RECORD NO. 21-10335

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

PLUMBERS & PIPEFITTERS LOCAL UNION 630 WELFARE FUND,
Plaintiff–Appellant

v.

GLAXOSMITHKLINE LLC, ET AL.,

Defendants–Appellees

On Appeal from the United States District Court
for the Southern District of Florida

PLAINTIFF-APPELLANT PLUMBERS & PIPEFITTERS LOCAL UNION 630 WELFARE FUND'S OPENING BRIEF

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March 29, 2021

Counsel for Plaintiff-Appellant

CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to Eleventh Circuit Rule 26.1-1, counsel for Plaintiff-Appellant Plumbers & Pipefitters Local Union 630 Welfare Fund hereby certifies that the following is a complete list of the trial judge(s), all attorneys, persons, associations of persons, firms, partnerships, or corporations that have an interest in the outcome of the particular case on appeal, including subsidiaries, conglomerates, affiliates, and parent corporations, including any publicly held corporation that owns 10% or more of the party's stock, and other identifiable legal entities related to a party:

- Abel, Jonathan C. – Counsel for Defendant-Appellee Nostrum Laboratories Inc.
- Acrotech Biopharma LLC – subsidiary of Defendant-Appellee Aurobindo Pharma USA, Inc.
- Actavis Holdco US, Inc. – non-party affiliate of Defendant-Appellee Actavis Mid Atlantic LLC
- Actavis LLC – non-party affiliate of Defendant-Appellee Actavis Mid Atlantic LLC
- Actavis Mid Atlantic LLC – Defendant-Appellee
- Actavis US Holding LLC – non-party affiliate of Defendant- Appellee Actavis Mid Atlantic LLC
- Ajanta Pharma Ltd. (**AJANTPHARM** (National Stock Exchange of India)) – Defendant-Appellee
- Ajanta Pharma USA Inc. – Defendant-Appellee
- Agneshwar, Anand – Counsel for Defendants-Appellees Sanofi US Services, Inc. and Sanofi-Aventis U.S. LLC

- Amneal Pharmaceuticals, Inc. (**AMRX**) – non-party parent company of Defendants-Appellees Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC
- Amneal Pharmaceuticals LLC – Defendant-Appellee
- Amneal Pharmaceuticals of New York, LLC – Defendant- Appellee
- Apotex Corporation – Defendant-Appellee
- Apotex Holdings Inc. – non-party parent company of Defendants-Appellees Apotex Corp. and Apotex Inc.
- Apotex Inc. – Defendant-Appellee
- Armada, Franciso – Counsel for Defendant-Appellee GlaxoSmithKline LLC
- Arnold & Porter Kaye Scholer LLP – Counsel for Defendants- Appellees Sanofi US Services, Inc. and Sanofi-Aventis U.S. LLC
- Atkinson Baker & Rodriguez PC – Counsel for Defendants-Appellees Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation
- Auro AR LLC – subsidiary of Defendant-Appellee Aurobindo Pharma USA, Inc.
- Auro Health LLC – Defendant-Appellee
- Auro Medics Pharma LLC – subsidiary of Defendant-Appellee Aurobindo Pharma USA, Inc.
- Auro Packaging LLC – subsidiary of Defendant-Appellee Aurobindo Pharma USA, Inc.
- Auro Science LLC – subsidiary of Defendant-Appellee Aurobindo Pharma USA, Inc.
- Auro Science PTY Ltd. – subsidiary of Defendant-Appellee Aurobindo Pharma USA, Inc.
- Auro Vaccines LLC – subsidiary of Defendant-Appellee

- Aurobindo Pharma, Ltd. (**AUROPHARMA** (National Stock Exchange of India)) – Defendant-Appellee
- Aurobindo Pharma USA, Inc. – Defendant-Appellee
- Aurobindo Pharma USA LLC – subsidiary of Defendant- Appellee Aurobindo Pharma USA, Inc.
- Aurolife Pharma LLC – subsidiary of Defendant-Appellee Aurobindo Pharma USA, Inc.
- AuroLogistics LLC – subsidiary of Defendant-Appellee Aurobindo Pharma USA, Inc.
- Baird, Lisa M. – Counsel for Defendant-Appellee Par Pharmaceutical, Inc.
- Bandy, Kevin M. – Counsel for Defendants-Appellees Aurobindo Pharma USA, Inc. and Aurohealth LLC
- Baker, Douglas A. – Counsel for Defendants-Appellees Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation
- Battisti, Nicole – Counsel for Defendants-Appellees Zydus
- Bayman, Andrew T. – Counsel for Defendants-Appellees Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation
- BlackRock, Inc. (**BLK**) – non-party owning more than 10% of Defendant-Appellee Lannett Co., Inc.'s stock
- Blank Rome LLP – Counsel for Defendant-Appellee Apotex Corp.
- Blaschke, Matthew J. – Counsel for Defendants-Appellees Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation
- Blevins, Valerie J. – Counsel for Defendant-Appellee GlaxoSmithKline LLC
- Boehringer Ingelheim Corporation – Defendant-Appellee

- Boehringer Ingelheim International GmbH – Defendant-Appellee
- Boehringer Ingelheim Pharmaceuticals, Inc. – Defendant-Appellee
- Boehringer Ingelheim Promeco, S.A. de C.V. – Defendant-Appellee
- Boehringer Ingelheim USA Corporation – Defendant-Appellee
- Brueckner, Leslie – Counsel for Plaintiff-Appellant
- Burke, Maura – Counsel for Defendant-Appellee Lannett Co., Inc.
- Cadila Healthcare Limited (**CADILAHC** (National Stock Exchange of India)) – Defendant-Appellee and parent company of Defendant-Appellee Zydus Pharmaceuticals (USA) Inc.
- Calabrese, Susanne – Counsel for Defendant-Appellee Lannett Co., Inc.
- Cárdenas, Cristina – Counsel for Defendant-Appellee Heritage Pharmaceuticals Inc.
- Carlton Fields PA – Counsel for Defendants-Appellees Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation
- Cheffo, Mark S. – Counsel for Defendant-Appellee GlaxoSmithKline LLC
- Cohen, Lori G. – Counsel for Defendants-Appellees Teva Pharmaceuticals USA, Inc., Actavis Mid Atlantic, LLC, and Watson Laboratories, Inc.
- Coleman Jr., Booker T. – Counsel for Defendants-Appellees Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories Limited, and Dr. Reddy's Laboratories, SA
- Contract Pharmacal Corp. – Defendant-Appellee
- Conroy Simberg – Counsel for Defendant-Appellee Nostrum Laboratories Inc.
- Cosgrove, Paul – Counsel for Defendants-Appellees Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC

- Cosio, Eduardo – Counsel for Defendant-Appellee Geri-Care Pharmaceuticals, Corp.
- Cosio Law Group – Counsel for Defendant-Appellee Geri-Care Pharmaceuticals Corp.
- Daniel, Laurie W. – Counsel for Defendant-Appellees Glenmark Pharmaceuticals, Inc. USA, f/k/a Glenmark Generics Inc. USA, and Glenmark Pharmaceuticals, Ltd.
- Das, Devarati – Counsel for Defendant-Appellee Sandoz Inc.
- De Zayas, Veronica Louise – Counsel for Defendant-Appellee Pfizer Inc.
- Dean, Mead, Egerton, Bloodworth, Capouano & Bozarth, P.A. – Counsel for Defendant-Appellee Zydus Pharmaceuticals (USA) Inc.
- Dearman, Mark J. – Counsel for Plaintiff-Appellant
- Dechert LLP – Counsel for Defendant-Appellee GlaxoSmithKline LLC
- Devereaux, Stephen B. – Counsel for Defendants-Appellees Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation
- Dr. Reddy's Laboratories Inc. – Defendant-Appellee
- Dr. Reddy's Laboratories, Ltd. (**RDY**) – Defendant-Appellee
- Dr. Reddy's Laboratories, S.A. – Defendant-Appellee
- Duffy, Ann Marie – Counsel for Defendant-Appellee Sandoz Inc.
- Eichlin, John – Counsel for Defendant-Appellee Strides
- Eisenstein, Ilana H. – Counsel for Defendants-Appellees Sanofi-Aventis U.S. LLC and Sanofi US Services, Inc.
- Emcure Pharmaceuticals Ltd. – non-party parent company of Heritage Defendants-Appellees

- Endo International plc (**ENDP**) – non-party parent company of Defendant-Appellee Par Pharmaceutical, Inc.
- Evans Fears & Schuttert LLP – Counsel for Defendant- Appellee GlaxoSmithKline LLC
- Fahey, Patrick M. – Counsel for Defendants-Appellees Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation
- Fear, Chad R. – Counsel for Defendant-Appellee GlaxoSmithKline LLC
- Fox Rothschild LLP – Counsel for Defendant-Appellee Lannett Co., Inc.
- Friedman, Robert B. – Counsel for Defendants-Appellees Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer
- Geri-Care Pharmaceuticals Corp. – Defendant-Appellee
- Gladbach, Eric Francis – Counsel for Defendants-Appellees Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation
- Glassman, Julie B. – Counsel for Defendant-Appellee Geri-Care Pharmaceuticals Corp.
- GlaxoSmithKline (America) Inc. - Defendant-Appellee
- GlaxoSmithKline LLC - Defendant-Appellee
- GlaxoSmithKline PLC (**GSK**) - Defendant-Appellee
- Glenmark Pharmaceuticals, Inc., USA – Defendant-Appellee
- Glenmark Pharmaceuticals Ltd. (**GLENMARK** (National Stock Exchange of India)) – Defendant-Appellee
- Graham, Glen T. – Counsel for Defendants-Appellees Wockhardt USA LLC (formerly known as Wockhardt USA, Inc.) and Wockhardt Ltd.

- Gramke, Megan B. – Counsel for Defendants-Appellees Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories Limited, and Dr. Reddy's Laboratories, SA
- Greenberg Traurig LLP – Counsel for Defendants-Appellees Teva Pharmaceuticals USA, Inc., Watson Laboratories, Inc., and Actavis Mid Atlantic, LLC
- Haas, Frances M. – Counsel for Defendant-Appellee GlaxoSmithKline LLC
- Hari, Hrishikesh – Counsel for Defendant-Appellee GlaxoSmithKline LLC
- Hatzis, Georgia – Counsel for Defendants-Appellees Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC
- Heinz, Noah – Counsel for Plaintiff-Appellant
- Heis, Jennifer Snyder – Counsel for Defendant-Appellee PAI Holdings, LLC
- Henry, Terry M. – Counsel for Defendant-Appellee Apotex Corp.
- Hepler Broom LLC – Counsel for Defendants-Appellees Sanofi US Services, Inc. and Sanofi-Aventis U.S. LLC
- Heritage Pharmaceuticals, Inc. – Defendant-Appellee
- Herrera, Sujey – Counsel for Defendant-Appellee Heritage Pharmaceuticals Inc.
- Holland & Knight LLP – Counsel for Defendants-Appellees Contract Pharmacal Corporation, Glenmark Pharmaceuticals Inc., USA, f/k/a Glenmark Generics Inc., USA and Glenmark Pharmaceuticals Ltd., f/k/a Glenmark Generics Ltd.
- Hollingsworth LLP – Counsel for Defendant-Appellee Sandoz, Inc.
- Hollows, Allison – Counsel for Defendant-Appellee Lannett Co., Inc.
- Hook, April N. – Counsel for Defendants-Appellees Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation

- Horton, Rachel A.H. – Counsel for Defendants-Appellees Sanofi-Aventis U.S. LLC and Sanofi US Services, Inc.
- Ipsaro, John R. – Counsel for Defendants-Appellees Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories Limited
- Ironshore, Inc. – insurer of Defendant-Appellee Aurobindo Pharma USA, Inc.
- Kalas, John M. – Counsel for Defendant-Appellee Sandoz Inc.
- Katz, Clifford – Counsel for Defendants-Appellees Wockhardt USA LLC (f/k/a Wockhardt USA Inc.) and Wockhardt Ltd.
- Keller Lenkner LLC – Counsel for Plaintiff-Appellant
- Keller, Ashley C. – Counsel for Plaintiff-Appellant
- Kelley Drye & Warren – Counsel for Defendants-Appellees Wockhardt USA LLC (f/k/a Wockhardt USA Inc.) and Wockhardt Ltd.
- King & Spalding LLP – Counsel for Defendants-Appellees Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation
- Kitchens, Madison – Counsel for Defendants-Appellees Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation
- Klarfeld, Joshua – Counsel for Defendants-Appellees Aurobindo Pharma USA, Inc. and Auro Health LLC
- Kornilova, Anna – Counsel for Defendant-Appellee Sandoz Inc.
- Kretzschmar, Caitlyn – Counsel for Defendant-Appellee Sandoz Inc.
- Krigbaum, Stephen J. – Counsel for Defendants-Appellees Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation
- Lannett Co., Inc. (**LCI**) – Defendant-Appellee
- Lefkowitz, Jay P. – Counsel for Defendant-Appellee GlaxoSmithKline LLC

- Levin, Drew M. – Counsel for Defendant-Appellee Nostrum Laboratories Inc.
- Liederman, Arthur – Counsel for Defendants-Appellees Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited
- Linklaters LLP – Counsel for Defendant-Appellee Strides Pharma, Inc.
- Lindquist, Elizabeth Francesca – Counsel for Defendants-Appellees Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation
- Maichl, Linda E. – Counsel for Defendants-Appellees Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories Limited
- Mamounas, Joseph – Counsel for Defendant-Appellee Contract Pharmacal Corporation
- Mateo, Daniel – Counsel for Defendants-Appellees Glenmark Pharmaceuticals Inc., USA, f/k/a Glenmark Generics Inc., USA and Glenmark Pharmaceuticals Ltd., f/k/a Glenmark Generics Ltd.
- McCloud, Charles L. – Counsel for Defendant-Appellee Pfizer Inc.
- McClure, Anthony R. – Counsel for Defendants-Appellees Ranbaxy Inc. and Sun Pharmaceutical Industries, Inc.
- McGrath North Mullin & Kratz PC – Counsel for Defendants- Appellees Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation
- McMinn, Donald – Counsel for Defendant-Appellee Sandoz Inc.
- McVeigh, Amy – Counsel for Defendants-Appellees Glenmark Pharmaceuticals Inc., USA, f/k/a Glenmark Generics Inc., USA and Glenmark Pharmaceuticals Ltd., f/k/a Glenmark Generics Ltd.
- McWaters, Kyle M. – Counsel for Defendant-Appellee Sandoz Inc.
- Merkl, Neil – Counsel for Defendants-Appellees Wockhardt USA LLC (f/k/a Wockhardt USA Inc.) and Wockhardt Ltd.

- Mezzina, Paul – Counsel for Defendants-Appellees Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation
- Montgomery, Evan D. – Counsel for Defendant-Appellee GlaxoSmithKline LLC
- Mooney, Nichole M. – Counsel for Defendants-Appellees Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited
- Morrison Mahoney LLP – Counsel for Defendant-Appellee Zydus Pharmaceuticals (USA) Inc.
- Moyo, Elizabeth L. – counsel for Defendants-Appellees Ranbaxy Inc. and Sun Pharmaceutical Industries, Inc.
- Mullins, Edward M. – Counsel for Defendant-Appellee Par Pharmaceutical, Inc.
- Murphy, Melissa F. – Counsel for Defendant-Appellee Apotex Corp.
- Muskett, Eileen Oakes – Counsel for Defendant-Appellee Lannett Co., Inc.
- Mylan, Inc. – Defendant-Appellee
- Mylan Institutional LLC – Defendant-Appellee
- Mylan Laboratories Ltd. – Defendant-Appellee
- Mylan Pharmaceuticals, Inc. – Defendant-Appellee
- Nelson Mullins Riley & Scarborough LLP– Counsel for Defendant-Appellee GlaxoSmithKline LLC
- Natrol LLC – subsidiary of Defendant-Appellee Aurobindo Pharma USA, Inc.
- Nostrum Laboratories Inc. – Defendant-Appellee
- Novartis AG – (**NVS**) non-party parent company of Defendant- Appellee Sandoz Inc.

- Nyemaster Goode PC – Counsel for Defendant-Appellee GlaxoSmithKline LLC
- O'Neill, Amy L. – Counsel for Defendants-Appellees Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation
- Par Pharmaceutical, Inc. – Defendant-Appellee
- PAI Holdings, LLC – Defendant-Appellee
- Petrosinelli, Joseph G. – Counsel for Defendant-Appellee Pfizer Inc.
- Pfizer, Inc. (**PFE**) – Defendant-Appellee
- Phillips Lytle LLP – Counsel for Defendant-Appellee GlaxoSmithKline LLC
- Pietragallo Gordon Alfano Bosick & Raspanti LLP – Counsel for Defendants-Appellees Mylan Inc., Mylan Pharmaceuticals Inc., and Mylan Institutional LLC
- Pigman, Heather – Counsel for Defendant-Appellee Sandoz Inc.
- Plumbers & Pipefitters Local Union 630 Welfare Fund – Plaintiff-Appellant
- Porter Wright Morris & Arthur LLP – Counsel for Defendants- Appellees Ranbaxy Inc. and Sun Pharmaceutical Industries, Inc.
- Powers, James G. – Counsel for Defendants-Appellees Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation
- Prease, Lauren – Counsel for Defendant-Appellee Sandoz Inc.
- Ranbaxy Inc. – Defendant-Appellee
- Rankin, W. Jason –Counsel for Defendants-Appellees Sanofi US Services, Inc. and Sanofi-Aventis U.S. LLC
- Reed Smith – Counsel for Defendants-Appellees Heritage Pharmaceuticals Inc., and Par Pharmaceutical, Inc.

- Reefer, Jason M. – Counsel for Defendants-Appellees Mylan Inc., Mylan Pharmaceuticals Inc., and Mylan Institutional LLC
- Reinhart, Honorable Bruce E. – U.S. Magistrate Judge
- Reissaus, Andrew L. – Counsel for Defendant-Appellee Sandoz Inc.
- Rodriguez, Justin D. – Counsel for Defendants-Appellees Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation
- Rosenberg, Honorable Robin L. – U.S. District Court Judge
- Rothschild, Philip – Defendants-Appellees Glenmark Pharmaceuticals Inc., USA, f/k/a Glenmark Generics Inc., USA and Glenmark Pharmaceuticals Ltd., f/k/a Glenmark Generics Ltd.
- Rubenstein, Brian H. – Counsel for Defendants-Appellees Actavis Mid-Atlantic LLC, Teva Pharmaceuticals USA, Inc., and Watson Laboratories, Inc.
- Ruehlmann, Gregory A. – Counsel for Defendants-Appellees Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation
- Sabnis, Cheryl A. – Counsel for Defendants-Appellees Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation
- Sachse, Will W. – Counsel for Defendant-Appellee GlaxoSmithKline LLC
- Sandoz Inc. – Defendant-Appellee
- Sanofi-Aventis U.S. LLC – Defendant-Appellee
- Sanofi (**SNY**) – Defendant-Appellee Sanofi, a publicly traded corporation, indirectly holds a 100% interest in Sanofi-Aventis U.S. LLC and Sanofi US Services Inc.
- Sanofi US Services Inc. – Defendant-Appellee
- Sapp, Richard J. – Counsel for Defendant-Appellee GlaxoSmithKline LLC

- Schachtman, Nathan A. – Counsel for Defendants-Appellees Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories Limited, and Dr. Reddy's Laboratories, SA

- Scully, Samantha – Counsel for Defendant-Appellee Sandoz Inc.

- Sentenac, Mark Alan – Counsel for Defendants-Appellees Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation

- Seth, Neal – Counsel for Defendants-Appellees Ajanta Pharma Ltd., Ajanta Pharma USA Inc., and Torrent Pharma Inc.

- Sheehan, Thomas J. – Counsel for Defendant-Appellee GlaxoSmithKline LLC

- Sheppard, James Robert III – Counsel for Defendants- Appellees Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation

- Shipman & Goodwin – Counsel for Defendants-Appellees Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation

- Shook, Hardy & Bacon, LLP – Counsel for Defendant- Appellee GlaxoSmithKline LLC

- Stearns Weaver Miller Weissler Alhadeff & Sitterson, PA – Counsel for Defendant-Appellee Pfizer Inc.

- Strides Pharma, Inc. – Defendant-Appellee

- Strides Pharma Science Ltd. (**STAR** (National Stock Exchange of India)) – non-party parent company of Defendant-Appellee Strides Pharma, Inc.

- Sun Pharmaceutical Holdings USA, Inc. – non-party parent company of Defendants-Appellees Ranbaxy Inc. and Sun Pharmaceutical Industries, Inc.

- Sun Pharmaceutical Industries, Inc. – Defendant-Appellee

- Sun Pharmaceutical Industries Ltd. (**SUNPHARMA** (National Stock Exchange of India)) – Defendant-Appellee

- Tam, Jonathan S. – Counsel for Defendant-Appellee GlaxoSmithKline LLC
- Teva Pharmaceutical Industries Ltd. (**TEVA**) – non-party parent company of Defendants-Appellees Actavis Mid-Atlantic LLC; Teva Pharmaceuticals USA, Inc.; and Watson Laboratories, Inc.
- Teva Pharmaceuticals U.S.A., Inc. – Defendant-Appellee
- Thoma, Oliver Peter – Counsel for Defendants-Appellees Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation
- Thomas, Jane – Counsel for Defendant-Appellee Apotex Corp.
- Thompson, Sara – Counsel for Defendants-Appellees Teva Pharmaceuticals USA, Inc., Actavis Mid Atlantic, LLC, and Watson Laboratories, Inc.
- Torrent Pharma Inc. – Defendant-Appellee
- Torrent Pharmaceuticals Ltd. (**TORNTPHARM**) – non-party parent company of Defendant-Appellee Torrent Pharma Inc.
- Trischler, Clem C. – Counsel for Defendants-Appellees Mylan Inc., Mylan Pharmaceuticals Inc., and Mylan Institutional LLC
- Tutt, Diane H. – Counsel for Defendant-Appellee Nostrum Laboratories Inc.
- Tween, Douglas – Counsel for Defendant-Appellee Strides Pharma, Inc.
- Ulmer & Berne LLP – Counsel for Defendants-Appellees Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals of New York, LLC, Aurobindo Pharma USA, Inc., Auro Health LLC, Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories Limited, Dr. Reddy's Laboratories, SA, and PAI Holdings, LLC
- Viatris Inc. (**VTRS**) – Defendants–Appellees Mylan Pharmaceuticals Inc., Mylan Institutional LLC, Mylan Inc., and Mylan Laboratories Ltd., are wholly owned indirect subsidiaries of non-party Viatris Inc., a publicly traded company
- Vintage Pharmaceuticals, LLP – non-party affiliate of Defendant-Appellee Par Pharmaceutical, Inc.

- Watson Laboratories, Inc. – Defendant-Appellee
- Weinstein, Corey – Counsel for Defendants-Appellees Ajanta Pharma USA Inc. and Ajanta Pharma Ltd.; and Defendant- Appellee Torrent Pharma Inc.
- Westby, Sarah A. – Counsel for Defendants-Appellees Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation
- White, Sara – Counsel for Defendants-Appellees Ranbaxy Inc. and Sun Pharmaceutical Industries, Inc.
- Wiley Rein LLP – Counsel for Defendants-Appellees Ajanta Pharma USA Inc. and Ajanta Pharma Ltd.; and Defendant- Appellee Torrent Pharma Inc.
- Williams & Connolly LLP – Counsel for Defendant-Appellee Pfizer, Inc.
- Winters, Daniel – Counsel for Defendants-Appellees Glenmark Pharmaceuticals Inc., USA, f/k/a Glenmark Generics Inc., USA and Glenmark Pharmaceuticals Ltd., f/k/a Glenmark Generics Ltd.
- Wockhardt Bio AG (**WBIO**) – non-party parent company of Defendants-Appellees Wockhardt USA LLC and Wockhardt Limited
- Wockhardt, Ltd. (**WOCKPHARMA** (National Stock Exchange of India)) – Defendant-Appellee
- Wockhardt USA LLC – Defendant-Appellee
- Wong, Andrew – Counsel for Defendants-Appellees Wockhardt USA LLC and Wockhardt Limited
- Yearick, Garth – Counsel for Defendants-Appellees Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation
- Yoo, Thomas J. – Counsel for Defendants-Appellees Glenmark Pharmaceuticals Inc., USA, f/k/a Glenmark Generics Inc., USA and Glenmark Pharmaceuticals Ltd., f/k/a Glenmark Generics Ltd.

- Yoon, Sojin – Counsel for Defendant-Appellees Wockhardt USA LLC (f/k/a Wockhardt USA Inc.) and Wockhardt Ltd.

- Zousmer, Julia – Counsel for Defendants-Appellees Boehringer Ingelheim

Dated: March 29, 2021

Respectfully submitted,

/s/ *Ashley Keller*

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STATEMENT REGARDING ORAL ARGUMENT

Appellant respectfully requests oral argument because this appeal turns on two questions of first impression in this Court, one involving class-representative standing, and a second involving the application of fundamental preemption principles to a complex statutory and regulatory regime. Oral argument would assist the Court in clarifying and testing the parties' arguments.

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JURISDICTIONAL STATEMENT

Federal subject matter jurisdiction is proper under 28 U.S.C. §1332, as amended by the Class Action Fairness Act of 2005, 28 U.S.C. §1332(d)(2), because (a) there are at least 100 class members; (b) the matter in controversy exceeds $5 million; and (c) at least one Plaintiff is a citizen of a different state than at least one Defendant. This Court has appellate jurisdiction under 28 U.S.C. §1291 because the district court's order fully disposed of Plumbers' action.

STATEMENT OF THE ISSUES

1. Where a putative class representative's claim derives from one state's law, does constitutional standing bar that putative representative from bringing claims on behalf of class members who have the same injuries but whose claims would sound in a different state's law?

2. In *Mutual Pharmaceutical Co. v. Bartlett,* 570 U.S. 472 (2013), the Supreme Court held that state claims are preempted when they require a defendant to stop selling a drug that the FDA has found safe and effective based on the available scientific evidence. But the Court's holding did "not address state design-defect claims that parallel the federal misbranding statute," which "requires a manufacturer to pull even an FDA-approved drug from the market when it is 'dangerous to health.'" *Id.* at 487 n.4 (quoting 21 U.S.C. §352(j)). This case squarely presents the question the Supreme Court left open: where plaintiffs plead a

defect in a drug based on post-approval scientific evidence the FDA never considered, is state law preempted even though both state and federal law require drug sellers to remove the unsafe product from the market?

CONSTITUTIONAL, STATUTORY, AND REGULATORY ADDENDUM

Supremacy Clause of the Constitution

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

U.S. Const. art. VI, cl. 2.

Food, Drug, and Cosmetics Act, Prohibited Acts

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 344, 350d, 355, or 360bbb-3 of this title.

***

(g) The manufacture within any Territory of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

21 U.S.C. § 331.

Food, Drug, and Cosmetics Act, Penalties

(a) Violation of section 331 of this title; second violation; intent to defraud or mislead

(1) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.

(2) Notwithstanding the provisions of paragraph (1) of this section, if any person commits such a violation after a conviction of him under this section has

become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.

(b) Prescription drug marketing violations

(1) Notwithstanding subsection (a), any person who violates section 331(t) of this title by—

(A) knowingly importing a drug in violation of section 381(d)(1) of this title,

(B) knowingly selling, purchasing, or trading a drug or drug sample or knowingly offering to sell, purchase, or trade a drug or drug sample, in violation of section 353(c)(1) of this title,

(C) knowingly selling, purchasing, or trading a coupon, knowingly offering to sell, purchase, or trade such a coupon, or knowingly counterfeiting such a coupon, in violation of section 353(c)(2) of this title, or

(D) knowingly distributing drugs in violation of section 353(e)(1) of this title,

shall be imprisoned for not more than 10 years or fined not more than $250,000, or both.

***

(c) Exceptions in certain cases of good faith, etc.

No person shall be subject to the penalties of subsection (a)(1) of this section,

(1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or

(2) for having violated section 331(a) or (d) of this title, if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 331(a) of this title, that such article is not adulterated or misbranded, within the meaning of this chapter designating this chapter or to the effect, in case of an alleged violation of section 331(d) of this title, that such article is not an article which may not, under the provisions of section 344 or 355 of this title, be introduced into interstate commerce; or

21 U.S.C. § 333

Food, Drug, and Cosmetics Act, Definition of Misbranding

A drug or device shall be deemed to be misbranded—

(a) False or misleading label

(1) If its labeling is false or misleading in any particular. Health care economic information [is not considered misleading under certain conditions.]

***

(f) Directions for use and warnings on label

Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement. . . .

***

(i) Drug; misleading container; imitation; offer for sale under another name

(1) If it is a drug and its container is so made, formed, or filled as to be misleading; or

(2) if it is an imitation of another drug; or

(3) if it is offered for sale under the name of another drug.

(j) Health-endangering when used as prescribed

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.

***

(p) Packaging or labeling of drugs in violation of regulations

If it is a drug and its packaging or labeling is in violation of an applicable regulation issued pursuant to section 1472 or 1473 of Title 15.

21 U.S.C. § 352

Food and Drug Administration Regulation on Approved Drugs

Adulteration and misbranding of an approved drug.

All drugs, including those the Food and Drug Administration approves under section 505 of the act and this part, are subject to the adulteration and misbranding provisions in sections 501, 502, and 503 of the Act [codified at 21 U.S.C. §§ 351–353]. FDA is authorized to regulate approved new drugs by regulations issued through informal rulemaking under sections 501, 502, and 503 of the Act.

21 C.F.R. § 314.170

INTRODUCTION

N-Nitrosodimethylamine (NDMA) is a byproduct of rocket fuel combustion. It is used to induce tumors in animal experiments. Long-recognized by the scientific community as a potent carcinogen, NDMA serves no medicinal purpose whatsoever. In late 2019, after the well-known brand-name drug Zantac and its generic equivalent ranitidine had been on the market for nearly four decades, the Food and Drug Administration (FDA) finally learned the truth about this dangerous drug: it degrades into NDMA. Alerted to Zantac's cancer hazard by independent scientists, the FDA recalled all ranitidine containing unacceptable levels of NDMA. Shortly thereafter, the agency concluded that *no* ranitidine was safe and withdrew *all* ranitidine from the nation's shelves. Today, Americans are safe from this dangerous drug. Unfortunately, FDA's actions came too late for scores of people who suffered often fatal cancers from using Zantac.

Drug companies made billions selling prescription Zantac, and most of that money came from third-party payors (TPPs). One such payor was Plumbers & Pipefitters Local Union 630 Welfare Fund (Plumbers), a not-for-profit, self-funded welfare-benefit plan that pays or reimburses its members for the costs of prescription drugs. *See* Third-Party Payors Class Action Complaint (TPPCAC) ¶23. Plumbers has reimbursed for prescription ranitidine since before 2010. TPPCAC ¶219. Plumbers seeks damages for paying for a dangerous drug on the false promise it was

safe, and seeks to represent a class of TPPs who likewise paid or reimbursed for this dangerous drug.

The district court first pared down Plumbers' suit to a small number of states on standing grounds, then dismissed it as preempted altogether. These holdings should be reversed. The district court did not doubt Plumbers had standing *for itself*, but nonetheless held it lacked standing to bring claims for class members in other states. This was incorrect for the simple reason that standing is jurisdictional and does not turn on the source of law for the claims. Three circuit courts have addressed this question, and all have rejected the district court's position.

The district court's preemption rulings are no more persuasive. Plumbers' suit is allowed under state law, which imposes a duty on companies not to sell unreasonably dangerous products, and federal law does not preempt the suit. The reason is simple. The Food Drug and Cosmetic Act (FDCA) has no express preemption clause and does not occupy the field of drug safety, so preemption applies only when federal and state law *conflict*. In that case, the Supremacy Clause requires state law to yield. But the Constitution does not void state laws where no conflict exists. That is true here. State law prohibits Defendants from selling dangerous drugs like Zantac. And the federal misbranding provision of the FDCA, 21 U.S.C. §§352(j); (p); (a)(1); §331, requires the same thing. Indeed, the FDA compelled Defendants—under federal law—to cease all ranitidine sales.

On those facts, the district court's decision that compliance with both state and federal law was *impossible* makes little sense. It certainly finds no support in preemption precedent, including *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013), on which the district court heavily relied. In *Bartlett*, the plaintiff proved to a jury that state design-defect law required the defendant to strengthen the warnings for its drug. On appeal, the Defendant argued that federal law forbade those label changes, making compliance with the laws of both sovereigns impossible. Plaintiff proposed that joint compliance was possible because Defendant could withdraw from the market altogether, but the Supreme Court rejected that workaround and applied ordinary conflict preemption. In doing so, the Court made crystal-clear that its holding did *not* extend to "the rare case in which state or federal law actually require[d] a product to be pulled from the market." 570 U.S. at 487, n.3.

This is that case. As Plumbers alleged in its pleadings and will prove at trial, state *and* federal law required Defendants to stop selling Zantac long before the FDA learned the truth and forced that result. Here, the state and federal duties do not conflict because they are parallel. Defendants cannot hide behind the Supremacy Clause to avoid state-law liability for the harm done by their dangerous drug.

STATEMENT OF THE CASE

I. FACTS[1]

TPPs covered the prescription version of Zantac and its generic equivalent ranitidine for more than thirty years. TPPCAC ¶219. Never during that time did drug companies disclose what independent scientists and FDA have finally uncovered: Zantac degrades into staggering amounts of NDMA, a potent and well-known human carcinogen. TPPCAC ¶¶10, 283, 328, 338. Hundreds of thousands of Americans fell prey to Zantac's cancer danger.

This tragedy did not have to happen. The corporations that made billions of dollars manufacturing, distributing, and selling Zantac for the past thirty years knew, or easily could have discovered, that it contains dangerous levels of NDMA. TPPCAC ¶330. Instead of taking action to make Zantac's dangers known to consumers, these corporations did nothing. For decades, they reaped enormous profits from an unreasonably dangerous drug in violation of both state and federal law. TPPCAC ¶190.

A. Plumbers Is a TPP That Covered Zantac.

Plumbers is a not-for-profit, self-funded welfare benefit plan that pays for or reimburses its members' prescription drug costs. TPPCAC ¶23. Plumbers has been

[1] Plaintiff's claims were rejected by the district court on a motion to dismiss; the facts relevant to this appeal are accordingly the allegations in the pleadings.

reimbursing its members for the prescription form of Zantac since before 2010. TPPCAC ¶219. Like all TPPs, Plumbers does not pay or reimburse for every drug; instead, it has a "drug formulary" that lists which drugs it will cover and at what cost levels. TPPCAC ¶¶129–43. Because having their drug covered at the lowest out-of-pocket costs to a consumer drives profits, drug companies have a strong incentive to market to TPPs. TPPCAC ¶136. As one would expect, a drug that is more expensive, less effective, or less safe than its rivals that treat the same conditions will have difficulty in receiving robust coverage from TPPs. Many safe, cheap, effective drugs treat heartburn and related conditions.

B. Zantac Was a Hugely Profitable Drug.

Zantac belongs to a class of drugs known as H2 blockers that help to decrease the acidity of the stomach. TPPCAC ¶186. It was developed in the late 1970s by a predecessor to the pharmaceutical giant, GlaxoSmithKline (GSK). TPPCAC ¶188–89. Having witnessed the huge success of Tagament, also an H2 blocker, GSK was determined to get a piece of the fast-growing antacid market. TPPCAC ¶187.

GSK pushed the FDA to approve Zantac and succeeded in 1983. TPPCAC ¶190. The company knew that the exclusivity period following FDA-approval, before the generics rush in, is the time to maximize profits. GSK did so. A necessary part of this strategy was gaining formulary coverage for Zantac, which it achieved after a heavy marketing push. TPPCAC ¶¶206–09. Zantac delivered previously

unprecedented profits, making pharmaceutical history as the first drug ever to generate $1 billion in annual sales. TPPCAC ¶190. The success of this "blockbuster" drug sparked a series of corporate mergers and acquisitions that propelled GSK to the top of the pharmaceutical industry.

In the 1990s, GSK joined with another industry giant, Pfizer, to expand Zantac's market reach even further. TPPCAC ¶191. Together, these companies executed a plan to get FDA approval for an over-the-counter (OTC) version of the drug that patients could take without a prescription or any guidance from a doctor. TPPCAC ¶192–94. Eventually, the companies were forced by antitrust issues to transfer the marketing rights for OTC Zantac to Boehringer Ingelheim. TPPCAC ¶197–98.

For decades, Zantac continued to generate huge profits in both its branded and generic forms. As recently as 2018, it remained one of the top ten antacid drugs sold in the United States. TPPCAC ¶215. It was just a year later that the FDA learned about Zantac's true safety profile and forced the drug companies to pull Zantac from the nation's shelves.

C. The Truth About Zantac Comes Out.

In late 2019 and early 2020, the FDA received two separate Citizen Petitions from groups of concerned, independent scientists. The first petition alerted the agency that Zantac may contain exceedingly high levels of NDMA. TPPCAC ¶227.

The second indicated that the NDMA was coming *from the Zantac itself*—providing evidence that over time, and especially when exposed to heat, ranitidine degrades, throwing off dangerous amounts of NDMA. TPPCAC ¶¶485–86.

These Citizen Petitions got the FDA's immediate attention. And for good reason. Discovered in the early 1900s as a byproduct of rocket fuel, NDMA is a well-known and potent carcinogen. TPPCAC ¶5. EPA and the International Agency for Research on Cancer classify it as a probable human carcinogen. TPPCAC ¶232. The World Health Organization cites "conclusive evidence" that NDMA can cause cancer. TPPCAC ¶236. Both the Department of Health and Human Services and the FDA have concluded that exposure to NDMA can cause cancer. TPPCAC ¶¶234–35. Today, NDMA has only one recognized use: to induce tumors in animals that are subject to experimentation.

Prompted by the Citizen Petitions, the FDA quickly took action to investigate. Its initial testing identified Zantac products containing "unacceptable levels" of NDMA. TPPCAC ¶483. Based on those results, the FDA requested that companies recall any Zantac confirmed to contain NDMA above acceptable levels. As the FDA explained, a recall is warranted where the agency concludes that a product is in violation of the laws it administers. Generally, the FDA asks companies to perform recalls voluntarily; if they resist, FDA may initiate seizure proceedings.

In early 2020, the FDA performed additional testing, which revealed that the NDMA in Zantac increases over time and can rise to dangerous levels as the product approaches its expiration date. TPPCAC ¶488. These results "eroded [the FDA's] confidence" that *any* Zantac product could remain stable and safe through its labeled expiration date. *Id.* That loss of confidence prompted FDA to call for the immediate withdrawal of *all* Zantac from the market without any delay for NDMA testing. The FDA was not alone in taking swift action to protect the public against any further harm from Zantac. By 2020, forty-three other countries and jurisdictions had restricted or outright banned any further sales of the drug. TPPCAC ¶489.

D. Defendants Knew or Should Have Known About Ranitidine's Dangers Decades Sooner.

The tragedy of the Zantac story is it did not have to happen this way. From early on, there were huge red flags pointing to Zantac's cancer hazard. But instead of warning the public, raising concerns with the FDA, or even further investigating the issue themselves, the drug companies did nothing. They were too intent on protecting their profits from this blockbuster drug.

For example, in 1983, a group of Italian scientists published a study showing that NDMA is produced when Zantac mixes with nitrites in the stomach's gastric fluids. TPPCAC ¶¶222–25. Nitrites are chemicals contained in certain foods, particularly processed meats. The Italian scientists made a simple suggestion: people using Zantac, especially those using it for extended periods, should be

advised to eat a diet low in nitrites or avoid taking the medication close in time to meals. Discovery has revealed similar studies that were never shared with the public or the FDA.

People using Zantac never got sound advice. Instead, the drug companies spent millions on advertising campaigns showing people taking Zantac *long-term* to control heartburn caused by food like tacos and pizza, which are notoriously *high* in nitrites. TPPCAC ¶¶285; 288–309. And they downplayed the potential hazard flagged by the Italian scientists, deeming the risk "unrealistic" because most people would take Zantac for only a short time. TPPCAC ¶8.

In 1987, GSK published a study that further downplayed the risk. TPPCAC ¶¶224–25. The study examined the gastric contents of human patients and reported finding uniformly safe levels of NDMA. But that study, which GSK conducted itself, failed to employ the widely accepted, gold-standard method for measuring NDMA, relying instead on inferior technology. *Id.* Worse, GSK discarded two-thirds of the samples—those with the highest levels of ranitidine—out of concern that those samples would contain supposedly false-positive "high concentrations of N-nitroso compounds," of which NDMA is one. TPPCAC ¶224. With that omission, it is no wonder the study produced exactly the results GSK wanted. The company and indeed the entire industry claimed this manipulated study showed ranitidine did not increase nitrosamines.

E. Selling Pharmaceuticals Is Only Lawful with FDA Approval

The FDCA both sets the regulatory structure for pharmaceuticals and directly imposes specific requirements on drugs in interstate commerce.

Selling even a perfectly safe and effective new drug without FDA pre-approval violates federal law. 21 U.S.C. §355(a). The manufacturer who develops a new drug—referred to as the brand-name drug—must submit a New Drug Application (NDA) to the FDA. The FDA only approves a drug once it determines based on scientific evidence and data submitted by the NDA applicant that it is safe and effective. *Id.* §355(d); *see also Bartlett*, 570 U.S. at 476 ("for the FDA to consider a drug safe, the drug's 'probable therapeutic benefits must outweigh its risk of harm'" (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 140 (2000)). Once an NDA is approved, it comes with ongoing duties to send new and emerging scientific information to the FDA and to unilaterally update the drug's label when the evidence warrants it. *See* 21 C.F.R. §314.70.

After the brand-name manufacturer enjoys the period of exclusivity designed to spur innovation, other drug manufacturers can file Abbreviated New Drug Applications (ANDAs) to sell a virtually identical drug called a generic. *See* 21 U.S.C. §355(j). Generic drugs may differ in some respects from the branded drug (for example, the expiration date), but the warnings and precautions, active ingredient, and dosage must be the same. *Id.* Generic drug companies cannot, under

what the courts have termed the "duty of sameness," unilaterally change or update a warning label where the branded drug has not yet been changed.

F. Congress Made Pharmaceutical Manufacturers and Sellers Responsible for Patient Safety by Imposing a Continuing Duty Not to Sell Misbranded Drugs.

A drug can be illegal to sell under federal law even if it has been FDA-approved. *See Bartlett*, 570 U.S. at 487 n.4 ("The misbranding statute requires a manufacturer to pull even an FDA-approved drug from the market when it is [misbranded]…." (citing 21 U.S.C. §352(j))). That is because FDA approval of a generic or branded drug is necessary to lawfully sell the drug, but it is not sufficient. All participants in the distribution system—from manufacturers to retailers—have a continuing duty under federal law not to sell "misbranded" drugs. *See* 21 U.S.C. §§331, 333–334 (authorizing civil and criminal penalties for manufacturing, selling, receiving, or delivering a misbranded drug into interstate commerce). A drug is misbranded 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"; if "its packaging or labeling is in violation of an applicable [FDA] regulation"; or if its "labeling is false or misleading in any particular." 21 U.S.C. §352(j); (p); (a)(1).

The FDCA's misbranding provision gives important powers to the FDA, since it can both enforce the statute and create regulations that trigger criminal liability.

But the definition of a misbranded drug is unambiguously broader than merely failing to comply with FDA regulations. That is obvious from the text of the statute itself, which refers to FDA regulations in only one of the definitions of misbranding. *See* 21 U.S.C. §352(p). The other statutory definitions forbid the manufacture or sale of a drug that is dangerous to health when used as labeled or that has a false or misleading label. 21 U.S.C. §§352(j), (a)(1). Those two definitions turn solely on the statutory text; they do not depend on FDA regulations. Indeed, "it has remained a central premise of federal drug regulation that the manufacturer," not the FDA, "bears responsibility for the content of its label at all times" and "is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Wyeth v. Levine*, 555 U.S. 555, 570–71 (2009).

The FDA's regulations confirm that NDA or ANDA approval in the past offers no dispensation in the present from the misbranding provisions of the FDCA. The agency implemented a separate regulatory section to make just this point, titled "Adulteration and misbranding of an *approved* drug." 21 C.F.R. §314.170 (emphasis added). This section states: "All drugs, including those the Food and Drug Administration approves under [the NDA and ANDA provisions], are subject to the adulteration and misbranding provisions" of the FDCA. *Id.* At the time this provision was promulgated, "several comments urged that this section be deleted, believing that the only lawful procedure for dealing with adulterated or misbranded

approved new drugs is by withdrawal of approval of the application." 50 Fed. Reg. 7452, 7488 (Feb. 22, 1985). The FDA disagreed, explaining:

> the new drug provisions do not insulate approved drugs and antibiotics from the general adulteration and misbranding provisions of the act. As FDA has previously noted, the statutory scheme contemplates FDA's application of the adulteration and misbranding standards to all drugs, irrespective of whether those drugs have been subject to the premarket approval requirements of the act.

Id.

Federal misbranding law applies up and down the supply chain. It applies to manufacturers and retailers alike, both of which must not manufacture, receive, or sell a misbranded drug in interstate commerce. *See* 21 U.S.C. §§331, 333–334. Congress was so intent on protecting consumers from misbranded drugs that it created criminal liability with no *mens rea*—a strict liability crime. *See United States v. Dotterweich*, 320 U.S. 277, 281 (1943) (The FDCA "dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing.").

FDA pre-approval and liability for misbranding post approval are complements in Congress's regulatory scheme. FDA approval speaks authoritatively on the safety and effectiveness of a drug *at that time* based on the information available. But FDA approval "do[es] not give drug manufacturers an unconditional right to market their federally approved drug *at all times* with the precise label initially approved by the FDA." *Wyeth*, 555 U.S. at 592 (Thomas, J.,

concurring) (emphasis added). Science develops. New risks come to light. And so, "[t]he misbranding statute requires a manufacturer to pull even an FDA-approved drug from the market when it is 'dangerous to health' even if 'used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.'" *Bartlett*, 570 U.S. at 487 n.4 (quoting 21 U.S.C. §352(j)).

G. The Proceedings Below

Once the public heard the truth about Zantac, thousands filed lawsuits seeking relief for the harm that the drug caused them. In February 2020, those lawsuits were centralized before the district court. *See In re Zantac (Ranitidine) Prods. Liab. Litig.*, 437 F. Supp. 3d 1368 (J.P.M.L. 2020). Plumbers was a plaintiff and putative class representative in the TPPCAC.

The TPPCAC alleged an array of state law claims, stating at length the scientific reasons ranitidine degrades into NDMA, the tests that should have revealed that fact, and the studies that put Defendants on notice that ranitidine causes cancer. Taken as true, the allegations show what the FDA's rapid recall upon learning the risks confirmed: no one with an accurate understanding of ranitidine's risks would consume or sell it (or, of course, reimburse for it). It is inherently defective. Defendants' marketing and continued representations that it was safe were misrepresentations.

II. THE RULINGS BELOW

Defendants moved to dismiss on an array of grounds, but only preemption and standing are relevant here. On preemption, Generic Defendants argued that all claims were preempted because none of them could change the design or label of ranitidine without pre-approval from the FDA. Plaintiffs responded that state law forbids the sale of any drug that is unjustifiably dangerous due to its defective design. And that duty is harmonious with federal law when a drug is misbranded, which is to say, when 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," 21 U.S.C. §352(j), or where the drug's label is "false or misleading in any particular," 21 U.S.C. §352(a)(1). Because federal law forbids the manufacture, sale, or receipt of misbranded drugs, 21 U.S.C. §331, and state law requires the same thing, the two regimes do not conflict. On standing, Defendants argued that class representatives could not bring claims on behalf of putative class members from other states.

After a hearing, the district court issued five Orders, three of which are relevant in this appeal.

The first Order, D.E.2512 ("Generic Order"), granted the generic manufacturer defendants' preemption motion. Crucially, the court "assume[d]," for the purposes of its order, "that Plaintiffs have adequately alleged that ranitidine

products were misbranded" under the FDCA. D.E.2512 at 30. Nonetheless, the court held that *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), and *Bartlett*, 570 U.S. 472, required a finding of preemption. The court explained,

> *Mensing* and *Bartlett* further instruct that the ability to comply with both federal and state law by withdrawing misbranded ranitidine products from the market does not defeat pre-emption. A claim based on an allegation that a generic drug's labeling renders the drug misbranded is a pre-empted claim because the drug's manufacturer cannot independently and lawfully change FDA-approved labeling.

D.E.2512 at 27. The district court opined it was "of no matter" that "federal law imposes criminal liability on a drug manufacturer that introduces a misbranded drug into interstate commerce" because only the United States, not a private plaintiff, can enforce it. *Id.* at 28. Similarly, the court deemed Supreme Court cases about parallel claims irrelevant because they "did not address impossibility preemption." D.E.2512 at 36 (referring to *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), and *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996)).

The court further concluded that preemption applies to factual allegations, not to claims. *Id.* at 29 ("[A]llegations that [generic] ranitidine products were defectively designed because they break down into NDMA and claims based on failure to warn consumers that the products contained NDMA or could break down into NDMA when ingested" are "pre-empted."). Accordingly, the court required

"Plaintiffs' counsel" to "identify these allegations and to omit them from the claims against Generic Manufacturer Defendants upon repleading the Master Complaints." *Id.* at 29.

The court relied upon the reasoning in the Generic Order when it issued the second Order relevant here, which granted the brand-name manufacturer defendants' preemption motion. *See* D.E.2532 ("Brand Order") at 24 ("As with generic drugs, a claim based on an allegation that a brand-name drug's FDA-approved formulation renders the drug misbranded" that is, any claim based on the design of ranitidine, "is a pre-empted claim because the drug's manufacturer cannot independently and lawfully change a drug formulation that the FDA has approved."). The court similarly ordered Plaintiffs to "omit [misbranding] allegations from claims against the [brand-name] Defendants when repleading." *Id.* at 25.

The third relevant Order dismissed swaths of Plumbers' claims on standing and shotgun pleading grounds. On standing, the court held "that a named plaintiff lacks standing to assert claims on behalf of putative class members whose claims arise under other states' laws." D.E.2515 ("Standing Order") at 36. Consequently, it dismissed all claims for "reimburse[ment] for ranitidine products in Alaska, Arkansas, California, Connecticut, Delaware, the District of Columbia, Hawaii, Idaho, Kansas, Massachusetts, New Hampshire, New York, North Dakota, Oklahoma, Puerto Rico, Rhode Island, South Dakota, Vermont, Virginia,

Washington, or West Virginia." *Id.*; *see also id.* at 38. The court relied on "this District's precedent," and rejected the three court of appeals cases on point because they were out-of-circuit, and so "not binding on the Court." *Id.* at 36–37. The dismissals were "without prejudice," but required any amendment to be "consistent with this Order." *Id.* at 54. The standing dismissal was not curable *by Plumbers*, since it would not be "consistent with" the Standing Order to replead claims on behalf of putative class members in other states. The dismissal was only curable in the limited sense that plaintiffs' counsel could, in theory, identify and add new class representatives from each of the other states in the brief time permitted to amend.

III. STANDARD OF REVIEW

A court of appeals "review[s] *de novo* the district court's grant of a Rule 12(b)(6) motion to dismiss for failure to state a claim, accepting the complaint's allegations as true and construing them in the light most favorable to the plaintiff." *Chaparro v. Carnival Corp.*, 693 F.3d 1333, 1335 (11th Cir. 2012). And it "also review[s] *de novo* … whether federal law preempts a state law claim." *Graham v. R.J. Reynolds Tobacco Co.*, 857 F.3d 1169, 1181 (11th Cir. 2017) (en banc).

SUMMARY OF THE ARGUMENT

1. Plumbers has standing to represent plaintiffs in other states. Ordinary standing analysis turns on injury in fact, traceability, and redressability. These prongs focus on real-world facts and injuries, not the source of the legal entitlement.

Lujan v. Defs. of Wildlife, 504 U.S. 555, 576 (1992) ("[T]here is absolutely no basis for making the Article III inquiry turn on the source of the asserted right."). Plumbers has standing for itself under this test, since it paid real money to reimburse for a drug with concealed health risks.

Plumbers also has class-representative standing. Class-representative standing turns on the relationship between the injury-in-fact the class representative alleges and the injury-in-fact that underlies the absent class members' claims. *Fox v. Ritz-Carlton Hotel Co.*, L.L.C., 977 F.3d 1039, 1046 (11th Cir. 2020). Like ordinary standing, this inquiry turns on the real-world facts and injuries, not the source of the legal entitlement. Here, Plumbers' real-world injury (reimbursing for a worthless drug) is *identical* to the absent class members' injuries (reimbursing for the same worthless drug). Class-representative standing requires no more.

Whenever this Court and the Supreme Court have examined class-representative standing, they have looked to the *type* of injury at issue, not the source of law. Where state laws are *substantively different* (*e.g.*, different elements or defenses), class certification may be impermissible under Rule 23. But the district court improperly rooted its holding in standing, not Rule 23.

The First, Second, and Seventh Circuits have all rejected the district court's rule, and no court of appeals has accepted it. Perhaps that is so because the district court's approach would upend class action doctrine. Federal courts have allowed

multi-state class actions where the law is similar, and this Court has noted certification is a real possibility in such circumstances. Not so under the district court's rule. The district court's approach contradicts the logic underlying CAFA, and, if taken seriously, may render that law unconstitutional.

2. The FDCA does not impliedly preempt state claims that impose the same duties as the FDCA. Preemption flows from the Supremacy Clause, and modern doctrine recognizes different categories of preemption. Congress often preempts certain state duties expressly, for example, by preempting any state requirements that differ in any way from federal law. For statutes with that type of express preemption clause, a line of Supreme Court cases has recognized so-called *parallel* claims. *Bates*, 544 U.S. at 447. Claims are parallel if the federal and state duties are the same, even if the wording to describe the duty differs. Because the FDCA has no express preemption clause, implied impossibility preemption applies here. Under that doctrine, state law is preempted only if compliance with both federal and state law is impossible. It follows that a parallel claim, as the Supreme Court has defined it, *always* survives implied impossibility preemption, because it is *always* possible to comply with two duties where those duties are the same.

For that very reason, no implied impossibility precedent has *ever* barred parallel claims. The Supreme Court cases the district court relied on are in accord with Plumbers' position. They applied impossibility preemption to state law claims

that required generic manufacturers to change their drug label where federal law did not allow the change. *Mensing*, 564 U.S. 604; *Bartlett*, 570 U.S. 472. This case is different, as *Bartlett* said expressly. *Id.* at 487 n.4 ("We do not address state design-defect claims that parallel the federal misbranding statute…. [T]he misbranding provision is not applicable here."). The question *Bartlett* did not address is squarely posed here. And it is simple to resolve. Where state and federal law impose the same duty, it is not impossible to obey both sovereigns.

The original public meaning of the Supremacy Clause supports that conclusion. The framers wrote the Supremacy Clause so that courts would apply federal law as the law of the state, but of higher priority, much like a later-in-time law. On that conception, as originalist scholarship and contemporary cases show, a state law is preempted by a federal law if, imagining it as a later-in-time state enactment, it would repeal state law by implication. This amounts to a rule that state laws are preempted when they logically contradict federal law.

Both state tort law and the FDCA's misbranding provision require Defendants to pull a dangerous drug from the market. No court could think a later-in-time law impliedly repeals an earlier law that requires the same conduct. It is axiomatic that the *same* duty cannot contradict itself. The district court evaded this outcome by misapplying basic preemption doctrine in myriad ways. Its erroneous judgment should be reversed.

ARGUMENT

IV. PLUMBERS HAS STANDING TO REPRESENT PLAINTIFFS IN OTHER STATES.

The district court held "that a named plaintiff lacks standing to assert claims on behalf of putative class members whose claims arise under other states' laws." D.E.2515 at 36. This holding misapplies the standing jurisprudence of this Court and the Supreme Court and erects a substantial new hurdle to efficient resolution of multi-state claims without any justification.

A. Plumbers Has Constitutional Standing.

Plumbers has constitutional standing. Article III, Section 2 of the Constitution vests judicial power in federal courts to decide "Cases" or "Controversies." The "irreducible constitutional minimum of standing" requires three elements:

> [1] an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical[;]
> [2] a causal connection between the injury and the conduct complained of—the injury has to be fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court[; and]
> [3] it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

Lujan, 504 U.S. at 560–61 (quotations, citations, and alterations removed). Time and again, the Supreme Court has emphasized that standing analysis precedes the merits and is about *actual*, *in-fact*, *real-world* injury, not technical legal details.

Technical legal violations cannot *confer* Article III jurisdiction, *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547–48 (2016), just as the failure to satisfy a claim's elements does not deprive a court of its judgment power. *See Steel Co. v. Citizens for Better Env't*, 523 U.S. 83, 103 (1998) (standing is not defeated by lack of "a cause of action"). In sum, "the cause of action ***does not affect*** the Article III standing analysis." *Thole v. U. S. Bank N.A.*, 140 S. Ct. 1615, 1620 (2020) (emphasis added). Even more strongly: "there is ***absolutely no basis*** for making the Article III inquiry turn on the source of the asserted right." *Lujan*, 504 U.S. at 576 (emphasis added).

Applying these principles, Plumbers has standing. It reimbursed real money for a drug that was worthless—or, at the very least, sold at a premium by concealing serious health risks. Plumbers alleges that the law of the states and territories entitles it to a refund. Whether that is true is a merits question. But there is no question that a "direct dollars-and-cents injury" is the hallmark of injury in fact that supports standing. *Doremus v. Bd. of Ed. of Hawthorne*, 342 U.S. 429, 434 (1952). The injury is manifestly traceable to Defendants' actions, and easily redressable by money damages. *See* TPPCAC ¶¶491–95. The constitutional standing inquiry is straightforward under ordinary doctrine.

B. Plumbers Has Class-Representative Standing.

That Plumbers is suing for both itself and for absent class members does not alter the constitutional analysis. The class-representative standing "inquiry focuses

on the relation between the class representative's injuries and those he alleges on behalf of the class." *Fox*, 977 F.3d at 1046. Just as in ordinary standing analysis, this inquiry looks at *real-world injuries*, not the source of law: "To determine whether the named plaintiffs ha[ve] class representative standing, we compare[] those two individual injuries to the injuries they alleged on behalf of the proposed class." *Id.* at 1047.

In *Fox*, a plaintiff alleged that a restaurant in a Ritz-Carlton hotel charged him an illegal automatic gratuity and a sales tax on that gratuity, and sought to represent a class of those who similarly were overcharged at *other* Ritz-Carltons. The district court held that Fox had no standing with respect to Ritz-Carlton locations he had never visited. *Id.* at 1043. This Court reversed, explaining that the district court "conflate[d] the requirements of individual standing with those for a class representative." *Id.* at 1047. The proper inquiry was whether "the named plaintiff and class members have the same interest and suffer the 'same injury.'" *Id.* (quoting *Prado-Steiman ex rel. Prado v. Bush*, 221 F.3d 1266, 1279 (11th Cir. 2000)). And "[b]ecause Fox has the same interest and suffered the same injury as the class members, he has class representative standing to bring the claims he alleged." *Id.*

So too here. Plumbers' own injury is that it overpaid for prescription ranitidine. The putative class members are *other* third-party payors who similarly overpaid for the *same* drug, and so were injured in the same ways for the same

reasons. That demonstrates class-representative standing under this Court's precedent, and the district court's contrary holding was erroneous.

C. That Absent Class Members' Claims Arise Under Other States' Laws Is Not Relevant to Standing.

The district court misconstrued this simple reasoning by looking to the legal source of the cause of action rather than the real-world *type* of injury suffered. Its reasoning proceeded in three steps. *First*, class-representative standing must exist for each claim. *Second*, a cause of action under one state's law (for example, negligence under Florida law) is a different *claim* from a cause of action under another state's law (for example, negligence under Virginia law). *Third*, a class representative lacks standing for any cause of action by a putative class member under the laws of any state the class representative does not invoke for its own individual suit. The critical flaw in this analysis is at the second step.

All agree that individual standing does not turn on the merits or source of law. The Supreme Court has so held. *E.g.*, *Thole*, 140 S. Ct. at 1620 ("[T]he cause of action does not affect the Article III standing analysis."); *Lujan*, 504 U.S. at 576 ("[T]here is absolutely no basis for making the Article III inquiry turn on the source of the asserted right."). There is no reason to think class-representative standing is any different. The cases reinforce that facts and real-world injuries are what matter. *E.g.*, *Fox*, 977 F.3d at 1047 ("compar[ing]" the class representatives' "individual injuries to the injuries they alleged on behalf of the proposed class").

Prado-Steiman, the very case the district court relied on, D.E.2515 at 35, illustrates this principle. There, class representatives sued officials in Florida alleging "ten substantive, classwide claims." 221 F.3d at 1270. This Court reviewed the class certification decision under Rule 23(f). *Id.* at 1278. Defendants argued that no class representative had standing to assert seven out of ten classwide claims, and this Court agreed, remanding to the district court to develop further facts about the injuries of each class representative:

> It is not enough that a named plaintiff can establish a case or controversy between himself and the defendant by virtue of having standing as to one of many claims he wishes to assert. Rather, 'each claim must be analyzed separately, and a claim cannot be asserted on behalf of a class unless at least one named plaintiff ***has suffered the injury*** that gives rise to that claim.'

Id. at 1280 (emphasis added) (quoting *Griffin v. Dugger*, 823 F.2d 1476, 1483 (11th Cir. 1987)). In examining *claims*, this Court examined the real-world injuries alleged, not the source of the right.

The Supreme Court has similarly focused on injuries and facts. In *Gratz v. Bollinger*, a class representative challenged the University of Michigan's consideration of race in its admissions process. 539 U.S. 244, 260 (2003). The class representative's standing for an injunction was predicated on his willingness to "apply as a transfer student" if consideration of race were eliminated. *Id.* at 262. This raised a class representative standing question: did he, as a prospective

"transfer" have "standing to represent absent class members" who challenged "undergraduate *freshman* admissions"? *Id.* (emphasis added). Before answering this question, the Court raised the "question whether the relevance of this variation, if any, is a matter of Article III standing at all or whether it goes to the propriety of class certification pursuant to Federal Rule of Civil Procedure 23(a)." *Id.* The Court "note[d] that there is tension in our prior cases" on whether the question is one of "standing or adequacy." *Id.* at 263 n.15. Either way, after examining the University's policies, the Court found the requirement was "clearly satisfied" because "the University's use of race in undergraduate transfer admissions does not implicate a significantly different set of concerns than does its use of race in undergraduate freshman admissions." *Id.* at 265. Like this Court, the Supreme Court looked to possible differences in the "set of concerns" or real-world facts and proof necessary, not the source of the legal entitlement.

The district court's reasoning ignored the inquiry required by precedent. Instead, it equivocated the meaning of the term "claim" to say that a "claim" deriving from a different state's law *necessarily* could not be raised by a class representative, which must mean it lacks standing for that claim. This equivocation flows from the different possible meanings of the term "claim." It is true that in other contexts one might say that negligence under Florida and Virginia law are two separate claims even if the facts and legal standard to prevail are the same. Not so in the standing

context. When *Gratz*, *Fox*, and *Prado-Steiman* speak of "claims," they mean a real-world "set of concerns," or, equivalently, the facts and injuries that give rise to a case or controversy. These are the proper object of any standing inquiry; the merits and source of law are not, because the court *has no power* to consider them until it assures itself of jurisdiction.

The district court erred by looking solely to the source of law, not to a comparison of the set of concerns, facts, or injuries underlying Plumbers' claims and the putative class members' claims. Under a proper analysis, Plumbers has standing to bring this case because its injuries are the same as those of the putative class members it seeks to represent.

D. Every Court of Appeals to Have Considered This Issue Has Held That Standing Doctrine Does Not Bar Representation of Out-Of-State Class Members.

No court of appeals supports the district court's decision. Here, the district court found no standing *even without identifying any differences* among the state laws. Two circuits to have addressed this issue have concluded that, as *Gratz* tentatively suggested, even when differences *do exist* between a class representative's claim and an absent class member's claim, that is purely a matter of Rule 23 class certification, not standing. One circuit leaves some room for standing based on the precise differences identified. Either way, affirming would open a square circuit conflict with at least the First, Second, and Seventh Circuits.

The Seventh Circuit considered the issue first in *Morrison v. YTB Int'l, Inc.*, 649 F.3d 533 (7th Cir. 2011). There, an Illinois class representative asserted a claim on behalf of a nationwide class against an Illinois defendant for violating state consumer fraud law. The district court dismissed the claims of the non-Illinois putative class members on standing grounds, and the Seventh Circuit reversed. *Id.* at 536–39. Judge Easterbrook explained that the word "standing" "is not an accurate description" because the case had "no problem with standing." *Id.* at 535–36.

> Plaintiffs have standing if they have been injured, the defendants caused that injury, and the injury can be redressed by a judicial decision. Plaintiffs allege that they are victims of a pyramid scheme that saddled them with financial loss, which YTB caused. The judiciary can redress that injury by ordering YTB to pay money to the victims. Nothing more is required for standing.

Id. at 536 (citation omitted). The only real questions were whether Illinois law or the law of many different states applied, and, if the latter, whether "a class action arising under the consumer-fraud laws of [multiple states would] be manageable" under the Rule 23 standard. *Id.* If such an action *was* manageable under Rule 23, standing would never present an obstacle on Judge Easterbrook's view.

The Second Circuit came to the same conclusion in *Langan v. Johnson & Johnson Consumer Cos.*, 897 F.3d 88 (2d Cir. 2018). *Langan* involved a Connecticut plaintiff who brought class claims under the consumer protection laws

of twenty other states. 897 F.3d at 91. The Second Circuit found no standing problem:

> The only point of contention is whether Langan has standing to bring a class action on behalf of unnamed, yet-to-be-identified class members from other states under those states' consumer protection laws…. [A]s long as the named plaintiffs have standing to sue the named defendants, any concern about whether it is proper for a class to include out-of-state, nonparty class members with claims subject to different state laws is a question of predominance under Rule 23(b)(3), not a question of "adjudicatory competence" under Article III.

Id. at 92–93 (citations and quotation omitted).

The Second Circuit quoted the "tension" language from *Gratz*, then explained in detail why "considering variations in state laws as questions of predominance under Rule 23(b)(3), rather than standing under Article III, makes sense." *Id.* at 95. First, doing so "acknowledges the obvious truth that class actions *necessarily involve* plaintiffs litigating injuries that they themselves would not have standing to litigate." *Id.* (emphasis added). Because "class action plaintiffs are not required to have individual standing to press any of the claims belonging to their unnamed class members, it makes little sense to dismiss the state law claims of unnamed class members for want of standing when there was no requirement that the named plaintiffs have individual standing to bring those claims in the first place." *Id.* (citation omitted). Put another way, since standing proceeds claim-by-claim, why does Plumbers have standing to bring *other plaintiffs'* claims in Florida? Whatever

answer one gives to that question applies with equal force to the claims of plaintiffs in other states; Plumbers is asserting *someone else's* claims either way. It is no less a constitutional "case" or "controversy" if those absent claimants hail from Florida or Alaska.

Second, this approach "accords with the Supreme Court's preference for dealing with modest variations between class members' claims as substantive questions, not jurisdictional ones." *Id.*[2] The Second Circuit reversed and remanded with instructions for the district court to consider whether the laws of other states were sufficiently similar to allow certification of the class. *Id.* at 96–99.

The First Circuit similarly upheld standing, though, unlike the Second and Seventh Circuits, it determined that differences among state laws could implicate both Rule 23 and Article III. In *In re Asacol Antitrust Litigation*, plaintiffs filed suit

[2] The Newberg treatise elaborates on why courts tend to resolve these and similar problems under Rule 23 rather than standing: "First, while standing doctrine is primarily concerned with ensuring that a real case or controversy exists, Rule 23(a)'s requirements are designed precisely to address concerns about the relationship between the class representative and the class. Hence, Rule 23 is a more appropriate tool to utilize in accessing these problems…. Finally, the class certification approach has the virtue of resolving disjuncture questions in a nonconstitutional manner and thus of avoiding unnecessary constitutional adjudication." William B. Rubenstein, 1 Newberg on Class Actions, §2:6 (5th ed. 2020). Most circuits "follow the class certification approach, limiting the standing inquiry to the class representative's individual standing to bring suit and considering any disjuncture between those injuries and the class's to be a matter of class certification under Rule 23." *Id.*; *see also id.* at n.8 (citing cases, including *Prado-Steiman*, 221 F.3d at 1279–80 (11th Cir. 2000)).

against Warner Chilcott, alleging class claims under the laws of twenty-six jurisdictions. 907 F.3d 42, 44 (1st Cir. 2018). Class representatives lived in only four states, however, leaving only absent class members in the remaining twenty-two. Warner Chilcott moved to dismiss on standing grounds, just as Defendants did here. The First Circuit's initial analysis matched that of the Second and Seventh Circuits:

> [W]hether a plaintiff may represent persons who themselves have standing to bring the claims alleged [seems like] a question to be addressed under Rule 23, rather than a question of standing. After all, that is how one would presumably proceed in seemingly analogous situations outside of Rule 23. For example, in deciding whether a fiduciary, a parent, a personal representative, or a partner may prosecute a claim on behalf of another person, courts generally focus not on whether the putative representative independently satisfies Article III standing, but rather on whether that party qualifies under the applicable law as a representative of the one who does have standing.

Id. at 48.

However, the court reasoned that such a "simple and quick answer" was insufficient in light of *Gratz*. *Id.* Instead, it ruled that the "Article III focus" should be on "the incentives of the named plaintiffs to adequately litigate issues of importance to them," which is "an application to aggregate litigation of the basic Article III requirement that a plaintiff possess… a personal stake in the outcome." *Id.* at 49 (citations omitted). Under this approach, "the question of standing is not:

Are there differences between the claims of the class members and those of the class representative? Rather, the pertinent question is: Are the differences that do exist the type that leave the class representative with an insufficient personal stake in the adjudication of the class members' claims?" *Id.*

The First Circuit treated differences as relevant both to standing (under the "personal stake" analysis outlined above) *and* the Rule 23 inquiry the other circuits require. It held that New York law had an additional element of "deception" that deprived the named plaintiff (whose state did not have such an element) of the personal stake necessary to litigate on behalf of New Yorkers. *Id.* at 50. But like the Second and Seventh Circuits, the court found class representative standing under the laws of *twenty-one* states other than those under which the plaintiff brought his own claim. *Id.*

There are sound reasons to prefer the Rule 23 approach to the hybrid approach crafted by *Asacol*, but in this appeal, as in *Gratz*, the answer is clear either way. The district court did not rely on any purported difference between state laws—it held Plumbers automatically lacked standing to bring claims from other states. This is error under the approach of every court of appeals to consider the issue.

E. The District Court's Proposed Rule Produces Absurd Results and Defies Fundamental Principles of Federal Jurisdiction.

The district court's approach to standing would render nationwide class actions under state law essentially impossible, even where they satisfied Rule 23.

This Court has stated that "if a claim is based on a principle of law that is uniform among the states, class certification is a realistic possibility." *Klay v. Humana, Inc.*, 382 F.3d 1241, 1262 (11th Cir. 2004). Not so under the district court's ruling: a nationwide class, even if realistically possible, would require far more named plaintiffs—at least one from each state or territory—to proceed. Normally, increasing geographic representation on the plaintiff side of the "v" is a jurisdiction *killer* because complete diversity is required. It is ironic indeed that the district court's rule would *compel reliance* on CAFA's *minimal* diversity exception for a nationwide class to have any hope of satisfying Article III's case or controversy requirement. 28 U.S.C. §1332(d)(2)(A).

On that score, the district court's rule also contradicts the basic premises of CAFA. *See* 28 U.S.C. §1332(d)(2)(A).[3] To begin with, Congress plainly expected that nationwide class actions not based on federal law were possible in federal court, otherwise it would not have passed a statute to authorize removal in cases with minimal diversity and *no federal question*.

More fundamentally, if one follows the district court's logic, CAFA itself would be unconstitutional. The district court's decision dismissed the claims under

[3] CAFA is particularly relevant here since the parties are not completely diverse, and so could not litigate these claims in federal court but for that law. *See* TPPCAC ¶23 (Plumbers is a citizen of Florida); ¶55 (Defendant Apotex Corp. is a citizen of Florida).

other states' laws because "named plaintiffs cannot rely on unidentified persons within those states to state a claim for relief." D.E.2515 (quoting *In re Terazosin Hydrochloride Antitrust Litig.*, 160 F. Supp. 2d 1365, 1371 (S.D. Fla. 2001)). CAFA, however, does exactly this. CAFA grants "jurisdiction of any civil action" with more than $5,000,000 at issue where "any member of a class of plaintiffs is a citizen of a State different from any defendant…." 28 U.S.C. §1332(d)(2)(A). Defendants regularly remove under CAFA *before* class certification, and by its plain text can do so even if all named plaintiffs and all defendants are from the same state (so long as *putative*, unidentified class members are from another state). *E.g.*, *Morrison*, 649 F.3d at 535; *cf. State Farm Fire & Cas. Co. v. Tashire*, 386 U.S. 523, 531 (1967) (upholding minimal diversity under Article III, "so long as any two adverse parties are not co-citizens"). This comports with federal constitutional diversity jurisdiction only if courts *may* "rely on unidentified persons" to create federal jurisdiction.

The district court's rule invites a preposterous hypothetical: a putative class by one Florida plaintiff against a Florida defendant, representing a class of persons in Florida and Alabama under state law. CAFA would allow removal *by virtue of* the "unidentified" Alabama putative class members. But, once in federal court, the Alabama claims would need to be *dismissed for lack of standing* because there is no Alabama class representative! Jurisdictional bootstrapping for me, but not for thee.

The doctrine, precedent, and first principles all require reversing the district court's standing determination.

V. THE FDCA DOES NOT IMPLIEDLY PREEMPT STATE TORT CLAIMS THAT IMPOSE THE SAME DUTIES AS THE FDCA.

The FDCA does not preempt state law that imposes the same requirements. This rule is consistent with basic preemption principles: state laws are not preempted unless they conflict with federal law, and laws that are the same do not conflict. It is consistent with established precedent applying the FDCA: no case has *ever* held that the FDCA preempts independent state law duties that require the same thing as the FDCA. It is consistent with common sense: federal policy is not undermined in any way by a state law that requires the same thing as federal law. And it is consistent with the original public meaning of the Supremacy Clause: the framers drafted the Supremacy Clause to create preemption only where federal law could be read as an implied repeal of state law, and a later-in-time statute would never be read to repeal an earlier law that imposed the same requirements.

A. Federal Law Does Not Preempt Parallel State Law Duties.

Preemption flows from the Supremacy Clause, which provides:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof… shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

U.S. Const. Art. VI, cl. 2. Any state law that "interferes with or is contrary to federal law, must yield." *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 108 (1992) (internal quotation marks omitted). Occasionally, Congress decides to occupy an entire field of law, such that *any* state regulation in the same domain will necessarily conflict with federal law. *Arizona v. United States*, 567 U.S. 387, 401 (2012) ("Where Congress occupies an entire field, as it has in the field of alien registration, even complementary state regulation is impermissible. Field preemption reflects a congressional decision to foreclose any state regulation in the area, *even if it is parallel to federal* standards." (emphasis added)). But where Congress decides not to occupy the field, the resulting statute, by definition, allows state laws to regulate the same conduct to the extent they impose parallel duties.

This principle applies even where Congress manifests an *express* intent to preempt state laws. For example, in *Bates*, the Supreme Court held that the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which expressly preempts all state pesticide requirements "in addition to or different from" federal law, did not preempt state requirements that were parallel to the federal requirements. 544 U.S. 431, 447 (2005) (quoting 7 U.S.C. §136v(b)). The Court started with the simplest case: "state regulation requiring the word 'poison' to appear in red letters, for instance, would not be pre-empted if an EPA regulation imposed the same requirement." *Id.* at 444. The Court then held that state common law duties are also

not preempted if they are "equivalent to, and fully consistent with" the federal law. *Id.* at 447. Borrowing its analysis from the Medical Device Amendments to the FDCA, the Court dubbed such requirements "parallel." *Id.* ("The 'parallel requirements' reading… finds strong support in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).").

The Court further explained that "[t]o survive pre-emption, the state-law requirement need not be phrased in the *identical* language as its corresponding [federal] requirement." *Bates*, 544 U.S. at 454. Thus, if federal law required a label to say "Poison" in red letters, and the state law duty required a reasonable warning, then a plaintiff could prevail by showing that the label lacked a reasonable warning *because* it did not say "Poison" in red letters. The failure to comply with federal law put the defendant out of compliance with state law too, making the duties parallel. Ample case law in this circuit and elsewhere apply these familiar principles to parallel claims. *See, e.g.*, *Mink v. Smith & Nephew Inc.*, 860 F.3d 1319, 1329 (11th Cir. 2017); *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1234 (9th Cir. 2013) (en banc); *Hughes v. Bos. Sci. Corp.*, 631 F.3d 762, 769 (5th Cir. 2011); *Bausch v. Stryker Corp.*, 630 F.3d 546, 558 (7th Cir. 2010).

If state common law duties that "parallel" federal requirements survive preemption under the *express* preemption clause at issue in *Bates*, it follows *a fortiori* that such duties cannot fall to implied conflict preemption. That is because

implied conflict preemption is a far tougher row for defendants to hoe. Implied conflict preemption applies where it is "*impossible* for a private party to comply with both state and federal requirements." *English v. General Elec. Co.*, 496 U.S. 72, 79 (1990) (emphasis added). Indeed, a defendant most show actual impossibility; the mere "possibility of impossibility" is not enough. *Merck Sharp & Dohme v. Albrecht*, 139 S. Ct. 1668, 1678 (2019). But it cannot be impossible to simultaneously comply with *identical* state and federal duties. And "identical" is just a synonym for "parallel" under *Bates*. State laws that survive the express preemption clause at issue in *Bates* survive implied, impossibility preemption per force.

1. FDCA precedent does not support preemption of parallel duties.

It is a defendant's burden to establish impossibility preemption and it is a "demanding defense." *Wyeth*, 555 U.S. at 573. Yet Defendants can point to no impossibility preemption case that has *ever* applied the FDCA to preempt parallel state law duties. (Indeed, Defendants cannot identify any case in *any context* finding implied impossibility preemption where state duties require the same thing as federal law.)

The Supreme Court's opinions in *Mensing*, 564 U.S. 604, and *Bartlett*, 570 U.S. 472, recognize straightforward instances of impossibility preemption. In both cases, the plaintiffs alleged and sought to prove that state law required the

defendants, generic drug manufacturers, to include stronger warnings on their generic-drug labels. *Mensing*, 564 U.S. at 609; *Bartlett*, 570 U.S. at 475. That state-law requirement conflicted directly with federal law, which *prohibits* generic drug companies from unilaterally changing their labels. *See* 21 U.S.C. §§355(j)(2)(A)(v); 355(j)(4)(G). It was impossible for the defendants to satisfy their state-law duty to strengthen their drug warnings without violating the federal law that prohibited them from doing so. *Mensing*, 564 U.S. at 618; *Bartlett*, 570 U.S. at 480. That impossibility meant that the Supremacy Clause required state law to yield.

Neither *Mensing* nor *Bartlett* involved a situation in which the plaintiff asserted that the FDCA required the same conduct as state tort law. As noted, Defendants cannot identify *any* case reading the FDCA to impliedly preempt state law duties that require the same thing as the FDCA. And that is not surprising, because such a result would defy common sense. The purpose of preemption doctrine is to ensure that state laws do not frustrate the clearly expressed requirements of federal law. But it is well-established that Congress did not intend the FDCA to occupy the entire field of pharmaceutical regulation. *Wyeth*, 555 U.S. at 575 (The lack of any express preemption clause, "coupled with [Congress's] certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness."). Necessarily, Congress thought some state law duties

would be consistent with the purposes of the FDCA. And if *any* state law duties are consistent with the purposes of the FDCA, it is duties that require *the same thing* as the FDCA. Unless Defendants adopt the remarkable position that Congress intended the FDCA to displace the entire field of pharmaceutical safety, Defendants' preemption argument must fail. Indeed, Defendants cannot offer a single, solitary example—in the FDCA context or any other—where it would be impossible to simultaneously perform identical duties. One might as well endeavor to square the circle or identify where two parallel lines cross. Defendants cannot and will not meet this challenge as a matter of logic and law.

2. The original public meaning of the supremacy clause confirms that the FDCA does not preempt parallel duties.

Applying federal law to preempt parallel state duties not only would conflict with established precedent, but also would ignore the original public meaning of the Supremacy Clause. The test for conflict preemption under the original public meaning inquires whether federal and state law logically contradict. Where they do not, preemption cannot apply.

The Supremacy Clause reflects a federalism balance struck by the framers after they discarded the Articles of Confederation. To better protect the people's cherished liberties, it was necessary to "split the atom of sovereignty"—with a *truly* sovereign federal government created from the fission. *Gamble v. United States*, 139 S. Ct. 1960, 1968 (2021) (internal quotations and citation omitted). But the

framers feared that state courts might treat federal law the same way American courts routinely treat the laws of foreign sovereigns such as England or France: helpful authority that may be followed or ignored based on principles of comity and sound considerations of domestic policy. *E.g.*, *Bank of Augusta v. Earle*, 38 U.S. 519, 520 (1839).

The Supremacy Clause makes clear that federal law is "supreme" and is the "Law of the Land" to require each state to treat validly enacted federal law as if it were enacted by the state itself, "rather than as the law of another sovereign." Caleb Nelson, *Preemption*, 86 Va. L. Rev. 225, 249 (2000). In addition, the phrase "supreme" gave a "rule of priority," requiring states to treat federal law as not only enacted by the state's legislature, but also later-in-time, allowing federal law to expressly repeal state law. *Id.* at 250. Express preemption clauses in federal legislation have this effect.

Moreover, even without express language, federal law—like any later-in-time law—that is *inconsistent* with state law could repeal it. *Id.* at 253–54. Chief Justice Marshall employed this understanding, opining that "[a] law, absolutely repugnant to another, [] entirely repeals that other *as if express terms of repeal were used*." *McCulloch v. Maryland*, 17 U.S. 316, 425–26 (1819) (emphasis added). Thus, if a prior-in-time law is "absolutely repugnant" to a later-in-time law, courts presumed

in 1789 (and still presume today) that the legislature intended to repeal the earlier statute, even without express words of repeal in the later-enacted legislation.[4]

In short, the Supremacy Clause mandates that when state and federal law are alleged to conflict, courts must: (i) act as if both were enacted by the same sovereign; (ii) treat federal law as if it were enacted later in time; and (iii) determine if federal law impliedly repeals some or all of the state law at issue. This would occur only if the federal law logically contradicted the state law. Justice Thomas's opinion in *Mensing* adopted this originalist reading, explaining that the Supremacy Clause "plainly contemplates conflict pre-emption by describing federal law as effectively repealing contrary state law." *Mensing*, 564 U.S. at 621 (2011) (plurality) (citing Nelson); *see also Wyeth*, 555 U.S. at 590 (Thomas, J., concurring) (citing Nelson);

[4] Professor Nelson and Justice Thomas have further argued for treating the "notwithstanding" language of the Supremacy Clause as a *non obstante* provision. Under English law received at the time of the framing, courts applied a strong "general presumption against implied repeals." Nelson, Preemption, 86 Va. L. Rev. at 241–42. That strong presumption authorized courts to avoid a plain-text reading of later-enacted statutes to harmonize them with preexisting law. "In the words of Matthew Bacon's New Abridgment of the Law, '[a]lthough two Acts of Parliament are seemingly repugnant, yet if there be no Clause of *non Obstante* in the latter, they shall if possible have such Construction, that the latter may not be a Repeal of the former by Implication.'" Nelson, Preemption, 86 Va. L. Rev. at 242 (quoting 4 Matthew Bacon, A New Abridgment of the Law at 631 (London, W. Strahan 4th ed. 1778) (emphasis added). The "notwithstanding" language in the Supremacy Clause prevents courts from deploying strained interpretations of Congress's intent to avoid an implied repeal. Because Plumbers' argument relies on a plain reading of the FDCA, it is wholly consistent with this view.

Kansas v. Garcia, 140 S. Ct. 791, 807 (2020) (Thomas, J., concurring joined by Gorsuch, J.) (citing Nelson).

The original understanding of the Supremacy Clause confirms the doctrinal result reached above. Viewing the FDCA as a later-enacted statute, a court would be unlikely to find even a *similar*, but *not identical*, provision of state law impliedly repealed. When a state law is parallel under the Supreme Court's precedent, it cannot be repealed by implication. No court looking at two statutes (or a statute and the common law) that impose the *same* duty would conclude that the later one impliedly repeals the earlier one.

B. Plumbers' Tort Claims Are Not Impliedly Preempted Because They Impose the Same Duties on Defendants as the FDCA.

The FDCA does not preempt Plumbers' claims. As Plumbers has alleged, and will prove at trial, by selling ranitidine, Defendants violated the state-law duty not to sell unreasonably dangerous products *and* the federal-law duty not to manufacture, receive, sell, or market misbranded drugs. The Supreme Court has made clear that parallel state common law claims are not preempted even where Congress has expressly prohibited state law from imposing any requirements "in addition to or different from" federal law. *Bates*, 544 U.S. 431, 447 (2005) (quoting 7 U.S.C. §136v(b)). It cannot be impossible to perform state duties that match the ones imposed by the FDCA. Whatever the FDCA states by implication, it does not state that affront to basic logic.

1. Ranitidine Is Misbranded.

Start with the facts supporting the federal duty not to sell ranitidine. The pleadings allege that NDMA is a potent carcinogen, and cite the broad scientific consensus that it "has caused cancer in nearly every laboratory animal tested so far." TPPCAC ¶231; ¶¶232–48. The pleadings allege—and all agree—that no ranitidine product listed NDMA as an ingredient, TPPCAC ¶338, warned of its cancer risk, TPPCAC ¶328, or in any other way mitigated its dangers. No manufacturer, prior to the recent citizen petitions, ever told the FDA about the dangers of NDMA in ranitidine. TPPCAC ¶283. The pleadings allege that ranitidine degrades into NDMA in the human stomach and over time under normal storage conditions. TPPCAC ¶¶10, 258, 271–76. Tests have shown NDMA levels "as high as 304,500 ng per tablet, which is 3,171 times the maximum daily limit." TPPCAC ¶5. When this information became public, the FDA and comparable regulators from *forty-three different countries* restricted or banned ranitidine. TPPCAC ¶489.

Taking the allegations as true, the pleadings make plain as day that ranitidine 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." 21 U.S.C. §352(j). A risk of cancer is the quintessence of a "danger[] to health." And ranitidine's label did not provide any suggestions or recommendations that removed or reduced the risk of cancer. Moreover, this risk is *completely* unjustified, since

ranitidine treats non-life-threatening conditions and has many close substitutes that do not cause cancer.

The FDA, of course, concluded ranitidine was not dangerous to health when it approved the drug *in 1983*. And, if the jury were to simply second-guess that determination based on the *same evidence* presented to the FDA *then*, that may present a preemption concern. *See Bartlett*, 570 U.S. at 487, n.4 ("Because the jury was not asked to find whether new evidence concerning sulindac that had not been made available to the FDA rendered sulindac so dangerous as to be misbranded under the federal misbranding statute, the misbranding provision is not applicable here."). But here, the FDA ordered a recall and told consumers to dispose of any ranitidine they had in their homes as soon as it learned what good science revealed. TPPCAC ¶473–87. Surely the FDA's recent actions "allow[] the court to draw the reasonable inference" that it encountered new, and scientifically significant information. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). With the benefit of discovery, Plumbers will be able to show precisely what information the FDA considered in 1983, and which of the pieces of information that led it to withdraw ranitidine were new and scientifically significant. The district court "assume[d], without finding, that Plaintiffs have adequately alleged that ranitidine products were misbranded." D.E.2512 at 30.

2. Ranitidine Is Illegal to Sell Under State Law

Next, consider the state duty. The district court denied Defendants' state law motions to dismiss as moot, and has not ruled on choice-of law. D.E.2513 at 45. But it seems unlikely there are many states that would not deem ranitidine defective and illegal to sell.

For example, the complaint alleges breach of the "implied warranty of merchantability and fitness for ordinary purpose" in every state, citing each provision. TPPCAC ¶580. A pharmaceutical drug that is dangerous to health when used as labeled obviously is not merchantable or fit for its ordinary purpose (i.e., consumption by patients). *See* TPPCAC ¶585. Similarly, the complaint alleges negligence in selling a dangerous drug. TPPCAC ¶¶656–76. Selling a cancer-causing drug to treat heartburn and indigestion falls far below the duty of care under negligence principles—such products simply cannot be sold in a non-negligent way.

The complaint also alleges fraud and misrepresentation theories because Defendants' advertising and labeling induced purchases of their product by falsely claiming it was safe. *See* TPPCAC ¶¶607–09; 621–32; 634–46. Simply put, federal law does not allow sale of drugs without true representations about risks, and neither does state law.

The complaint pleads many counts in many states—perhaps some go beyond federal law. The Supreme Court proposed a practical option in *Bates*, suggesting

that "[i]f a defendant so requests, a court should instruct the jury on the relevant [] misbranding standards, as well as any regulations that add content to those standards" to ensure the federal and state standards are genuinely equivalent. 544 U.S. at 454. The district court could do the same for the FDCA misbranding standard to guarantee the jury finds liability only when *both* the federal and state standards are met.

3. Finding a Parallel Claim Here Is Consistent with *Bartlett*.

Bartlett involved an FDA-approved medication, sulindac, that remained FDA-approved throughout the lawsuit. Unlike ranitidine, sulindac was never subject to recall or withdrawal, even after the FDA "completed a comprehensive review of [sulindac's] risks and benefits." Most importantly, the *Bartlett* plaintiffs did *not* allege or ask the jury to find that "new evidence concerning sulindac that had not been made available to the FDA rendered sulindac so dangerous" as to violate the federal misbranding statute. 570 U.S. at 487, n.4. Unlike here, there was no allegation that federal law imposed the same requirement that plaintiffs were attempting to impose through state tort law.

To be sure, in *Bartlett*, the Court considered the argument that it was not "literally impossible" for the defendant to comply with both sovereigns' laws because it could have chosen "not to make sulindac at all." *Bartlett*, 570 U.S. at 488. After all, federal law does not *require* anyone to sell FDA-approved drugs. *Bartlett*

rejected this argument, reasoning that if a defendant's *option* to stop-selling were enough to overcome preemption, the doctrine would be a dead letter. *Id.* Where there was no dispute that the FDA-approved drug complied with federal law, the Court reasoned that it would undermine the policies of the FDCA to require the manufacturer "to cease acting altogether in order to avoid liability." *Id.*

The distinction between *Bartlett* and this case is obvious and dispositive. In *Bartlett* the plaintiffs suggested that state tort law required a drug manufacturer to either (a) alter its warning label in direct violation of federal law or (b) *because the label violated state (but not federal) law*, pull the drug from the market. Here, by contrast, Plumbers has alleged, and will show at trial, that the FDCA *prohibited* Defendants from selling ranitidine *and* that state law required the same thing.

If there were any doubt that this distinction is material, the Supreme Court removed it in *Bartlett* by noting its decision did *not* address "the rare case in which state or federal law actually requires a product to be pulled from the market." 570 U.S. at 487, n.3; *see also id.* at n.4 (not addressing "claims that parallel the federal misbranding statute"). When the Supreme Court says it is not deciding a question, that means the question held open is not controlled by its holding. The Supreme Court went out-of-its-way to note that the situation here is materially different from the situation in *Bartlett*. Any argument by Defendants that the distinction is irrelevant ignores the Supreme Court's own view.

The distinction between this case and *Bartlett* is also consistent with the purposes of preemption. Allowing state laws to stop the sale of medicine that federal law treats as safe and effective—as the Plaintiffs sought in *Bartlett*—would undermine the uniform federal regulatory regime for prescription drugs. By contrast, allowing Plumbers to enforce state law duties barring the sale of ranitidine would not undermine the federal regulatory scheme in any way. To prevail on its claim, Plumbers must prove that federal law imposes the identical duty.

C. The District Court's Preemption Reasoning Is Flawed.

1. Parallel claims are not categorically unavailable in implied preemption cases.

The district court reasoned that it was categorically "irrelevant" whether Plumbers' claims imposed parallel duties with the FDCA because "*Reigel*, *Bates*, and *Lohr* did not address impossibility preemption." D.E.2512 at 36 (referring to *Bates*, 544 U.S. 431; *Riegel* 552 U.S. 312, and *Lohr*, 518 U.S. 470). But that ignores the *logic* of impossibility preemption, which imposes a *higher* bar than the express preemption clauses examined in *Reigel, Bates*, and *Lohr*. Each of those clauses invalidated state-law requirements differing *in any way* from federal requirements. *See* 7 U.S.C. §136v(b) (pesticides, "in addition to or different from"); 21 U.S.C. §360k(a)(1) (medical devices, "different from, or in addition to"). If state and federal law were not exactly the same, state law was preempted. Any state claim

would survive preemption under *those* stringent express preemption clauses, cannot be preempted by implied impossibility preemption.[5]

The district court further justified its decision by reasoning that Plaintiffs' theory would "render pre-emption caselaw meaningless," because: "a plaintiff could avoid pre-emption simply by asserting, for example, that a drug's labeling was 'false or misleading in any particular' or that the drug was 'dangerous to health when used' as prescribed." D.E.2512 at 28 (quoting 21 U.S.C. §352(a)(1), (j)). The district court is mistaken. Merely "asserting" misbranding is not enough. That legal conclusion must be plausibly supported by factual content. *See Iqbal*, 556 U.S. at 678. Here, it is. Among other things, the FDA—in reliance on terrifying new science—withdrew ranitidine from the market.

The preemption cases to which the district court referred—*Mensing* and *Bartlett*—did *not* include any allegations or argument that federal law required the manufacturers to stop selling drugs. By contrast, Plumbers alleged precisely that, a distinction that *Bartlett* expressly noted was material. Under Plumbers' theory, *Mensing*, *Bartlett*, and the Court's other impossibility preemption cases are rightly

[5] The district court's reasoning fails on its own terms because the Supreme Court has looked to *Reigel*, *Bates*, and *Lohr* time and again in its impossibility preemption cases on pharmaceuticals. *See, e.g.*, Bartlett, 570 U.S. at 482, 487 & n.4, 492–93 (citing *Riegel* once, *Lohr* once, and *Bates* six times, including when discussing "parallel claims" in footnote 4); *Wyeth*, 555 U.S. at 565, 567, 574, 577, 579, 582, 587 (citing *Riegel* twice, *Lohr* three times in the majority and twice in a concurrence, and *Bates* in the majority and both concurrences).

decided. It hardly renders those precedents "meaningless" to allow an alternative theory—uniquely supported by this case's facts—that *Bartlett* left open.

2. Parallel claims are not enforcement of the FDCA.

The lower court did not disagree with Plumbers' definition of misbranding under the FDCA; and it assumed that Plumbers adequately pleaded that ranitidine was misbranded. D.E.2512 at 30. It nonetheless ruled that the federal misbranding statute was "of no matter" because only the United States, not a private plaintiff, can enforce it. D.E.2512 at 28; *see also* D.E.2513 at 31 (same reasoning). That is a truthful irrelevancy. Plumbers has never tried to enforce the FDCA. Its complaint contains no claim, in substance or in form, titled "private right of action under the Food, Drug, and Cosmetic Act." Plumbers pleaded state law claims and nothing more. Its causes of action would exist even if the FDCA did not.

It is true that Plumbers *referenced* the FDCA to show that its requirements parallel state law. How could it be otherwise? Conflict-of-law analysis under the Supremacy Clause turns on showing harmony between state and federal law. Demonstrating that state and federal duties are the same does not alter the source of law that creates the cause of action. *Cf. Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352–53 (2001). Under the district court's reasoning, plaintiffs could never reference federal law, even for background or to show consistency, without somehow seeking to enforce it. That is not, and never has been, the law.

CONCLUSION

For the foregoing reasons, the district court's ruling should be reversed, and the case remanded for further proceedings.

Dated: March 29, 2021

Respectfully submitted,

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Dated: March 29, 2021

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CERTIFICATE OF SERVICE

On March 29, 2021, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Eleventh Circuit by using the CM/ECF system. All participants in this case are registered CM/ECF users, and service will be accomplished by the CM/ECF system.

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