients should be on these highly carcinogenic N-nitrosamines” (including NDMA), and categorized NDMA as “of highest concern with respect to mutagenic and carcinogenic potential.”¹³

62. In 1989, the Agency for Toxic Substances and Disease Registry (ATSDR) stated that it is “reasonable to expect that exposure to NDMA by eating, drinking or breathing could cause cancer in humans” and that the “carcinogenicity of orally-administered NDMA has been demonstrated unequivocally in acute, intermediate and chronic durations studies” in animals and “it is important to

¹¹ World Health Org., *Guidelines for Drinking Water Quality, N-Nitrosodimethylamine (NDMA)* (3d ed. 2008), https://www.who.int/water_sanitation_health/dwq/chemicals/ndmasummary_2ndadd.pdf.

¹² International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), *Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk, M7(R1)*, March 2017; https://database.ich.org/sites/default/files/M7_R1_Guideline.pdf.

¹³ Nitrosamines EMEA-H-A5(3)-1490 - Assessment Report (europa.eu) (June 25, 2020), https://www.ema.europa.eu/en/documents/referral/nitrosamines-emea-h-a53-1490-assessment-report_en.pdf.

recognize that this evidence also indicates that oral exposures of acute and intermediate duration are sufficient to induce cancer.” Moreover, “hepatotoxicity has been demonstrated in all animal species that have been tested and has been observed in humans who were exposed to NDMA by ingestion or inhalation.”¹⁴

63. 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.

64. Most recently, beginning in the summer of 2018, there have been recalls of several generic drugs used to treat high blood pressure and heart failure—Valsartan, Losartan, and Irbesartan—because the medications contained nitrosamine impurities that do not meet the FDA’s safety standards.

65. This continued in 2020 when the FDA required recalls of numerous generic manufacturers’ metformin.¹⁵

66. NDMA is a genotoxin that interacts with DNA and may subsequently induce mutations. Genotoxins are not considered to have a safe threshold or dose due to their ability to alter DNA.

67. The FDA has set an acceptable daily intake (“ADI”) level for NDMA at 96 ng. That means that consumption of 96 ng of NDMA a day would increase the risk of developing cancer by 0.001% over the course of a lifetime. That risk increases as the level of NDMA exposure increases. However, any level above

¹⁴ ATSDR Toxicological Profile For N-Nitrosodimethylamine (December 1989), <http://www.atsdr.cdc.gov/toxprofiles/tp141.pdf>.

¹⁵ <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-metformin>.

96 ng is considered unacceptable.¹⁶

68. In studies examining carcinogenicity through oral administration, mice exposed to NDMA developed cancer in the kidney, bladder, liver, and lung. In comparable rat studies, cancers were observed in the liver, kidney, pancreas, and lung.

69. In other long-term animal studies in 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.

70. Numerous *in vitro* studies confirm that NDMA is a mutagen—causing genetic mutations in human and animal cells.

71. Overall, the animal data 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.

72. The EPA classified NDMA as a probable human carcinogen “based on the induction of tumors at multiple sites in different mammal species exposed to NDMA by various routes.”¹⁷

73. Pursuant to EPA cancer guidelines, “tumors observed in animals are generally assumed to indicate

¹⁶ U.S. Food & Drug Admin., *FDA Updates and Press Announcements on Angiotensin II Receptor Blocker (ARB) Recalls (Valsartan, Losartan, and Irbesartan)* (Feb. 28, 2019), <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan>.

¹⁷ *Id.*

that an agent may produce tumors in humans.”¹⁸

74. 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. These studies consistently show increased risks of various cancers.

75. In a 2000 epidemiological cohort study looking at occupational exposure of workers in the rubber industry, researchers observed significant increased risks for NDMA exposure for esophagus, oral cavity, and pharynx cancer.¹⁹

76. In a 2011 epidemiological cohort study looking at NDMA dietary exposure with 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.²⁰

77. NDMA is also known to be genotoxic – meaning, it can cause DNA damage in human cells. Indeed, multiple studies demonstrate that NDMA is genotoxic both *in vivo* and *in vitro*. However, recent studies have shown that the ability of NDMA to cause mutations in cells is affected by the presence of enzymes typically found in living humans, suggesting

¹⁸ See U.S. Env'tl. Protection Agency, Risk Assessment Forum, *Guidelines for Carcinogen Risk Assessment* (Mar. 2005), https://www3.epa.gov/airtoxics/cancer_guidelines_final_3-25-05.pdf.

¹⁹ Straif et al., *Exposure to High Concentrations of Nitrosamines and Cancer Mortality Among a Cohort of Rubber Workers*, 57 *Occup. Env'tl. Med* 180–87 (2000).

²⁰ Loh et al., *N-nitroso Compounds and Cancer Incidence: The European Prospective Investigation into Cancer and Nutrition (EPIC)–Norfolk Study*, 93 *Am. J. Clinical Nutrition* 1053–61 (2011).

that “humans may be especially sensitive to the carcinogenicity of NDMA.”²¹

78. In addition to studies demonstrating that NDMA directly causes cancer, research shows that exposure to NDMA (1) can exacerbate existing but dormant (*i.e.*, not malignant) tumor cells; (2) promote otherwise “initiated cancer cells” to develop into cancerous tumors; and (3) reduce the ability of the body to combat cancer as NDMA is immunosuppressive. Thus, in addition to NDMA being a direct cause of cancer itself, NDMA can also be a contributing factor to a cancer injury caused by some other source.

III. NDMA IS DISCOVERED IN RANITIDINE-CONTAINING PRODUCTS, LEADING TO MARKET WITHDRAWAL

79. Pharmacy and testing laboratory Valisure LLC and ValisureRX LLC (collectively, “Valisure”) filed a Citizen Petition calling for the recall of all ranitidine-containing products due to detecting exceedingly high levels of NDMA when testing ranitidine pills using gas chromatography-mass spectrometry. FDA and European regulators started reviewing the safety of ranitidine with a specific focus on the presence of NDMA. This set off a cascade of recalls of ranitidine-containing products by GSK, other brand-name manufacturers, generic manufacturers, and retailers, including Walgreens.

80. The FDA’s Director for Drug Evaluation and Research, Dr. Janet Woodcock, issued a statement

²¹ World Health Org., *supra* note 14.

warning that some ranitidine medicines may contain NDMA.

81. Defendants voluntarily recalled all ranitidine products and removed them from shelves.

82. The FDA ordered manufacturers of ranitidine to test their products and recommended using liquid chromatography with high-resolution mass spectrometer (“LC-HRMS”) testing protocol, which “does not use elevated temperatures.”

83. Defendant GSK voluntarily recalled all ranitidine-containing products internationally. As part of the recall, GSK publicly acknowledged that unacceptable levels of NDMA were discovered in Zantac.

84. The FDA announced the results of testing, finding unacceptable levels of NDMA in ranitidine-containing products, and requested that drug makers begin to voluntarily recall their ranitidine-containing products if the FDA or manufacturers discovered NDMA levels above the acceptable limits.

85. The FDA issued a statement notifying consumers who wished to continue taking ranitidine to consider limiting their intake of nitrite-containing foods, *e.g.*, processed meats and preservatives like sodium nitrite. This advice *mirrored* an admonition issued by Italian scientists in 1981 after finding that ranitidine reacted with nitrites *in vitro* to form toxic and mutagenic effects in bacteria. The prudent advice of Dr. de Flora published in October 1981 in *The Lancet* was 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.”²² If GSK had only heeded Dr. de Flora’s advice in 1981, prior to the approval of NDA 18-703, millions of people might have avoided exposure to NDMA formed as a result of ranitidine’s interaction with the human digestive system.

86. Research laboratory, Emery Pharma, submitted a Citizen Petition to the FDA, showing that the ranitidine molecule is heat-labile and under certain temperatures progressively accumulates NDMA.

87. Emery’s Citizen Petition outlined its substantial concern that ranitidine is a time-and temperature-sensitive pharmaceutical product that develops NDMA when exposed to heat, a common occurrence during shipping, handling, and storage. Emery requested that the FDA issue a directive to manufacturers to clearly label ranitidine with a warning that “by-products that are probable carcinogens can be generated if exposed to heat.” In addition to warning about this condition, Emery requested agency directives to manufacturers and distributors to ship ranitidine products in temperature-controlled vehicles.

88. In response, on April 1, 2020, the FDA recounted that a recall is an “effective methods [sic.] of removing or correcting defective FDA-regulated products . . . particularly when those products present a danger to health.” The FDA sought the voluntary consent of manufacturers to accept the recall “to protect the public health from products that present a

²² Silvio de Flora, *Cimetidine, Ranitidine and Their Mutagenic Nitroso Derivatives*, *The Lancet*, Oct. 31, 1981, at 993–94.

risk of injury.” The FDA found that the recall of all ranitidine-containing products and a public warning of the recall was necessary because the “product being recalled presents a serious health risk.” The FDA, therefore, sent Information Requests to all applicants and pending applicants of ranitidine-containing products “requesting a market withdrawal.”

89. The FDA found its stability testing raised concerns that NDMA levels in some ranitidine-containing products stored at room temperature can increase with time to unacceptable levels. In the same vein, FDA testing revealed that higher NDMA levels were found as the products approached their expiration dates. The FDA’s testing eroded the agency’s confidence that any ranitidine-containing product would remain stable through its labeled expiration date. Consequently, the FDA requested a market withdrawal of all ranitidine products. The FDA also announced to the public that the Agency’s laboratory tests indicate that temperature and time contribute to an increase in NDMA levels in some ranitidine products. The FDA’s decision to withdraw the drug rendered moot Emery’s request for temperature-controlled shipping conditions.

90. The FDA’s reaction was consistent with comparable regulatory action throughout the world. Before the FDA acted, over 43 different countries and jurisdictions restricted or banned ranitidine-containing products.

91. The European Medicines Agency (“EMA”), the European Union’s equivalent to the FDA, through an Article 31 Referral, determined the sale of all ranitidine-containing products should be suspended. On April 30, 2020, the Human Medicines Committee

of the EMA “has recommended the suspension of all ranitidine medicines in the EU due to the presence of low levels of an impurity called N-nitrosodimethylamine (NDMA).” The EMA recognizes NDMA as a probable human carcinogen and issued a “precautionary suspension of these medicines in the EU” because “NDMA has been found in several ranitidine medicines above levels considered acceptable, and there are unresolved questions about the source of the impurities.”²³

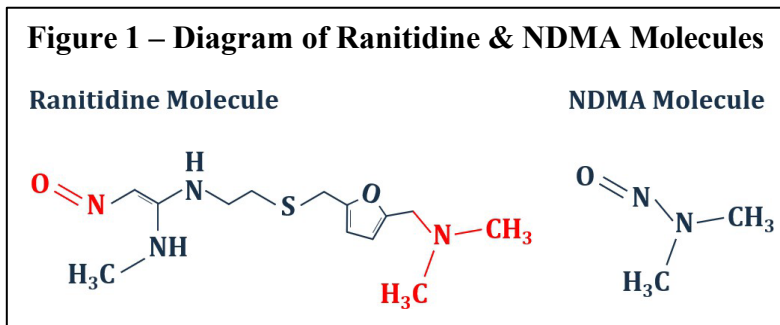
92. On September 17, 2020, after a ranitidine manufacturer requested that the EMA re-examine its decision and permit ranitidine to be marketed again in the EU, the EMA confirmed its prior recommendation to suspend all ranitidine medicines in the EU due to the presence of NDMA noting that it is a probable human carcinogen and that there is evidence that NDMA forms from the degradation of ranitidine itself with increasing levels seen over shelf life.²⁴

IV. HOW RANITIDINE TRANSFORMS INTO NDMA

²³ Eur. Med. Agency, *Suspension of Ranitidine Medicines in the EU* (Apr. 30, 2020), https://www.ema.europa.eu/en/documents/referral/ranitidine-article-31-referral-suspension-ranitidine-medicines-eu_en.pdf.

²⁴ Eur. Med. Agency, EMA Confirms Recommendation to Suspend All Ranitidine Medicines in the EU (Nov. 24, 2020), https://www.ema.europa.eu/en/documents/referral/ranitidine-article-31-referral-ema-confirms-recommendation-suspend-all-ranitidine-medicines-eu_en.pdf.

93. The ranitidine molecule itself contains the constituent molecules to form NDMA. See Figure 1.



94. The degradation occurs independently in two parts of the ranitidine molecule, with the products of the degradation combining to produce NDMA.

95. 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 U.S. water supply.²⁵ Indeed, in 2003, alarming levels of NDMA in drinking water processed by wastewater-treatment plants were specifically linked to the presence of ranitidine.²⁶

96. The high levels of NDMA observed in ranitidine-containing products are a function of various factors. The ranitidine molecule internally degrades to form NDMA. The degradation of

²⁵ Ogawa et al., *Purification and Properties of a New Enzyme, NG, NG-dimethylarginine Dimethylaminohydrolase, from Rat Kidney*, 264 J. Bio. Chem. 17, 10205–209 (1989).

²⁶ Mitch et al., *N-Nitrosodimethylamine (NDMA) as a Drinking Water Contaminant: A Review*, 20 Env. Eng. Sci. 5, 389–404 (2003).

ranitidine can increase over time under normal storage conditions, but more so with exposure to heat and/or humidity. Once in the body, ranitidine continues to degrade and can yield increasing levels of NDMA in the human digestive system, and when it interacts with nitrogenous products.

A. Formation of NDMA in the Environment of the Human Stomach

97. When the ranitidine molecule is exposed to the acidic environment of the stomach, particularly when accompanied by nitrites (a chemical commonly found in heartburn-inducing foods), the Nitroso molecule ($O=N$) and the DMA molecule ($H_3C-N-CH_3$) break off and reform as NDMA.

98. In 1981, Dr. Silvio de Flora, an Italian researcher from the University of Genoa, published the results of experiments he conducted on ranitidine in the well-known journal, *The Lancet*. When ranitidine was exposed to human gastric fluid in combination with nitrites, his experiment showed “toxic and mutagenic effects.”²⁷ Dr. de Flora hypothesized that these mutagenic effects could have been caused by the “formation of more than one nitroso derivative [which includes NDMA] under our experimental conditions.” *Id.* Dr. de Flora cautioned that, in the context of ranitidine ingestion, “it would seem prudent to ... suggest[] a diet low in nitrates and nitrites, by asking patients not to take these at times close to (or with) meals.”²⁸ *Id.*

²⁷ De Flora, *supra* note 25.

²⁸ This admonition came two years before the FDA approved

99. GSK knew of Dr. de Flora's publication because, two weeks later, GSK responded in *The Lancet*, claiming that the levels of nitrite needed to induce the production of nitroso derivatives (*i.e.*, NDMA) were not likely to be experienced by people in the real world.²⁹

100. This response reflects GSK's reputation for "adopting the most combative, scorched-earth positions in defense of its brands."³⁰ The company has no compunctions against distorting objective science to maintain its lucrative monopoly franchises, and its egregious conduct surrounding Zantac is not some isolated incident.

101. GSK endangered patient health while reaping billions of dollars in profits from Paxil, Wellbutrin, and Avandia. As we now know, the company was involved in covering up scientific data, offering illegal kickbacks to prescribing physicians, intimidating witnesses, and defrauding Medicare to profit from these medicines. In the wake of

Zantac in 1983. Notwithstanding, in 1998 GSK applied for and obtained an indication for OTC Zantac "[f]or the prevention of meal-induced heartburn at a dose of 75 mg taken 30 to 60 minutes prior to a meal." See Ctr. for Drug Eval. & Research, *Approval Package* (June 8, 1998), available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/98/20520s1Zantac.pdf. GSK thus specifically invited patients to take Zantac shortly before eating heartburn-inducing food.

²⁹ R. T., Brittain et al., *Safety of Ranitidine*, *The Lancet* 1119 (Nov. 14, 1981).

³⁰ Jim Edwards, *GSK's Alleged Coverup of Bad Avandia Data: A Snapshot of Its Poisonous Corporate Culture*, Moneywatch (July 13, 2010) <https://www.cbsnews.com/news/gsk-alleged-coverup-of-bad-avandia-data-a-snapshot-of-its-poisonous-corporate-culture/>.

Congressional hearings into the company's outrageous misbehavior,³¹ GSK's actions resulted in a criminal investigation and the then-largest guilty plea by a pharmaceutical company for fraud and failure to report safety data in the country's history.³² There is currently an open investigation of GSK and Sanofi being conducted by the Department of Justice relating to the failure to disclose to the federal government information about the potential presence of NDMA in Zantac.³³

102. GSK attended an FDA Advisory Committee in May 1982 where its representative testified and presented evidence relating to the safety of Zantac, including the potential for ranitidine to form nitrosamines. However, GSK failed to disclose its new evidence relating to ranitidine and the formation of a nitrosamine, specifically the formation of NDMA.

103. One month later, in June 1982, GSK submitted its draft Summary Basis of Approval and labeling for Zantac. Again, GSK failed to submit or otherwise disclose its new evidence relating to ranitidine and the formation of NDMA.

104. In its submission to the FDA, GSK discussed

³¹ *Staff Report on GlaxoSmithKline and the Diabetes Drug Avandia*, Senate Comm. on Finance, 111th Cong. 2d Sess. 1 (Comm. Print Jan. 2010).

³² U.S. Dep't of Justice, *GlaxoSmithKline to Please Guilty and Pay \$3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data* (July 2, 2012), <https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report>.

³³ https://www.sanofi.com/-/media/Project/One-Sanofi-Web/Websites/Global/SanofiCOM/Home/en/investors/docs/2020_07_29_HY_financial_report_EN.pdf.

its findings from internal studies performed in 1980 that ranitidine formed a different nitrosamine, n-nitroso-nitrolic acid, a potent mutagen, but explained that these results had no “practical clinical significance”³⁴:

Although N-nitroso-nitrolic acid was a potent mutagen, it is not likely to be formed in the stomach of a patient ingesting ranitidine, as an unrealistically large amount of nitrite needs to be present to form and maintain the nitrosamine. For this reason, and also because ranitidine was not carcinogenic in life-span studies in rodents, the in vitro nitrosation of ranitidine to a mutagenic nitrosamine does not seem to have practical clinical significance.

105. In 1980—before Zantac was approved by the FDA—GSK conducted another study to examine, among other things, how long-term use of ranitidine could affect the levels of nitrite in the human stomach.³⁵ Remarkably, GSK admitted that ranitidine use caused the proliferation of bacteria in the human stomach that are known to convert nitrates to nitrites, which leads to elevated levels of nitrite in the stomach environment. GSK acknowledged this could increase the risk of forming nitrosamines and, in turn, cancer, but then dismissed this risk because people were allegedly only expected to use ranitidine-containing products for a short-term period:

³⁴ Excerpted from the Summary Basis of Approval submitted to the FDA to obtain approval of Zantac in the early 1980s. This document was obtained through a Freedom of Information Act request to the FDA.

³⁵ The results of this study are discussed in the Summary Basis of Approval, obtained from the FDA.

The importance of this finding is not clear. High levels of nitrite could react with certain organic compounds to form nitrosamines, which are known carcinogens. To date, however, neither ranitidine nor cimetidine have been carcinogenic in rodents, so the level of human risk cannot be estimated from animal studies. Ranitidine is recommended only for short-term use and carcinogenic risk, if any, should thus be minimized.

106. GSK knew—and indeed specifically admitted—that ranitidine could react with nitrite in the human stomach to form nitrosamines and, at the same time, that long-term use of ranitidine could lead to elevated levels of nitrite in the human stomach. GSK also knew but did not disclose that it had new evidence showing that NDMA was generated by ranitidine under certain conditions.

107. In response to Dr. de Flora's findings, in 1982, GSK conducted a clinical study specifically investigating gastric contents in human patients.³⁶ The study, in part, specifically measured the levels of N-Nitroso compounds in human gastric fluid. GSK indicated that there were no elevated levels, and even published the results of this study five years later, in 1987. The study, however, was flawed. It did not use gold-standard mass spectrometry to test for NDMA, but instead, used a process that could not measure N-nitrosamines efficiently. And worse, in the testing it did do, GSK refused to test gastric samples that contained ranitidine in them out of concern that samples with ranitidine would contain "high concentrations of N-nitroso compounds being recorded."³⁷ In other words, GSK intentionally

³⁶ Thomas et al., *Effects of One Year's Treatment with Ranitidine and of Truncal Vagotomy on Gastric Contents*, 6 Gut. Vol. 28, 726–38 (1987).

³⁷ *Id.*

engineered the study to exclude the very samples most likely to contain a dangerous carcinogen.

108. Given the above information that was disclosed relating to the nitrosation potential and formation of nitrosamines, it is shocking that GSK conducted an internal study to assess the formation of NDMA and found that ranitidine, when exposed to sodium nitrite, formed hundreds of thousands of nanograms of NDMA. The GSK study was never published or disclosed to the public.

109. In 1983, the same year GSK started marketing Zantac in the United States, seven researchers from the University of Genoa published a study discussing ranitidine and its genotoxic effects (ability to harm DNA).³⁸ The researchers concluded, “it appears that reaction of ranitidine with excess sodium nitrite under acid conditions gives rise to a nitroso-derivative (or derivatives) [like NDMA] capable of inducing DNA damage in mammalian cells.” *Id.*

110. Then, again in 1983, Dr. de Flora, along with four other researchers, published their complete findings.³⁹ The results “confirm our preliminary findings on the formation of genotoxic derivatives from nitrite and ranitidine.” 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

³⁸ Maura et al., *DNA Damage Induced by Nitrosated Ranitidine in Cultured Mammalian Cells*, 18 Tox. Lttrs. 97–102 (1983).

³⁹ De Flora et al., *Genotoxicity of Nitrosated Ranitidine*, 4 Carcinogenesis 3, 255–60 (1983).

or the prescription of these anti-ulcer drugs at a suitable interval from meals.” This admonition carries weight considering GSK’s studies indicate that long-term ranitidine consumption, itself, leads to elevated levels of nitrites in the human gut.

111. 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.⁴⁰ These studies underscore the instability of the NDMA group on the ranitidine molecule and its ability to form NDMA in the environment of water-treatment plants that supply many U.S. cities with water.

112. In 2016, researchers at Stanford University conducted an experiment on healthy adult volunteers.⁴¹ They measured the NDMA in the urine of healthy individuals over the course of 24 hours, administered one dose of ranitidine, and then measured the NDMA in the urine of the same individuals for another 24 hours. The study reported that on average, the level of NDMA increased by 400 times, to approximately 47,000 ng. The only change during that 24-hour period was the consumption of ranitidine. In the study, the scientists further explained that previous studies have indicated a high metabolic conversion rate of NDMA, meaning it will be processed by the human body. This study showed

⁴⁰ Le Roux et al., *NDMA Formation by Chloramination of Ranitidine: Kinetics and Mechanism*, 46 *Envtl. Sci. Tech.* 20, 11095–103 (2012).

⁴¹ Zeng et al., *Oral intake of Ranitidine Increases Urinary Excretion of N-nitrosodimethylamine*, 37 *Carcinogenesis* 625–34 (2016).

that ranitidine generates NDMA in the human body.

113. Valisure is an online pharmacy that also runs an analytical laboratory that is ISO 17025 accredited by the International Organization for Standardization (“ISO”)—an accreditation recognizing the laboratories technical competence for regulatory purposes. 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.

114. In its Citizen’s Petition to the FDA, Valisure disclosed as part of its testing of ranitidine-containing products that in every lot tested there were exceedingly high levels of NDMA. Valisure’s ISO 17025 accredited laboratory used FDA recommended GC/MS headspace analysis method FY19-005-DPA for the determination of NDMA levels. As per the FDA protocol, this method was validated to a lower limit of detection of 25 ng. The results of Valisure’s testing show levels of NDMA well above 2 million ng per 150 mg Zantac tablet, shown below in Table 1.

Table 1 – Ranitidine Samples Tested by Valisure Laboratory Using GC/MS Protocol		
150 mg Tablets or equivalent	Lot #	NDMA per tablet (ng)

App-122

Reference Powder	125619	2,472,531
Zantac, Brand OTC	18M498M	2,511,469
Zantac (mint), Brand OTC	18H546	2,834,798
Wal-Zan, Walgreens	79L800819A	2,444,046
Wal-Zan (mint), Walgreens	8ME2640	2,635,006
Ranitidine, Strides	77024060A	2,951,649

115. This testing by GC-MS demonstrates the instability of the ranitidine molecule and its propensity to break down under higher temperatures.

116. 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. So Valisure developed a low temperature GC/MS method that could still detect NDMA but would only subject samples to 37 °C, the average temperature of the human body. This method was validated to a lower limit of detection of 100 ng.

117. 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. The inclusion of nitrite in gastric fluid testing is commonplace and helps simulate the environment of a human stomach.

118. Indeed, ranitidine-containing products were specifically advertised to be used when consuming foods containing high levels of nitrates, such as tacos or pizza.⁴²

119. The results of Valisure's tests on ranitidine tablets in biologically relevant conditions demonstrate significant NDMA formation under simulated gastric conditions with nitrite present (*see* Table 2).

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
Tablet	Not Detected	Not Detected
Simulated Gastric Fluid ("SGF")	Not Detected	Not Detected
Simulated Intestinal Fluid	Not	Not

⁴² See, e.g., Zantac television commercial, *Family Taco Night*, <https://www.ispot.tv/ad/dY7n/zantac-family-taco-night>; Zantac television commercial, *Spicy*, <https://youtu.be/jzS2kuB5wg>; Zantac television commercial, *Heartburn*, <https://youtu.be/Z3QMwkSUIEg>; Zantac television commercial, *Zantac Heartburn Challenge*, <https://youtu.be/qvh9gyWqQns>.

("SIF")	Detected	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

120. Under biologically relevant conditions, when nitrites are present, high levels of NDMA are found in one dose of 150 mg ranitidine, ranging between 245 and 3,100 times above the FDA-allowable limit. One would need to smoke over 500 cigarettes to achieve the same levels of NDMA found in one dose of 150 mg ranitidine at the 25 nanogram level (over 7,000 for the 50 nanogram level).

121. Following the release of Valisure Citizen's Petition, the FDA conducted additional laboratory tests, which showed NDMA levels in all ranitidine samples it tested, including API and the finished drug, both tablets and syrup. The FDA developed simulated gastric fluid ("SGF") and simulated intestinal fluid ("SIF") models to use with the LC-MS testing method to estimate the biological significance of *in vitro* findings. These models are intended to detect the formation of NDMA in systems that approximate the stomach and intestine.

122. When the scientific data is assessed overall, the literature demonstrates that the ingestion of ranitidine already containing NDMA combined with the presence of human-relevant levels of nitrite in the stomach—a substance that is commonly found in foods that induce heartburn and that is known to be

elevated in people taking ranitidine for longer than a month—the ranitidine molecule transforms into more NDMA which would dramatically increase a person’s risk of developing cancer.

B. Formation of NDMA in Other Organs of the Human Body

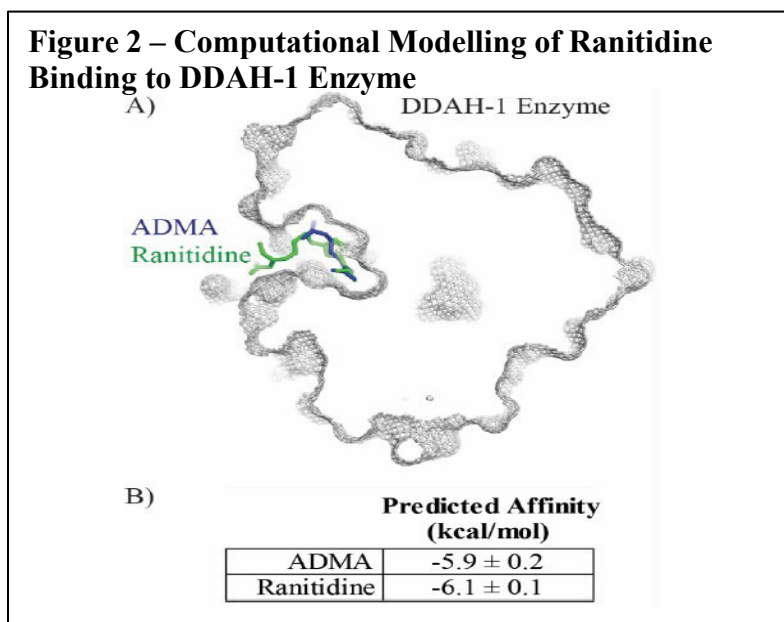
123. In addition to the gastric fluid mechanisms investigated in the scientific literature, Valisure identified a possible enzymatic mechanism for the liberation of ranitidine’s DMA group via the human enzyme dimethylarginine dimethylaminohydrolase (“DDAH”), which can occur in other tissues and organs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

124. Valisure explained that 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 pathways, particularly in weak acidic conditions such as that 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].”⁴³

125. Valisure reported as illustrated in Figure 2, below, computational modelling demonstrates that ranitidine (shown in green) can readily bind to the DDAH-1 enzyme (shown as a cross-section in grey)

⁴³ Ogawa, *et al.*, *supra* note 28.

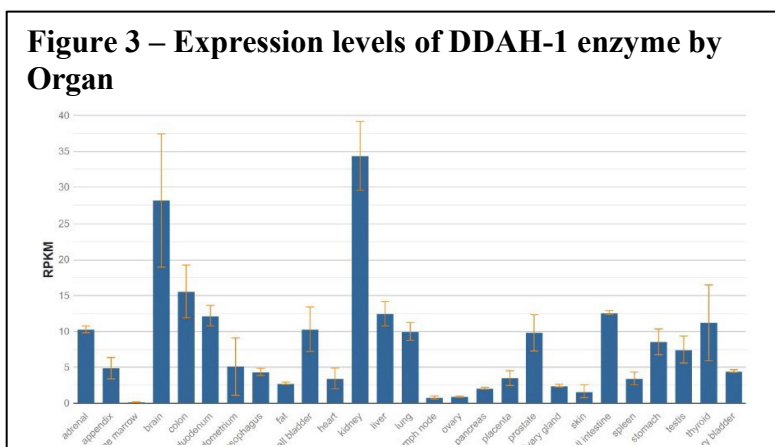
in a manner similar to the natural substrate of DDAH-1 known as



asymmetric dimethylarginine (“ADMA,” shown in blue).

126. Valisure reported that these results suggest 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.

127. Figure 3 below, derived from the National Center for Biotechnology Information, illustrates the expression of the DDAH-1 gene in various tissues in the human body.



128. DDAH-1 is most strongly expressed in the kidneys but also broadly distributed throughout the body, such as in the brain, colon, liver, small intestine, stomach, bladder, and prostate. Valisure noted that 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.

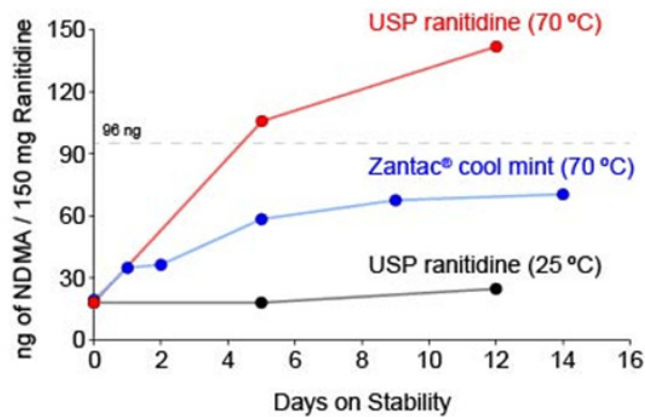
129. The possible enzymatic reaction of ranitidine to DDAH-1, or other enzymes, suggests that high levels of NDMA can form throughout the human body. Indeed, ranitidine metabolizes and circulates throughout the human body, crossing the placental and blood-brain barrier, within 1-2 hours. When ranitidine interacts with the DDAH-1 enzyme in various organs throughout the body, it breaks down into NDMA. This observation is validated by the Stanford study, discussed above.

C. Formation of NDMA by Exposure to Heat, Moisture, and/or Time

130. 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.

131. In response to Valisure, the FDA recommended that researchers use the LC-HRMS protocol for detecting NDMA in ranitidine because the “testing method does not use elevated temperatures” and has been proven capable of detecting NDMA. Emery Pharma, an FDA-certified pharmaceutical testing laboratory, conducted a series of tests on ranitidine. The researchers exposed ranitidine to 70 °C for varying periods of time. The results showed that increasing levels of NDMA formed based on exposure to heat. As reported by Emery Pharma, the following diagram reveals how NDMA accumulates over time when exposed to 70 °C:

Figure 4 – Rate of Development of NDMA when Exposed to Heat



132. 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.⁴⁴

133. The results of this data demonstrate that in

⁴⁴ Emery Pharma, *Emery Pharma Ranitidine: FDA Citizen Petition* (Jan. 2, 2020), available at <https://emerypharma.com/news/emery-pharma-ranitidine-fda-citizen-petition/>.

normal transport and storage, and especially when exposed to heat or humidity, the ranitidine molecule systematically breaks down into NDMA, accumulating 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 very real—a point underscored by the FDA’s swift removal of the product from the market.

134. 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.

135. The findings by Valisure unleashed an avalanche of regulatory authorities throughout the world demanding that the manufacturers of Zantac and/or ranitidine conduct testing of their products for the presence of NDMA as well as investigate the root cause as to how NDMA was being generated. In April 2020, the FDA requested that manufacturers immediately remove all ranitidine-containing products from the market.

136. In the interim between the Valisure findings being released to the public and the FDA announcement requesting recall of all ranitidine products in April 2020, the manufacturers were investigating the root cause of NDMA in their products.

137. After undertaking an investigation, GSK concluded that “the presence of NDMA in ranitidine drug substance is due to a slow degradation reaction occurring primarily in the solid state. The two constituent parts of NDMA, the nitroso group and the

dimethylamino group, are both derived from internal degradation reactions which occur at slow rates with the ranitidine molecule.”

138. Both brand-name and generic manufacturers could dictate the conditions under which API was transported to them. The labeling requirements do not apply to transporting API, in part because the finished product and API are packaged differently and may degrade under different conditions.

139. Brand-name and generic manufacturers failed to ensure that their Ranitidine-Containing Products (in both API and finished dose form) were kept safely from excessive heat and humidity.

**V. EVIDENCE DIRECTLY LINKS
RANITIDINE EXPOSURE TO
PLAINTIFF’S CANCER**

140. In addition to numerous epidemiology studies examining how NDMA causes cancer in humans, researchers have also specifically looked at ranitidine and found an association with bladder, esophageal, and kidney cancer.

141. In one epidemiological study looking at various cancer risks and histamine H₂-receptor antagonists (or H₂ blockers), including ranitidine, the data showed that ranitidine consumption increased the risk of prostate, lung, esophageal, pancreatic, and kidney cancer.⁴⁵

⁴⁵ Laurel A Habel et al., *Cimetidine Use and Risk of Breast, Prostate, and Other Cancers*, 9 *Pharmacoepidemiology & Drug Safety* 149–55 (2000).

142. A number of studies have been published over the years showing an increased risk of various cancers associated with use of ranitidine and/or H2 blockers.⁴⁶ Research reports have shown that ranitidine use was associated with a significant increase in the risk of bladder, breast, colorectal/intestinal, esophageal, gastric, kidney, liver, lung, pancreatic, and prostate cancer.⁴⁷

VI. GSK KNEW OR SHOULD HAVE KNOWN OF THE NDMA RISK BEFORE RANTITDINE WAS APPROVED

143. As early as 1981, *two years before GSK received approval* for NDA 18-703 and Zantac entered the market, research showed elevated rates of NDMA, when properly tested.⁴⁸ This was known or should have been known by all Defendants as the

⁴⁶ Robert W. Mathes et al., *Relationship Between Histamine2-receptor Antagonist Medications and Risk of Invasive Breast Cancer*, 17 Cancer Epi. Biomarkers & Prevention 1, 67–72 (2008); see also Jeong Soo Ahn et al., *Acid Suppressive Drugs and Gastric Cancer: A Meta-analysis of Observational Studies*, 19 World J. Gastroenterology 16, 2560 (2013); Shih-Wei Lai et al., *Use of Proton Pump Inhibitors Correlates with Increased Risk of Pancreatic Cancer: A Case-control Study in Taiwan*, 46 Kuwait Med J. 1, 44–48 (2014); Poulsen et al., *Proton Pump Inhibitors and Risk of Gastric Cancer – A Population Based Cohort Study*, 100 Brit. J. Cancer 1503–07 (2009); E Wennerström, *Acid-suppressing Therapies and Subsite-specific Risk of Stomach Cancer*, 116 Brit. J. Cancer 9, 1234–38 (2017).

⁴⁷ Richard H. Adamson & Bruce A. Chabne, *The Finding of N-Nitrosodimethylamine in Common Medicines*, The Oncologist, June 2020; 25(6): 460–62, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7288647/>.

⁴⁸ See *supra* ¶ 114 (discussing de Flora research).

information was available in medical literature.

144. In 1981, GSK, the originator of the ranitidine molecule, published a study focusing on the metabolites of ranitidine in urine using liquid chromatography.⁴⁹ Many metabolites were listed, though there is no indication that the study looked for NDMA.

145. Indeed, in that same year, Dr. de Flora published a note 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—a substance commonly found in food and in the body.⁵⁰ GSK was aware of this study because GSK specifically responded to the note and attempted to discredit it. GSK knew or should have known about this scientific exchange as it was published in a popular scientific journal. GSK was obligated to investigate this issue properly, but it failed to do so.

146. In its original pre-approval submission to the FDA, GSK explained that the level of nitrite present in Zantac would be unrealistic and, thus, these results had no “practical clinical significance.” Specifically, GSK stated:

Although N-nitroso-nitrolic acid was a potent mutagen, it is not likely to be formed in the stomach of a patient ingesting ranitidine, as an unrealistically large

⁴⁹ 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, 161–68 (1981).

⁵⁰ De Flora, *supra* note 25.

amount of nitrite needs to be present to form and maintain the nitrosamine. For this reason, and also because ranitidine was not carcinogenic in life-span studies in rodents, the in vitro nitrosation of ranitidine to a mutagenic nitrosamine does not seem to have practical clinical significance.

147. Around this same time—***before Zantac was approved by the FDA***— GSK conducted another study to examine, among other things, how long-term use of ranitidine could affect the levels of nitrite in the human stomach. Remarkably, in the study that was presented to the FDA, GSK admitted that ranitidine use caused the proliferation of bacteria in the human stomach that are known to convert nitrates to nitrites, which leads to elevated levels of nitrite in the stomach environment. GSK acknowledged this could increase the risk of developing NDMA and, in turn, cancer, but it then dismissed this risk because individuals were allegedly only expected to use ranitidine-containing products for a short-term period. In particular, GSK stated:

The importance of this finding is not clear. High levels of nitrite could react with certain organic compounds to form nitrosamines, which are known carcinogens. To date, however, neither ranitidine nor cimetidine have been carcinogenic in rodents, so the level of human risk cannot be estimated from animal studies. Ranitidine is recommended only for short-term use and carcinogenic risk, if any, should thus be minimized.

148. GSK knew—and indeed specifically admitted—that ranitidine could react with nitrite in the human stomach to form NDMA and, at the same time, that long-term use of ranitidine could lead to elevated levels of nitrite in the human stomach.

149. In response to Dr. de Flora’s findings, in 1982, GSK conducted a clinical study specifically investigating gastric contents in human patients. The study, in part, specifically measured the levels of N-Nitroso compounds in human gastric fluid. GSK indicated that there were no elevated levels, and even published the results of this study five years later, in 1987. That study, however, was also rigged. GSK did not use gold-standard mass spectrometry to test for NDMA; it instead used a process that could not measure N-nitrosamines efficiently. And worse, in the testing it did do, GSK refused to test gastric samples that contained ranitidine in them out of concern that samples with ranitidine would contain “high concentrations of N-nitroso compounds being recorded.” In other words, GSK intentionally rigged the study to exclude the very samples most likely to contain a dangerous carcinogen.

150. By 1987, after numerous studies raised concerns over ranitidine and cancerous nitroso compounds, GSK published a clinical study specifically investigating gastric contents in human patients and N-nitroso compounds.⁵¹ That study specifically indicated that there were no elevated levels of N-nitroso compounds (of which NDMA is one). But the study was flawed. It used an analytical

⁵¹ Thomas et al., *supra* note 39.

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. Not only is that approach not accurate, but 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.” Without the chemical being present in any sample, any degradation into NDMA could not, by design, be observed. The inadequacy of that test was knowable in light of its scientific publication in 1987. All Defendants either knew or should have known about the inadequacy of that study and should have investigated the issue properly and/or took action to protect consumers from the NDMA risks in their products. None did.

151. 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 of NDMA per day. In a 1995 epidemiological case-control study looking at NDMA dietary exposure with 746 cases, researchers observed statistically significant elevated rates of gastric cancer in persons exposed to more than 0.191 ng of NDMA per day. In another 1995 epidemiological case-control study looking at, in part, the effects of dietary consumption on cancer, researchers observed a statistically significant elevated risk of developing aerodigestive cancer in individuals who were exposed to 0.179 ng of NDMA per day.

152. In a 1999 epidemiological cohort study

looking at NDMA dietary exposure with 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.

153. In a 2000 epidemiological cohort study looking at 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.

154. In a 2011 epidemiological cohort study looking at NDMA dietary exposure with 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.

155. In a 2014 epidemiological case-control study looking at NDMA dietary exposure with 2,481 cases, researchers found a statistically significant elevated association between NDMA exposure and colorectal cancer.

156. In addition to studies demonstrating that NDMA directly causes cancer, research shows that exposure to NDMA (1) can exacerbate existing but dormant (i.e. not malignant) cancers, (2) promote otherwise “initiated cancer cells” to develop into cancerous tumors; and (3) reduce the ability of the body to combat cancer. Thus, in addition to NDMA being a direct cause of cancer itself, NDMA can also be a contributing factor to a cancer injury caused by some other source.

157. NDMA is also known to be genotoxic, which

means it can cause DNA damage in human cells. Indeed, multiple studies demonstrate that NDMA is genotoxic both in vivo and in vitro. However, recent studies have shown that the ability of NDMA to cause mutations in cells is affected by the presence of enzymes typically found in living humans, suggesting that “humans may be especially sensitive to the carcinogenicity of NDMA.”

VII. THE FEDERAL REGULATORY LANDSCAPE

158. A manufacturer is required to give adequate directions for the use of a pharmaceutical drug such that a “layman can use a drug safely and for the purposes for which it is intended,”⁵² and conform to requirements governing the appearance of the label.⁵³

159. “Labeling” encompasses all written, printed or graphic material accompanying the drug or device,⁵⁴ and therefore broadly encompasses nearly every form of promotional activity, including not only “package inserts” but also advertising.

160. “Most, if not all, labeling is advertising. The term ‘labeling’ is defined in the FDCA as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising.”⁵⁵

161. All drug manufacturers (brand and generic) are also responsible for conducting stability testing,

⁵² 21 C.F.R. § 201.5.

⁵³ *Id.* § 201.15.

⁵⁴ *Id.*; 65 Fed. Reg. 14286 (Mar. 16, 2000).

⁵⁵ *United States v. Research Labs.*, 126 F.2d 42, 45 (9th Cir. 1942).

which must be “designed to assess the stability characteristics of drug products.”⁵⁶ Manufacturers must adopt a written testing program that includes: “(1) Sample size and test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability; (2) Storage conditions for samples retained for testing; (3) Reliable, meaningful, and specific test methods; (4) Testing of the drug product in the same container-closure system as that in which the drug product is marketed; (5) Testing of drug products for reconstitution at the time of dispensing (as directed in the labeling) as well as after they are reconstituted.”⁵⁷

162. The purpose of stability testing is, in part, to determine the “appropriate storage conditions and expiration dates.”⁵⁸ And expiration dates, in turn, must be set to “assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use.”⁵⁹ An expiration date is “related to any storage conditions stated on the labeling, as determined by stability studies listed in § 211.166.”⁶⁰

163. Each manufacturer, whether brand or generic, must conduct its own tests to determine and set accurate retest or expiration dates.

164. The FDA made clear when it first adopted the expiration-date provision that the regulation means what it says. The purpose of the expiration date is not merely to consider the “stability of a

⁵⁶ 21 C.F.R. § 211.166(a).

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ *Id.* § 211.137(a).

⁶⁰ *Id.* § 211.137(b).

specific active ingredient.” Instead, a compliant expiration date must account for multiple factors, including “the stability of the inactive ingredients, the interaction of active and inactive ingredients, the manufacturing process, the dosage form, the container closure system, the conditions under which the drug product is shipped, stored, and handled by wholesalers and retailers, and the length of time between initial manufacture and final use.”⁶¹

165. The FDA expressly recognizes that an initial expiration date may not be the final expiration date: “Where data from accelerated studies are used to project a tentative expiration date that is beyond a date supported by actual shelf-life studies, there must be stability studies conducted . . . until the tentative expiration date is verified or the appropriate expiration date determined.”⁶²

166. After a drug is approved, a manufacturer can make changes to its drug application. To do so, manufacturers must comply with the requirements of §§ 314.70 and 314.71.

167. Some of the requirements in those regulations require a manufacturer of an approved drug to obtain FDA approval before implementing a label change.⁶³

168. But the FDA has long recognized a “changes being effected” (“CBE”) supplement that permits a manufacturer to make immediate changes, subject to FDA’s post-change review.⁶⁴

169. A manufacturer of an approved drug can use

⁶¹ 43 Fed. Reg. 45059 (Sept. 29, 1978).

⁶² 21 C.F.R. § 211.166(b).

⁶³ *Id.* § 314.70(b).

⁶⁴ *Id.* § 314.70(c)(3), (c)(6).

the CBE supplement to immediately make an “[a]ddition to a specification or changes in the methods or controls to provide increased assurance that the drug substance or drug product will have the characteristics of identity, strength quality, purity, or potency that it purports or is represented to possess.”⁶⁵ “A specification is defined as a list of tests, references to analytical procedures, and appropriate acceptance criteria that are numerical limits, ranges, or other criteria for the tests described.”⁶⁶

170. A manufacturer, therefore, need not seek FDA pre-approval to make changes to its stability studies to identify the appropriate expiration date—which must “assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use”⁶⁷—or to ensure that the drug is shipped and stored under appropriate conditions.

171. A manufacturer of an approved drug can also use the CBE supplement to make “moderate” changes “in the labeling to reflect newly acquired information” in order to “add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under § 201.57(c) of this chapter”; “add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product”; and “delete false, misleading, or unsupported indications for use or claims for

⁶⁵ *Id.* § 314.70(c)(6)(i).

⁶⁶ 65 Fed. Reg. 83042 (Dec. 29, 2000).

⁶⁷ 21 C.F.R. § 211.137(a).

effectiveness.”⁶⁸

172. Thus, GSK could have made these changes to its several NDAs for Zantac. Any change GSK made to its prescription Zantac labels to strengthen warnings when it first held them under NDAs 18-703, 20-095, and 20-251 would have warned Plaintiff about the presence of NDMA and the increased risk of cancer.

173. Also, at no time did GSK seek to make a change to the labels and warnings of Zantac to warn about the risk of cancer associated with NDMA. However, they did seek to make CBE regulation changes to all of these NDAs for other commercial purposes, which were approved by the FDA.

174. Also, a manufacturer of an approved drug may make minor changes to a label with no approval or notice, so long as that change is described in an annual report. The illustrative but non-exhaustive list of minor changes includes “[a] change in the labeling concerning the description of the drug product or in the information about how the drug product is supplied, that does not involve a change in the dosage strength or dosage form.”⁶⁹

175. A “minor change” further includes “[a]n extension of an expiration dating period based upon full shelf-life data on production batches obtained from a protocol approved in the NDA.”⁷⁰

176. At no time did GSK attempt to include a warning on the labels for ranitidine-containing products such as Zantac that consumers were at

⁶⁸ *Id.* § 314.70(c)(6)(iii)(A), (C), (D).

⁶⁹ *Id.* § 314.70 (d)(2)(ix).

⁷⁰ *Id.* § 314.70 (d)(2)(vi); *see also id.* § 314.70(d)(2)(vii), (x).

elevated risk of developing cancer if the products were: (i) exposed to excessive heat; (ii) exposed to excessive moisture/humidity; (iii) consumed with high-nitrite foods; (iv) consumed daily for a period of greater than a few months. The FDA never rejected such cancer warnings.

177. At no time did GSK attempt to change their labels on Zantac to delete a false or misleading expiration date, or to add a proper expiration date to ensure that ranitidine-containing products would not break down into NDMA prior to human consumption.

178. Based on the public scientific information, GSK knew or should have known that NDMA could form in ranitidine and Zantac by exposure to heat, humidity, nitrites, the conditions of the human stomach, and/or over time in storage.

179. At no time did any of GSK change their labels on Zantac to shorten the expiration date. GSK had the ability to unilaterally make such label changes for Zantac without prior FDA approval pursuant to the CBE regulation. Had any of GSK attempted such label changes, the FDA would not have rejected them.

180. Because they failed to include appropriate expiration dates on their Zantac products, GSK made false statements in the labeling of their Zantac products.

VIII. FEDERAL LAW REQUIRED GSK TO NOTIFY THE FDA ABOUT THE PRESENCE OF NDMA IN RANITIDINE-CONTAINING PRODUCTS SUCH AS ZANTAC

181. During the time that GSK manufactured and

sold ranitidine-containing products such as Zantac in the United States, the weight of scientific evidence showed that ranitidine exposed users to unsafe levels of NDMA. GSK failed to report these risks to the FDA.

182. GSK concealed the ranitidine-NDMA link from ordinary consumers in part by not reporting it to the FDA, which relies on drug manufacturers (or others, such as those who submit citizen petitions) to bring new information about an approved drug like ranitidine to the agency's attention.

183. Manufacturers (brand and generic) 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.

184. 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.

185. Every approval letter for an NDA issued to GSK contained the following directive from the FDA:

We remind you that you must comply with the requirements for an approved NDA set forth under 21 C.F.R. 314.80 and 314.81.

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

187. GSK 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 new information affecting the safety or labeling of ranitidine-containing products such as Zantac.

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

189. GSK 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 GSK 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.

190. 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 of GSK alerted the FDA to the risks of NDMA, the FDA would have required the manufacturers to remove ranitidine-containing products such as Zantac from the market.

IX. GOOD MANUFACTURING PRACTICES

191. 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.⁷¹

192. 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

⁷¹ 21 U.S.C. § 351(a)(2)(B).

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.

193. 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, all Defendants had a duty and were obligated to properly store, handle, and warehouse ranitidine and ranitidine-containing products such as Zantac.

194. Testing conducted by the FDA confirms that under accelerated conditions the elevated temperatures can lead to the presence of NDMA in the drug product.⁷² 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.

⁷² Woodcock Letter, *supra* note 38.

195. 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.

X. WALGREENS ALLEGATIONS

196. Walgreens states that it understands that “consumers want to feel confident the products they use are safe for their intended purposes.”⁷³

197. Walgreens claims it aims to do “business fairly and with integrity” which has led Walgreens to “drive responsible sourcing practices throughout our supply chain, protecting human rights and engaging with suppliers around ethical and environmental issues.”⁷⁴

198. According to Walgreens, “[p]atient safety lies at the heart of our management of pharmacy operations, and we strive to be the industry leader by continuously seeking ways to minimize risks to patients in our dispensing, pharmacy services and advance and pharmacy supply chain operations.”⁷⁵

199. Walgreens claims it engages in “ongoing supplier ethical compliance assessments” which includes “engaging with suppliers to improve when

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https://www.walgreens.com/topic/sr/sr_product_integrity_home.jsp (last accessed Nov. 23, 2021).

⁷⁴

https://www.walgreensbootsalliance.com/sites/www/files/asset/Walgreens-Boots-Alliance-2019-Corporate-Social-Responsibility-Report_2.pdf (last accessed Nov. 20, 2021).

⁷⁵ *Id.*

issues are detected.”

200. Walgreens also claims to screen suppliers against a matrix which assesses the suppliers’ management systems to discern whether they are operating in any way which violates Walgreens’ ethical sourcing commitments.⁷⁶

201. Walgreens’ supplier requirements demonstrate its knowledge that it is ultimately responsible for ensuring that (a) all of its products comply with CGMPs, (b) are not adulterated for failure to comply with CGMPs, and (c) are not misbranded.

202. 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.” Walgreens thus had a duty and was obligated to properly store, handle, and warehouse Zantac.

203. Testing conducted by the FDA confirms that improper storage of ranitidine has resulted in extremely high levels of NDMA. The FDA has also concluded that NDMA can increase in ranitidine even 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

⁷⁶ *Id.*

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.

204. Nothing prevented Walgreens from, on its own, taking actions to prevent accumulation of NDMA in Zantac products by ensuring storage and transport at the lower end of the temperature range contained on the labels. Nothing prevented Walgreens from ensuring that Zantac was not exposed to humidity or moisture.

205. In fact, Walgreens says that its “products . . . are rigorously analyzed for compliance with all applicable laws and regulations” as well as Walgreens’ “*own higher standards*,” and that its “own product safety analysis” sometimes “come to a *different, stricter* conclusion than some regulatory bodies.” (Emphasis added).⁷⁷

206. Based on the public scientific information, Walgreens knew or should have known that NDMA could form in ranitidine by exposure to heat, humidity, nitrites, the conditions of the human stomach, and/or over time in storage.

207. Based on the public scientific information, Walgreens had a duty to monitor for and/or discover defects in Zantac products.

208. Walgreens knew or should have known that Zantac had an inherent risk of degrading into NDMA

⁷⁷

https://www.walgreens.com/topic/sr/sr_product_integrity_home.jsp (last accessed Nov. 23, 2021).

because it has both a nitroso (N) and dimethylamine (DMA), which are all the ingredients needed to form NDMA.

209. The Zantac products Plaintiff consumed had excessive levels of NDMA in part because they were subjected to high levels of humidity and were stored for a long period of time (often in humid locations such as bathrooms).

210. During the time that Walgreens distributed and sold Zantac products in the United States, the weight of scientific evidence showed that ranitidine exposed users to unsafe levels of NDMA.

211. Walgreens failed to disclose that risk to consumers on the drug's label—or through any other means—and they failed to report those risks to the FDA.

212. The U.S. Pharmacopeia Convention (hereinafter “USP”) sets forth industry standards applicable—in relevant part—to distributors. Chapter 1079, entitled “Good Storage and Shipping Practices,” specified at relevant times:

Good storage and distribution practices apply to all organizations and individuals involved in any aspect of the storage and distribution of all drug products, including but not limited to the following: . . . Wholesale distributors; distribution companies involved in automobile, rail, sea, and air services.

213. USP 1079 states: “[A]ll organizations along the supply chain bear responsibility for ensuring that they handle drug products within adequate storage and distribution parameters that will not affect the

drug product identity, strength, quality, purity, or safety.”

214. As previously stated, research laboratory Emery Pharma submitted a Citizens Petition to the FDA showing that NDMA accumulates in ranitidine at unsafe rates when exposed to label-compliant temperature ranges that would occur during normal transport and storage conditions.

215. Emery’s Citizen Petition outlined its substantial concern that ranitidine is a time and temperature-sensitive pharmaceutical product that develops NDMA when exposed to heat, a common occurrence during shipping, handling, and storage. In addition to warning about this condition, Emery requested agency directives to manufacturers and distributors to ship ranitidine in temperature-controlled vehicles.

216. The FDA found its stability testing raised concerns that NDMA levels in some ranitidine-containing products stored at room temperature can increase with time to unacceptable levels. In the same vein, FDA testing revealed NDMA levels were higher as the products approached their expiration dates. The FDA’s testing eroded the agency’s confidence that any ranitidine-containing product could remain stable through its labeled expiration date.

**XI. RANITIDINE-CONTAINING PRODUCTS
SUCH AS ZANTAC ARE MISBRANDED
AND ADULTERATED BECAUSE THEY
CONTAIN DANGEROUS AND
BIOLOGICALLY RELEVANT LEVELS OF
NDMA**

217. The manufacture of any misbranded or adulterated drug is prohibited under federal law.⁷⁸

218. The introduction into commerce of any misbranded or adulterated drug is similarly prohibited.⁷⁹

219. Similarly, the receipt in interstate commerce of any adulterated or misbranded drug is also unlawful.⁸⁰

220. Among the ways a drug may be adulterated and/or misbranded is: “If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.”¹¹⁵

221. As recent regulatory action confirms, ranitidine was dangerous to health when used as prescribed.

222. It is unlawful to introduce a misbranded drug into interstate commerce.¹¹⁶ Thus, the Zantac ingested by Plaintiff was unlawfully distributed and sold.

223. Plaintiff purchased brand-name Zantac from Walgreens from 1987 until 2020. Plaintiff ingested the brand-name Zantac that he purchased from Walgreens over the course of those years.

224. Plaintiff, therefore, ingested branded Zantac manufactured or marketed by GSK.

225. The Zantac Plaintiff consumed used the same defective labels devised by GSK originally.

226. The amount of Zantac Plaintiff ingested that is attributable to GSK was more than de minimis;

⁷⁸ 21 U.S.C. § 331(g).

⁷⁹ *Id.* § 331(a).

⁸⁰ *Id.* § 331(c).

¹¹⁵ 21 U.S.C. § 352(j).

GSK's actions were a substantial contributing factor to Plaintiff's cancer and subsequent injuries.

**DEFENDANTS' WARRANTIES AND
REPRESENTATIONS**

**I. GSK'S WARRANTIES AND
REPRESENTATIONS**

227. GSK's ranitidine-containing Zantac product is accompanied by an FDA-approved label. By presenting consumers with an FDA-approved label, GSK made representations and express or implied warranties to consumers like Plaintiff that its products were consistent with the safety, quality, purity, identity, and strength characteristics reflected in the FDA-approved labels and/or were not adulterated and/or misbranded.

228. In addition, GSK affirmatively misrepresented and warranted to physicians and patients like Plaintiff through their websites, brochures, and other marketing or informational materials that their ranitidine-containing products complied with CGMPs and did not contain (or were not likely to contain) any ingredients besides those identified on the products' FDA-approved labels.

229. The presence of NDMA in GSK's ranitidine-containing products resulted in GSK's ranitidine-containing products containing an ingredient that is not also listed on GSK's FDA-approved label, which was the same label for the prescription ranitidine products Plaintiff's prescribing physicians prescribed to Plaintiff and that Plaintiff obtained from Walgreens and ingested. GSK willfully, recklessly, or

negligently failed to ensure that its ranitidine-containing products' labels and other advertising or marketing statements accurately conveyed information about its ranitidine-containing products.

230. Due to its status as a probable human carcinogen as listed by both the IARC and the EPA, NDMA is not an FDA-approved ingredient. Thus, GSK's ranitidine-containing products are adulterated and/or misbranded, and it was illegal for GSK to have introduced such ranitidine into commerce in the United States.¹¹⁷

II. WALGREENS' WARRANTIES AND REPRESENTATIONS

231. By selling drugs in the stream of commerce, Walgreens warranted to consumers such as Plaintiff that the ranitidine-containing products it sold were safe and effective.

232. During the relevant times listed herein, Plaintiff's physicians prescribed Zantac to Plaintiff.

233. During this relevant time period, Plaintiff filled these prescriptions for Zantac from Walgreens pharmacies, which, upon filling these prescriptions for Plaintiff, provided Plaintiff with prescription brand-name Zantac.

234. During these relevant time periods, Plaintiff regularly ingested the Zantac obtained by prescriptions from Walgreens pharmacies.

235. Plaintiff never would have accepted any prescriptions for Zantac, Plaintiff never would have purchased or obtained any prescriptions for Zantac

¹¹⁷ See 21 U.S.C. §§ 331(a), 351(a)(2)(B), 331(g).

from any Walgreens pharmacies, Plaintiff never would have ingested any of the Zantac obtained from Walgreens pharmacies, and Plaintiff's physicians never would have prescribed Zantac to Plaintiff if the label and labeling for prescription Zantac during the relevant times listed herein contained warnings and/or discussed the risks of developing cancer from ingesting prescription Zantac.

236. During the time that Plaintiff's physicians prescribed, and Plaintiff ingested the prescription Zantac obtained from Walgreens pharmacies, GSK held the NDA for prescription for several versions of brand-name Zantac.

237. As the holder of the NDA for prescription Zantac, GSK was responsible for the contents of the warnings and precautions contained in the label and labeling for prescription Zantac, including the failure to include any warnings about the presence of NDMA in Zantac and the risk of developing cancer in individuals who ingested prescription Zantac.

238. As the holder of the NDA for prescription Zantac, GSK had the ability to unilaterally add a warning or precaution in the label and labeling for prescription brand-name Zantac and prescription generic ranitidine to warn prescribing physicians and their patients and consumers such as Plaintiff about newly acquired information as described above related to the presence of NDMA in Zantac and the risks of patients and consumers such as Plaintiff of developing cancer, as a result of ingesting Zantac under the Changes Being Effected process under federal law, which GSK could have independently initiated without a requirement of prior FDA approval. Accordingly, GSK had the ability to

simultaneously satisfy and comply with its obligations towards Plaintiff and consumers and patients like Plaintiff both under state and federal law.

239. GSK knew or should have known about the new studies and research described above related to the presence of NDMA in Zantac and the risk of developing cancer in individuals who ingest Zantac (i.e., the newly acquired information) before Plaintiff and Plaintiff's physicians relied on the absence of any warnings in GSK's label and labeling for prescription Zantac about NDMA in Zantac or the risk of developing cancer, including Plaintiff's cancer, in individuals ingesting Zantac that led the prescribing physicians' decisions to prescribe and Plaintiff's decision to obtain and ingest Zantac.

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

241. Plaintiff's cancer was caused by Plaintiff ingestion of Zantac distributed and sold by Walgreens.

242. Had GSK warned Plaintiff's physicians and Plaintiff that ingesting prescription Zantac could lead to exposure to NDMA or, in turn, cancer, Plaintiff's physicians never would have prescribed, and Plaintiff never would have obtained from Walgreens and ingested prescription Zantac.

TOLLING OF STATUTE OF LIMITATIONS /
ESTOPPEL / FRAUDULENT CONCEALMENT

243. Plaintiff asserts 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.

244. 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 Plaintiff, Plaintiff's medical providers, and/or health facilities, yet Defendants failed to disclose the information to the public, including to Plaintiff.

245. 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 Plaintiff the true risks associated with use of Zantac. Due to Defendants' acts and omissions, Plaintiff's physicians were unaware of the increased risk of multiple types of cancer associated with the use of ranitidine due to its degradation into NDMA. Plaintiff's physicians did not warn Plaintiff of the true risks of ingesting Zantac including the increased risk of cancer. During the limitations period, Plaintiff could not reasonably have known or learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

246. Within the time period of any applicable statute of limitations, Plaintiff could not have discovered through the exercise of reasonable

diligence that exposure to Zantac is injurious to human health. Plaintiff's physicians did not warn Plaintiff that the true risks of ingesting NDMA in ranitidine included the increased risk of cancer. Plaintiff 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 Plaintiff have disclosed that Zantac would cause Plaintiff's injuries.

247. Despite acting with reasonable diligence, Plaintiff did not learn of the link between Plaintiff's cancer and Zantac exposure until a time within the statute of limitations for filing of Plaintiff's claims.

COUNT I
STRICT PRODUCTS LIABILITY – PRE-
APPROVAL DESIGN DEFECT
(As to GSK)

248. Plaintiff adopts, realleges, and incorporates by reference each allegation set forth in the preceding paragraphs as if fully stated herein.

249. GSK was the inventor of ranitidine and was the developer of prescription Zantac under NDA 18-709, 19-675, 20-095, and 20-251. GSK was also the developer of the various prescription and OTC Zantac products approved under NDAs 20-520 and 20-745, and all supplements.

250. NDAs 18-709, 19-675, 20-095, 20-251, 20-520, 20-745, and their respective supplements, were approved as new NDAs under section 505(b) of the FDCA.

251. GSK, as inventor and developer, knew or, by

the exercise of reasonable care, should have known, ordinary consumers such as Plaintiff would not have realized the potential risks and dangers of Zantac.

252. GSK owed a duty to all reasonably foreseeable users to design a safe product.

253. GSK breached their duty by failing to use reasonable care in the design of Zantac because the drug exposed users to unsafe levels of the carcinogen NDMA.

254. GSK breached its duty by failing to use reasonable care in the design of Zantac by negligently designing the drug with an inherent susceptibility to form NDMA. Alternative designs of the molecule—designs that were approved by the FDA—existed that substantially reduced the degradation of ranitidine into unsafe levels of NDMA.

255. GSK breached its duty by failing to use reasonable care in the design of their respective Zantac products before they were approved by the FDA:

- a. When placed in the stream of commerce, Zantac was defective in design and formulation, and, consequently, dangerous to an extent beyond that which an ordinary consumer would contemplate;
- b. When placed in the stream of commerce, Zantac was unreasonably dangerous in that it was hazardous and posed a grave risk of cancer and other serious illnesses when used in a reasonably anticipated manner;

- c. When placed in the stream of commerce, Zantac contained unreasonably dangerous design defects and were not reasonably safe when used in a reasonably anticipated or intended manner;
- d. Prior to approval by the FDA, GSK did not sufficiently test, investigate, or study Zantac and, specifically, the ability for Zantac to transform into the carcinogenic compound NDMA within the human body;
- e. Prior to approval by the FDA, GSK did not sufficiently test, investigate, or study Zantac 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;
- f. GSK failed to provide accurate expiration dates on the product label prior to the time such label was originally approved by the FDA;
- g. Prior to approval by the FDA, GSK failed to propose packaging for their Zantac which would have preserved the safety, efficacy, quality, and purity of the product;
- h. Prior to approval by the FDA, GSK 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;

- i. Prior to approval by the FDA, GSK knew or should have known their exposure to ranitidine could result in cancer and other severe illnesses and injuries;
- j. Prior to approval by the FDA, GSK did not conduct adequate stability testing of their product to ascertain shelf life, expiration, and proper storage, heat, and light specifications;
- k. Exposure to ranitidine-containing drugs such as Zantac presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug; and
- l. Prior to approval by the FDA, GSK possessed a columnar grade I ranitidine drug substance that was chemically identical to the ranitidine used in the products consumed by Plaintiff but was significantly less prone to degrade into NDMA. This morphology of ranitidine was available for use in the United States, but GSK chose to use an inferior design.

256. Prior to approval by the FDA, GSK could have employed safer alternative designs and

formulations. For example, GSK could have added ascorbic acid (Vitamin C) to each dose of Zantac, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

257. At the time of submitting the original proposed label for its Zantac products, GSK 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, GSK failed to warn Plaintiff of the risks of NDMA and in the warnings and precautions section of their Zantac products' label.

258. A reasonable company under the same or similar circumstances would have designed a safer product.

259. Had GSK provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with its Zantac products on the warnings and precautions section of their products' labels, Plaintiff could and would have avoided the risk of developing cancer and could and would have obtained alternative medication.

260. GSK's defective design of Zantac products was willful, wanton, malicious, and conducted with reckless disregard for the health and safety of users of the Zantac products, including Plaintiff. GSK risked the lives of consumers and users of its products, including Plaintiff, with knowledge of the safety problems associated with ranitidine-containing products, and suppressed this knowledge from the general public. GSK made conscious decisions not to warn or inform the unsuspecting public.

261. The defects in GSK's Zantac products were substantial and contributing factors in causing Plaintiff's injuries, and, but for GSK's misconduct and omissions, Plaintiff would not have sustained injuries.

262. As a direct and proximate result of GSK placing their defective Zantac products into the stream of commerce, and the resulting injuries, Plaintiff sustained personal injuries, mental anguish, loss of income, loss of earning capacity, pecuniary loss, and other damages which exceeds the jurisdictional minimum of this Court.

COUNT II
NEGLIGENCE – PRE-APPROVAL DESIGN
DEFECT
(As to GSK)

263. Plaintiff adopts, realleges, and incorporates by reference each allegation set forth in the preceding paragraphs as if fully stated herein.

264. GSK was the inventor of ranitidine and was the developer of prescription Zantac under NDA 18-709, 19-675, 20-095, and 20-251.

265. NDAs 18-709, 19-675, 20-095, 20-251, and their respective supplements, were approved as new NDAs under section 505(b) of the FDCA.

266. GSK, as inventor and developer, knew or, by the exercise of reasonable care, should have known, ordinary consumers such as Plaintiff would not have realized the potential risks and dangers of Zantac.

267. At all relevant times, GSK had a duty to exercise reasonable care in the development, manufacture, supply, storage, transport, packaging,

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

268. GSK's 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.

269. At all relevant times before each of their respective NDAs were approved by the FDA, GSK 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 would be ingested by consumers, such as Plaintiff.

270. Accordingly, at all relevant times before the approval of its NDAs, GSK knew or, in the exercise of reasonable care, should have known that use of Zantac could cause the types of injuries suffered by Plaintiff herein, and thus, created a dangerous and unreasonable risk of injury to the users of these products. GSK also knew or, in the exercise of reasonable care, should have known that users and consumers would be unaware of the risks and the magnitude of the risks associated with use of Zantac.

271. As such, GSK breached its duty of reasonable care and failed to exercise ordinary care in

the design, research, and development of Zantac products, in that GSK developed 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.

272. Readily available testing methods revealed the dangers of GSK's Zantac 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, developed and used to identify individual substances in a compound since 1955. If this testing method had been used by GSK to test ranitidine, as early as when GSK's predecessor first developed the ranitidine molecule, and certainly prior to the approval of all subsequent NDAs held by the GSK, they could have determined that ranitidine transform into NDMA under conditions likely to occur with the target market for ranitidine.

273. GSK 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 GSK, or scientifically knowable to GSK through appropriate research and testing by known methods,

at the time it sought approval from the FDA for their various respective NDAs for its Zantac products, but were not known to end users and consumers, including Plaintiff.

274. GSK owed a duty to all reasonably foreseeable users to design a safe product.

275. GSK breached its duty by failing to use reasonable care in the design of Zantac because the drug exposed users to unsafe levels of the carcinogen NDMA.

286. GSK breached its duty by failing to use reasonable care in the design of Zantac by negligently designing the drug with an inherent susceptibility to form NDMA. Alternative designs of the molecule—designs that were approved by the FDA—existed that substantially reduced the degradation of ranitidine into unsafe levels of NDMA.

287. GSK breached its duty by failing to use reasonable care in the design of its Zantac products before they were approved by the FDA:

- a. Designing, developing, manufacturing, producing, formulating, creating, and/or distributing Zantac without thorough and adequate pre- and post-market testing;
- b. Designing, developing, manufacturing, producing, formulating, creating, 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 prior to the approval of their respective NDAs;
- 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 GSK could reasonably foresee would use Zantac products;
- g. Failing to disclose to Plaintiff, 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 Plaintiff, 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 Plaintiff 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, GSK and Pfizer knew or should have known the products were not safe for their intended purpose; and
- k. Declining to make or propose appropriate product labeling or other promotional materials that would alert consumers and the general public of the risks.

276. GSK knew and/or should have known that foreseeable consumers, such as Plaintiff, would suffer injuries as a result of GSK's failure to exercise ordinary care in the design, development, manufacturing, labeling, distribution, storage, transport, and sale of Zantac.

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

278. GSK's negligence was the proximate cause of Plaintiff's injuries, i.e., absent GSK's negligence, Plaintiff would not have developed cancer.

279. GSK's conduct, as described above, was reckless and without regard for the safety of consumers including Plaintiff herein. GSK regularly risked the lives of consumers and users of their products, including Plaintiff, with full knowledge of the dangers of their products. GSK has made conscious decisions not to properly design, develop, and label their ranitidine products, including failing to propose a label for ranitidine that adequately informs the medical community and consumers of the risk of cancer as a result of NDMA contamination in ranitidine and failing to warn 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.

280. GSK's conduct as alleged herein was done with reckless disregard for human life, oppression, and malice. GSK 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 prior to the time their respective NDAs were approved by the FDA. Nonetheless, GSK and Pfizer deliberately crafted their label and warnings to mislead consumers. This was not done accidentally or through some justifiable negligence. Rather, GSK knew it 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 they would make selling the drugs. Their 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. Plaintiff was 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 Plaintiff's rights.

281. GSK's conduct, as described above, was willful, wanton, malicious, and conducted with reckless disregard for the health and safety of users of Zantac products, including Plaintiff.

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

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

284. As a proximate result of GSK negligently placing defective Zantac products into the stream of commerce, as alleged herein, Plaintiff suffered injuries, 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, and other damages.

285. As a proximate result of GSK negligently

placing defective Zantac products into the stream of commerce, as alleged herein, there was a measurable and significant interval of time during which Plaintiff suffered great mental anguish, personal injury, and other damages.

286. As a proximate result of GSK negligently placing defective Zantac products into the stream of commerce, as alleged herein, Plaintiff suffered injuries, 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, and other damages.

COUNT III
STRICT LIABILITY – FAILURE TO WARN
(As to GSK)

287. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

288. At all relevant times, GSK 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 Plaintiff, 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 GSK.

289. GSK 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 Plaintiff, and therefore had a continuing duty to warn of the risks associated with the use of Zantac products.

290. GSK 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 of ranitidine.

291. GSK, as a manufacturer and seller of pharmaceutical medications, is held to the knowledge of an expert in the field.

292. At the time of manufacture, GSK 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.

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

294. At all relevant times, GSK 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 GSK's Zantac products, including Plaintiff.

295. Even though GSK knew or should have known that ranitidine posed a grave risk of harm, it 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 GSK, or scientifically knowable to GSK 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 Plaintiff.

296. 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.

297. In fact, ranitidine-containing products had expiration dating periods of one or two years allowing the 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.

298. In setting expiration and/or retest dates for their ranitidine-containing drugs, GSK was 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.

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

300. GSK knew or should have known that its products created significant risks of serious bodily

harm to consumers, as alleged herein, and GSK failed to adequately warn consumers (i.e., the reasonably foreseeable users) of the risks of exposure to its products. GSK has 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, has made false and/or misleading statements concerning the safety of ranitidine-containing products.

301. At all relevant times, GSK's Zantac 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 Plaintiff, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by GSK.

302. Plaintiff was exposed to GSK's Zantac products without knowledge of their dangerous characteristics.

303. At all relevant times, Plaintiff used GSK's Zantac products for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

304. Plaintiff did not discover and could not have reasonably discovered the defects and risks associated with ranitidine-containing products prior to or at the time Plaintiff consumed them. Plaintiff relied upon the skill, superior knowledge, and judgment of GSK to know about and disclose serious health risks associated with using GSK's products.

305. GSK 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.

306. The information that GSK did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiff to utilize the products safely and with adequate protection. Instead, GSK: 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 its products, even after it 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.

307. This alleged failure to warn is not limited to the information contained on Zantac's labeling. GSK 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 GSK did not disclose these known risks through any medium.

308. GSK is liable to Plaintiff for injuries caused by its negligent, willful, or reckless conduct, as described above. GSK risked the lives of consumers and users of their products, including Plaintiff, by

consciously deciding not to warn or inform physicians, patients and the public of known safety problems associated with ranitidine-containing products.

309. Had GSK provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with its ranitidine-containing products, Plaintiff could have avoided the risk of developing injuries and could have obtained or used alternative medication.

310. As a direct and proximate result of GSK placing its defective Zantac products into the stream of commerce, and the resulting injuries, Plaintiff sustained personal injuries, mental anguish, loss of income, loss of earning capacity, pecuniary loss, and other damages which exceeds the jurisdictional minimum of this Court.

COUNT IV NEGLIGENCE – FAILURE TO
WARN
(As to GSK)

311. Plaintiff incorporates by reference each allegation set forth in the preceding paragraphs as if fully stated herein.

312. 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.

313. NDMA is a potent carcinogen in humans.

Higher exposure to NDMA over longer time periods leads to even higher risks of cancer.

314. 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.

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

316. In fact, Zantac 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.

317. In setting expiration and/or retest dates for their ranitidine-containing drugs, GSK was 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.

318. 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 GSK. GSK's 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. GSK had a continuing duty to provide appropriate and accurate warnings and precautions.

319. GSK, as a manufacturer and seller of pharmaceutical medication, is held to the knowledge of an expert in the field.

320. At all relevant times, GSK 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 Plaintiff, 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 GSK as holder of the various Zantac NDAs.

321. At all relevant times, GSK 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. GSK knew or should have known about each of these risks in time to warn consumers.

322. Even though GSK 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 GSK, or scientifically knowable to GSK through appropriate research and testing by known methods, at the time it manufactured, marketed, distributed, supplied, or sold the products, but were not known to end users and consumers, including Plaintiff.

323. GSK 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.

324. At the time of manufacture, GSK could have provided warnings or instructions regarding the full and complete risks of Zantac because it knew or should have known of the unreasonable risks of harm

associated with the use of and/or exposure to such products.

325. At various points in time, GSK possessed new information or new analyses of existing information that empowered it unilaterally to change the warnings and precautions section of its Zantac products' label.

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

327. GSK breached this duty for the Zantac products it manufactured, marketed, and sold. The warnings included on each ranitidine-containing product were unreasonably inadequate because it 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. Plaintiff and/or Plaintiff's doctors would have read and heeded these warnings. As a result, Plaintiff would not have ingested Zantac and would not have developed cancer or otherwise been harmed by exposure to NDMA in these products.

328. Despite this ability, GSK failed to warn of the risks of NDMA in the warnings and precautions section of its Zantac products' label.

329. Plaintiff was exposed to GSK's Zantac products without knowledge of their dangerous characteristics. Plaintiff could not have reasonably discovered the risks associated with ranitidine-containing products prior to or at the time Plaintiff

consumed the drugs. Plaintiff and Plaintiff's physicians relied upon the skill, superior knowledge, and judgment of GSK to know about and disclose serious health risks associated with using GSK's products.

330. At all relevant times, Plaintiff used and/or was exposed to GSK's Zantac products while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

331. GSK knew or should have known that the minimal warnings disseminated with its Zantac 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 GSK did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiff to avoid using the drug. Instead, GSK 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.

332. Had GSK provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with its Zantac products on the warnings and precautions section of its products' labels, Plaintiff could have avoided the risk of developing cancer and could have obtained or used alternative medication. However, as a result of GSK's concealment of the dangers posed by their Zantac products, Plaintiff was not alerted, and so could not avert Plaintiff's injuries.

333. GSK's conduct, as described above, was reckless.

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

335. GSK's lack of adequate warnings and instructions in the warnings and precautions section of their Zantac products' labels were a substantial factor in causing Plaintiff's injuries.

336. As a direct and proximate result of GSK's failure to provide an adequate warning of the risks of ranitidine-containing products, Plaintiff suffered injuries, 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, and other damages.

COUNT V

NEGLIGENT STORAGE AND
TRANSPORTATION
(As to All Defendants)

337. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

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

339. 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 their ability to provide precise, quality service. More precise, colder transportation is, of course, more expensive than less precise, warmer transportation.

340. 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.

341. 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.

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

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

344. 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.

345. 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.

346. Defendants, directly or indirectly, transported, stored, handled, and/or sold Zantac products that were used by Plaintiff.

347. 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.

348. Defendants breached this duty by failing to implement or enforce policies to ensure Zantac products remained free from excessive heat and humidity, as required both by the duty of reasonable care and the label.

349. At all relevant times, Defendants knew or

should have known of the need for storing and transporting Zantac products within the labeled temperature range and at low humidity. Yet, Defendants ignored this risk. They did not ensure Zantac products were stored at low humidity or within the temperature range on the label. Instead, some Zantac 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.

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

351. Plaintiff 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.

352. Defendants' negligence was a substantial factor in causing Plaintiff's injuries.

353. As a direct and proximate result of Defendants' failure to store and transport Zantac products properly, Plaintiff has suffered injuries, 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, and other damages.

354. As a direct and proximate result of these systematic failures, excessive levels of NDMA formed in the Zantac products the Defendants handled, stored and sold. These high levels of NDMA caused Plaintiff's injuries.

COUNT VIII
NEGLIGENT MISREPRESENTATION
(As to All Defendants)

355. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

356. The brand name Zantac ranitidine-containing products complained of were designed, manufactured, advertised, marketed, distributed, and/or sold by the Defendants, which Plaintiff regularly used and ingested.

357. At all relevant times, and in their relevant capacities described above, 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 do 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.

358. Defendants represented directly to consumers, including Plaintiff, via the media, advertising, website, social media, packaging, and promotions, among other misrepresentations and omissions described herein that:

- a. the Zantac products 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 would not result in excessive amounts of NDMA being formed in their bodies;
- c. the levels of NDMA in Zantac 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.

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

360. Defendants knew that their ranitidine-containing products would be used by their customers, such as Plaintiff, without inspection for defects and that any such inspection would not have advised Plaintiff of the fact that these products could cause the injuries which Plaintiff suffered. Such facts made the Defendants' Zantac products inherently and unreasonably dangerous in that Plaintiff was not apprised of, could not and would not contemplate the danger and/or the extent of the danger of contracting cancer and the associated injuries and complications as a result of their exposure to ranitidine and NDMA.

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

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

363. Defendants intended for Plaintiff and/or Plaintiff's physician(s) to rely on these representations.

364. 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 Plaintiff as to whether to purchase or consume Zantac products.

365. Plaintiff relied on the Defendants' statements regarding their Zantac products by using and ingesting the these in the manner in which they were intended or reasonably foreseeable to the Defendants.

366. Plaintiff would not have regularly used and ingested these Zantac products if Defendants did not make the foregoing misrepresentations.

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

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

369. Plaintiff was exposed to the Defendants' ranitidine-containing products whenever Plaintiff took them. Each exposure to Defendants' ranitidine-

containing products caused Plaintiff to be exposed to additional and accumulating NDMA, which then resulted in and directly caused Plaintiff to suffer severe bodily injuries, specifically cancer. Each exposure to these products was harmful and caused or contributed substantially to Plaintiff's injuries.

370. As a direct and proximate result of the Defendants' negligent misrepresentations concerning their Zantac products, Plaintiff has suffered injuries, 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, and other damages.

COUNT IX
BREACH OF EXPRESS WARRANTIES
(As to All Defendants)

371. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

372. The brand name Zantac ranitidine-containing products complained of were designed, manufactured, advertised, marketed, distributed, and/or sold by the Defendants, which Plaintiff regularly used and ingested.

373. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and/or promoting ranitidine-containing Zantac products, which are defective and unreasonably dangerous to consumers, including Plaintiff, thereby placing Zantac products into the stream of commerce.

These actions were under the ultimate control and supervision of Defendants.

374. 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 Zantac products, 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.

375. 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.

376. At all relevant times, Defendants expressly represented and warranted to the purchasers of their products, including Plaintiff, 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.

377. 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 ranitidine tablets were safe and effective, that it was safe and effective for use by individuals such as Plaintiff, and/or that it was safe and effective as consumer medication.

378. The representations about Zantac products, 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.

379. Plaintiff purchased Zantac products directly at Walgreens retail locations.

380. Plaintiff is a third-party beneficiaries of the various contracts that Defendants entered into for the distribution and retail sale of their Zantac products.

381. Defendants placed Zantac 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.

382. Defendants breached these warranties because, among other things, Zantac 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.

383. 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.

384. Plaintiff 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. Plaintiff reasonably relied upon Defendants to disclose known defects, risks, dangers, and side effects of its products if not stored, shipped and handled properly. Plaintiff would not have purchased Zantac had Defendants properly disclosed the risks associated with the products, either through advertising, labeling, or any other form of disclosure.

385. 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 Plaintiff could not have reasonably discovered that the risks expressly included in its warnings and labels were inadequate and inaccurate.

386. Plaintiff had no knowledge of, and could not reasonably have discovered, the falsity or incompleteness of Defendants' statements and representations concerning Zantac.

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

388. 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 Plaintiff's injuries, rather than expressly excluding such information and

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

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

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

391. As a proximate result of Defendants' breach of express warranty, as alleged herein, Plaintiff has suffered injuries, 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, and other damages.

COUNT X
BREACH OF IMPLIED WARRANTIES
(As to All Defendants)

392. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

393. This Count alleges a claim by Plaintiff for Zantac Plaintiff consumed and that each Defendant manufactured or sold.

394. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold Zantac

products, which were and are defective and unreasonably dangerous to consumers, including Plaintiff, thereby placing Zantac products into the stream of commerce.

395. Before the time Plaintiff used Zantac products, Defendants impliedly warranted to their consumers, including Plaintiff, that ranitidine-containing products were of merchantable quality and safe and fit for the use for which they were intended; specifically, as consumer medication.

396. Zantac was not merchantable, not safe, and not fit for its use as a consumer medication because it degraded into NDMA, a potent carcinogen. By selling Zantac despite these flaws, Defendants breached their implied warranties.

397. Plaintiff purchased Zantac products directly at Walgreens retail locations.

398. Plaintiff is a third-party beneficiary of the various contracts that GSK entered into for the distribution and retail sale of their Zantac products.

399. At all relevant times, Defendants were aware that consumers and users of their products, including Plaintiff, would use Zantac products as marketed by Defendants, which is to say that Plaintiff was a foreseeable user of Zantac products.

400. Defendants intended that Zantac products be used in the manner in which Plaintiff, in fact, used them and which Defendants impliedly warranted to be of merchantable quality, safe, and fit for this use, even though Zantac products were not safe because they degraded into NDMA.

401. In reliance upon Defendants' implied warranty, Plaintiff used Zantac products as instructed and labeled and in the foreseeable manner

intended, recommended, promoted, and marketed by Defendants.

402. Plaintiff could not have reasonably discovered or known of the risks of serious injury associated with Zantac products.

403. The harm caused by Defendants' ranitidine-containing products far outweighed their benefit, rendering the products more dangerous than an ordinary consumer or user would expect and more dangerous than alternative products.

404. Defendants' breach of these implied warranties was a substantial factor in causing Plaintiff's harm described herein, including personal injuries.

405. As a proximate result of Defendants' breach of express warranty, as alleged herein, Plaintiff has suffered injuries, 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, and other damages.

COUNT XI
COMMON LAW FRAUD
(As to All Defendants)

406. Plaintiff incorporates by reference every and every allegation of this Complaint as if fully stated herein.

407. Defendants intentionally and/or with reckless disregard for the truth misrepresented to Plaintiff material facts regarding the safety and effectiveness of Zantac.

408. Defendants knew or recklessly disregarded

the fact that these representations were false, yet made the deceitful representations to Plaintiff.

409. Defendants actively concealed and intentionally omitted material facts about the defects and dangers of ranitidine for the purpose that Plaintiff and the consuming public would rely on such information, or the absence of information, in selecting Zantac as a treatment.

410. The maker's knowledge of the falsity of the representation fundamentally supplies the element of "fraudulent utterance" required to make a misrepresentation actionable.

411. Defendants made the misrepresentations and omissions of material facts alleged herein with the intent to induce consumers, like Plaintiff, to take their Zantac products.

412. As a result of these false and deceitful representations and omissions made by Defendants, which Defendants knew to be untrue or for which Defendants recklessly disregarded the truth, Plaintiff in fact relied on such misrepresentations and omissions by purchasing and ingesting Defendants' Zantac products, thus causing the significant injuries and harm described herein.

413. As a direct and proximate result of the foregoing misrepresentations omissions, and deceitful intentions, Plaintiff sustained serious injuries of a personal and pecuniary nature. Plaintiff suffered serious injuries, including cancer and permanent disability and disfigurement. As a direct and proximate result of the foregoing misrepresentations, omissions, and deceitful intentions, Plaintiff requires and/or will require more healthcare and services and did incur medical, health, incidental, and related

expenses. Plaintiff will also require additional medical and/or hospital care, attention, and services in the future.

COUNT XII
ILLINOIS CONSUMER FRAUD ACT
(As to All Defendants)

414. Plaintiff incorporates by reference every and every allegation of this Complaint as if fully stated herein.

415. Defendants intentionally and/or with reckless disregard for the truth misrepresented to Plaintiff material facts regarding the safety and effectiveness of Zantac.

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

417. Defendants actively concealed and intentionally omitted material facts about the defects and dangers of ranitidine for the purpose that Plaintiff and the consuming public would rely on such information, or the absence of information, in selecting Zantac as a treatment.

418. The Defendants' intentional material misrepresentations and omissions as described fully in this Complaint constitute deceptive acts or practices under the Illinois Consumer Fraud Act.

419. The Defendants engaged in these deceptive acts or practices with the intent that Plaintiff would rely on the deceptions.

420. Defendants made the misrepresentations and omissions of material facts alleged herein with the intent to induce consumers, like Plaintiff, to

purchase their ranitidine-containing Zantac products.

421. The deceptions committed by Defendants as described herein occurred in the course of conduct involving trade and commerce, i.e., Defendants made such material misrepresentations and omissions as an inducement for Plaintiff and other consumers to purchase their products in the stream of commerce, from which Defendants collectively earned billions of dollars from the sales of ranitidine-containing Zantac products.

422. As a result of these false and deceitful representations and omissions made by Defendants, which Defendants knew to be untrue or for which Defendants recklessly disregarded the truth, Plaintiff in fact relied on such misrepresentations and omissions by purchasing and ingesting Defendants' Zantac products, thus causing the significant injuries and harm described herein.

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

JURY TRIAL DEMAND

Pursuant to 735 ILCS 5/2-1105, Plaintiff hereby demands a trial by jury on all the triable issues within this pleading.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests the Court to enter judgment in Plaintiff's favor and against Defendants for:

- a. actual or compensatory damages in such amount to be determined at trial and as provided by applicable law;
- b. pre-judgment and post-judgment interest;
- c. reasonable attorneys' fees as provided by law;
- d. costs and expenses of these actions;
- e. statutory damages, treble damages and other relief permitted by the laws of the states that will govern these actions; and
- f. any other relief the Court may deem just and proper.

DATED: April 12, 2023 **PARAFINCZUK WOLF,
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App-202

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that the foregoing was furnished via email to the below named counsel on this 12th day of April, 2023:

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Alliance, Inc.*

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Appendix F

[Filed: Apr. 3, 2025]

**EXHIBIT A FOR 180 CASES TO BE APPEALED
BY APRIL 4, 2025**

Plaintiff	Cook County Circuit Court Case No.	Date of Order of Dismissal
Ellen Smith (LEAD CASE)	2023L003569	3/24/2025
Olivia Adams	2023L003324	3/5/2025
Deanna Adelman	2023L004069	3/5/2025
Anthony Anderson	2023L003624	3/5/2025
Susan Austin	2023L003631	3/5/2025
Janardanan Ayyappan	2023L003327	3/5/2025
Cynthia Ballou	2023L003653	3/5/2025
Rita Banks (Estate of Wilbert Banks)	2023L003659	3/5/2025
Shirley Barney	2023L003341	3/5/2025
Venissa Barquet	2023L003675	3/5/2025
Mary Barrett	2023L003425	3/5/2025
Linwood Battle	2023L003673	3/5/2025
Norene Beard	2023L003431	3/5/2025
Jimetta Beasley	2023L003426	3/5/2025
Barbara Belcher	2023L003430	3/5/2025
Mary Betts	2023L003684	3/5/2025
Michael Borookhim	2023L003957	3/5/2025
Anthony Bouchard	2023L003697	3/5/2025

Plaintiff	Cook County Circuit Court Case No.	Date of Order of Dismissal
Sybil Bouse	2023L004044	3/5/2025
Anna Brandtjen (Es- tate of Anthony Brandtjen)	2023L004013	3/5/2025
Douglas Brenton	2023L003961	3/5/2025
Janet Brett	2023L003730	3/5/2025
Sandra Brogan	2023L003438	3/5/2025
Elvira Brown	2023L003735	3/5/2025
Erin Brown	2023L004043	3/5/2025
Shelley Bullock (Estate of Marilyn Holland)	2023L003463	3/24/2025
Owen Burdge	2023L004039	3/5/2025
Jimmy Burnside	2023L003761	3/5/2025
Boyd Cain	2023L003700	3/5/2025
Charles Caldwell	2023L004046	3/5/2025
Matt Callahan	2023L003762	3/5/2025
Alfredo Canizalez	2023L003766	3/5/2025
Serenia Carnegie	2023L004048	3/5/2025
Nancy Carnes (Estate of Mark Carnes)	2023L004094	3/5/2025
Missouri Carstaffney	2023L003767	3/5/2025
Allen Carter	2023L003667	3/5/2025
Norma Cetuk	2023L003768	3/5/2025
Helen Chow	2023L003704	3/5/2025

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Plaintiff	Cook County Circuit Court Case No.	Date of Order of Dismissal
Richard Christoffersen	2023L003988	3/5/2025
Nicole Christopher	2023L003707	3/5/2025
John Clare	2023L004104	3/5/2025
Dorothy Collins	2023L003791	3/5/2025
Gerald Combs	2023L004050	3/5/2025
Eddie Cooper	2023L004054	3/5/2025
Carolyn Coughlin	2023L003712	3/5/2025
Cynthia Covington	2023L003433	3/5/2025
Candace Crone	2023L003785	3/5/2025
Patricia Crouch	2023L004012	3/5/2025
Christine Currie	2023L003432	3/5/2025
Anthny Czerwein	2023L003440	3/5/2025
Daisy Damian	2023L003779	3/5/2025
Gemayel Davis	2023L003789	3/5/2025
Michael Davis	2023L004015	3/5/2025
Roncindra Davis	2023L003797	3/5/2025
Jeffrey Todd Davis	2023L003795	3/5/2025
Heidi DeClue	2023L003970	3/5/2025
Sharmayne Dicks	2023L003787	3/5/2025
Deborah Dodd	2023L003807	3/5/2025
Ruth Dorrance	2023L003815	3/5/2025
Deborah Drew	2023L003442	3/5/2025
Nanci Drury	2023L003444	3/5/2025
Richard Dusch	2023L003817	3/5/2025

Plaintiff	Cook County Circuit Court Case No.	Date of Order of Dismissal
Roland Eaglin	2023L003820	3/5/2025
Gary D. Eckrich	2023L003819	3/5/2025
Cathy Evans	2023L003842	3/5/2025
Jeanette Evans	2023L003847	3/5/2025
Georgia Ezeilo	2023L003434	3/5/2025
Pearl R. Fields	2023L003443	3/5/2025
William Fleming	2023L004011	3/5/2025
George Flint	2023L003454	3/5/2025
Robert Florkey	2023L003845	3/5/2025
Carolyn Foster (Estate of Aaron J. Foster)	2023L004093	3/5/2025
Dennis Fox	2023L003680	3/5/2025
Emilio Franco	2023L003848	3/5/2025
Katrina Frazier	2023L003852	3/5/2025
Ronald Fulmer	2023L003854	3/5/2025
Richard Gaiti	2023L004097	3/5/2025
Dinah George	2023L003879	3/5/2025
Larry German	2023L004102	3/5/2025
Jeffrey Gill	2023L003455	3/5/2025
Khaliefe Glover	2023L003763	3/5/2025
Emmanuel Goldstein	2023L003467	3/5/2025
Greg Gover	2023L003738	3/5/2025
Michael Hall	2023L003865	3/5/2025

Plaintiff	Cook County Circuit Court Case No.	Date of Order of Dismissal
Shayne (Shane) M. Hall	2023L003868	3/5/2025
Lashonda Hampton (Estate of Sheila Furr)	2023L003858	3/24/2025
Minnie Harris	2023L003871	3/5/2025
Douglas Harrison	2023L003869	3/5/2025
Joshua Hawkins	2023L003873	3/5/2025
Tina Herrin	2023L003874	3/5/2025
Tomasa Hill	2023L003876	3/5/2025
Lois Hinkle	2023L003464	3/5/2025
Sandra Holmes	2023L003739	3/5/2025
Willie Holmes	2023L003731	3/5/2025
John Holstein	2023L003465	3/5/2025
Dawn Hurr (Estate of Cassandra Day)	2023L003447	3/24/2025
Earl Johnson	2023L003466	3/5/2025
Lisha Johnson	2023L003467	3/5/2025
Maria Johnson	2023L003469	3/5/2025
Gary Johnston	2023L003470	3/5/2025
Gilbert Joines	2023L003705	3/5/2025
Kenya Knezevich	2023L003733	3/5/2025
Joan Knoph	2023L003890	3/5/2025
Leonard J. Lee	2023L003908	3/5/2025
Carol Lorenz	2023L004100	3/5/2025

Plaintiff	Cook County Circuit Court Case No.	Date of Order of Dismissal
Betty Lubar	2023L004061	3/5/2025
Lawrence Luckey	2023L003905	3/5/2025
David William Lundblom	2023L003907	3/5/2025
Carlos Maldonado	2023L003923	3/5/2025
David Mann	2023L003504	3/5/2025
Vicki McCall	2023L003930	3/5/2025
David McClelland	2023L003932	3/5/2025
Jean McDonnell	2023L003523	3/5/2025
Curtis McPherson	2023L003744	3/5/2025
Mark Meyer	2023L003529	3/5/2025
Micheal Miller	2023L003920	3/5/2025
Richard B. Moffitt	2023L004062	3/5/2025
Kerrie L. Moran	2023L003919	3/5/2025
Deborah Morgan	2023L004066	3/5/2025
Freedom Murray	2023L003915	3/5/2025
Azmi Mustafa	2023L004005	3/5/2025
Garard Naff	2023L003974	3/5/2025
Albert Nevarez, Jr.	2023L004004	3/5/2025
Robert Newman	2023L004077	3/5/2025
Marilyn Denise Oreoluwa	2023L004127	3/5/2025
Joshua Owens	2023L003533	3/5/2025
Gloria Y. Pacley	2023L003535	3/5/2025

Plaintiff	Cook County Circuit Court Case No.	Date of Order of Dismissal
Shanna Palmour	2023L003996	3/5/2025
Dina Peller	2023L003750	3/5/2025
Renita Perez	2023L004090	3/5/2025
Kaysandra Peyton	2023L003769	3/5/2025
Michele Dawn Piac- quadro	2023L003538	3/5/2025
Franco Polizzi	2023L003992	3/5/2025
Marlon Pucket	2023L003984	3/5/2025
Vadalina Quinones	2023L003542	3/5/2025
Jon Long (Estate of Da- vid Long Quintero)	2023L004107	3/5/2025
Sharon Renfro	2023L003951	3/5/2025
Patricia Rhem	2023L003939	3/5/2025
Danica Riley	2023L003752	3/5/2025
Vernon Risby	2023L003969	3/5/2025
Craig Rodkin	2023L004001	3/5/2025
Elvir Sabanovic	2023L003991	3/5/2025
Marco Antonio Sando- val	2023L003976	3/5/2025
Kimberly Sayles	2023L003941	3/5/2025
Louise Scott	2023L003567	3/5/2025
Sammy Shah	2023L003943	3/5/2025
Patricia Siebert	2023L003568	3/5/2025
Joseph T. Silva	2023L003916	3/5/2025

Plaintiff	Cook County Circuit Court Case No.	Date of Order of Dismissal
Pamela Smith	2023L003812	3/5/2025
Rebecca Smith	2023L003574	3/5/2025
Talton Smith	2023L003575	3/5/2025
Donna Snyder (Estate of Ronald Lee Snyder)	2023L003782	3/5/2025
Melisa Sobota	2023L003579	3/5/2025
Rose A. South	2023L003986	3/5/2025
Christian Spining	2023L003813	3/5/2025
Olivia Sutton	2023L003841	3/5/2025
Jeffrey Tantleff	2023L003826	3/5/2025
Johnnie Tarver	2023L004032	3/5/2025
Tinisha Thomas	2023L003582	3/5/2025
David Thureau	2023L003827	3/5/2025
Shane Tomczak	2023L004086	3/5/2025
Elizabeth Francy Torres Vieira	2023L003833	3/5/2025
Timmy Trahan	2023L003583	3/5/2025
Courtney Turner	2023L003830	3/5/2025
Detlef Vance	2023L004110	3/5/2025
Tina Ayers Vick	2023L003713	3/5/2025
Nate Vortherms	2023L003893	3/5/2025
Kyla Voss (Estate of Daryle Peters)	2023L003990	3/24/2025
Cynthia M. Ward	2023L003882	3/5/2025

Plaintiff	Cook County Circuit Court Case No.	Date of Order of Dismissal
Christopher Warren (Estate of Danielle Barney)	2023L003664	3/24/2025
Karleythia Washington	2023L003793	3/5/2025
Stephen Weidenhamer	2023L004106	3/5/2025
Mary Jane White	2023L003584	3/5/2025
Kazuko Williams	2023L004052	3/5/2025
Paul Williams	2023L003586	3/5/2025
Quincy Carl Williams	2023L003834	3/5/2025
Rory Williams	2023L003587	3/5/2025
Myisha Wright	2023L003832	3/5/2025
Allen Wronko	2023L003831	3/5/2025
Robert Yasick	2023L003592	3/5/2025

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