UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF ARKANSAS (Central Division)

BOBBY JOE YOUNG, INDIVIDUALLY AND AS REPRESENTATIVE OF THE ESTATE OF SHIRLEY ANN YOUNG, DECEASED, KENNETH W. YOUNG, BOBBY J. YOUNG, JR., AND COREY A. YOUNG, *Plaintiffs*, v. MERCK & CO., INC., *Defendant*.	No. 4:25-cv-00999-LPR

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANT AND MOTION TO DISMISS

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FEDERAL RULE OF CIVIL PROCEDURE 7.1 DISCLOSURE STATEMENT

The Chamber of Commerce of the United States of America is a not-for-profit, tax-exempt organization incorporated in the District of Columbia. The Chamber has no parent company, and no publicly held company has 10% or greater ownership in the Chamber.

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INTEREST OF *AMICUS CURIAE*

The Chamber of Commerce of the United States of America ("the Chamber") is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases, like this one, that raise issues of concern to the nation's business community.

This is such a case because it presents a clear example of the concerning phenomenon of plaintiffs using artful pleading to try to avoid federal preemption defenses by pharmaceutical manufacturers and other defendants at the motion-to-dismiss stage. Preemption shields defendants from burdensome and improper litigation of state-law claims in circumstances where federal law controls. But, as in this case, plaintiffs often strategically plead around preemption defenses in hopes that, even when the outcome is not meaningfully in doubt, they may avoid dismissal, force burdensome and expensive discovery, and thereby obtain a settlement. This problem is particularly evident in the context of litigation against drug manufacturers, including many of *amicus*'s members, where the federal Food, Drug & Cosmetic Act (FDCA) preempts many state-law claims but that reality may not be immediately evident on the face of an artfully pleaded complaint. The Chamber and its members thus have a substantial interest in the policing of the pleading tactics at play in this case.[1]

[1] No counsel for any party authored this brief in whole or in part, and no entity or person, aside from *amicus curiae*, its members, or its counsel, made any monetary contribution intended to fund the preparation or submission of this brief.

SUMMARY OF ARGUMENT

Often a plaintiff's end game is not to win a judgment on the merits; it is to make litigation costly enough for a defendant that the defendant settles simply to avoid those costs. One way to do so is to artfully plead around dispositive defenses in an effort to get past the pleading stage and force a defendant to endure costly and burdensome discovery.

This regularly occurs in product-liability cases involving FDA-approved drugs. Determining that a claim is preempted by the FDCA can be remarkably simple—as easy as showing that any alleged "newly acquired information" was not actually new or did not justify a unilateral change to the label under the applicable regulations or that the manufacturer communicated with FDA and the agency made clear that it would not approve a label change. But plaintiffs regularly seek to delay the inevitable, artfully pleading around this straightforward preemption defense by making conclusory allegations of "new" information or omitting key information about FDA's knowledge and communications.

Allowing such claims to survive motions to dismiss results in one of two undesirable outcomes. First, defendants may be forced to go through burdensome, costly discovery to obtain summary judgment based on their simple preemption defense. In such a case, the high costs of discovery—costs that have skyrocketed in past decades thanks to electronic discovery—are needless and wasteful. Or, second, defendants may decide those costs are not worth it and settle the case, despite a meritorious preemption defense. This, too, is undesirable in no small part because it incentivizes the next plaintiff to engage in similar pleading tactics with hopes of a similar result.

This case illustrates this phenomenon. While Plaintiffs here allege that their claims are not preempted because Merck could have unilaterally amended the label to give the warning Plaintiffs say state law required, the documents that Merck points to disprove this. Preemption is thus a

simple, outcome-determinative defense in this case. But Plaintiffs have—like many plaintiffs before them—sought to hide the ball, survive the motion-to-dismiss stage, and obtain costly discovery.

The Chamber respectfully submits that this Court should recognize the pleading tactics afoot and the problems they wreak. Seeing through those, the Complaint should be dismissed.

ARGUMENT

I. Plaintiffs regularly try to avoid preemption defenses at the motion-to-dismiss stage through artful pleading, leading to burdensome and wasteful discovery.

As explained in Merck's motion, the FDCA preemption question for a failure-to-warn claim involving a prescription drug is straightforward: did the manufacturer have the right under federal law to unilaterally change its label in the way allegedly required by state law? *See* ECF 22 ("Merck Br.") 13–18 (explaining the legal framework for FDCA preemption). As the Supreme Court has recognized, "[g]enerally speaking, a manufacturer may only change a drug label" under federal law "after the FDA approves a supplemental application." *Wyeth v. Levine*, 555 U.S. 555, 568 (2009). If state law would require a pharmaceutical manufacturer to change its label when federal law requires FDA's prior approval, the state law is preempted under the doctrine of "impossibility preemption" because it would be "impossible for a party to follow both federal and state law." *Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699, 708 (2d Cir. 2019). The Supreme Court recognized in *Wyeth v. Levine*, however, that not all failure-to-warn claims are preempted on this basis, because FDA has promulgated a regulation, called the "changes being effected" (CBE) regulation, 21 C.F.R. § 314.70 (capitalization omitted), that allows manufacturers to unilaterally make certain types of label changes if the regulation's standards are met. In particular, a manufacturer can change the label to add or strengthen a warning if, and only if, the manufacturer has "newly acquired information" that rises to the level of "reasonable evidence of a causal

association with a drug." 21 C.F.R. §§ 314.70(c)(6)(iii), 201.57(c)(6)(i); *see also* Merck Br. 16–17.

Courts have understood this to mean that, to avoid preemption, a failure-to-warn plaintiff must show that such "newly acquired information" existed and allowed the manufacturer to change the label in accordance with the CBE regulation. *See, e.g.*, *Gibbons*, 919 F.3d at 708. Information is "newly acquired" only if it was "not previously submitted" to FDA and it "reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA." 21 C.F.R. § 314.3 (defining "newly acquired information"); *see also id.* § 601.12(f)(6) (similar). And even if such newly acquired information exists, failure-to-warn claims are independently preempted where FDA rejected the putative label change or where it is clear that FDA would have rejected it. Preemption in cases like this thus often turns on (1) what information was submitted to FDA, and (2) whether "the drug manufacturer fully informed the FDA of the justifications for the warning" that the plaintiff contends was required by state law and whether "the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning." *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 302–03 (2019). Merck's motion to dismiss focuses primarily on the first path to preemption. *See* Merck Br. 22–24.

Concluding that the FDCA preempts failure-to-warn claims in this context should often be a simple endeavor. Does the alleged information relied on by the plaintiff constitute "newly acquired information" that justified a unilateral change under the CBE regulation? If not, that is the end of the inquiry, and the claim is preempted. And, even the plaintiff does identify such information, is there clear evidence "that the FDA would not have approved the change[?]" *Gayle v. Pfizer Inc.*, 452 F. Supp. 3d 78, 87 (S.D.N.Y. 2020), *aff'd*, 847 F. App'x 79 (2d Cir. 2021) (mem.).

Importantly, the Supreme Court recently held that preemption in this context "is a legal [question] for the judge, not a jury" to decide. *Merck Sharp & Dohme*, 587 U.S. at 316. As such, it should be a prime candidate for resolution early in the litigation, including at the motion-to-dismiss stage.

Unfortunately, however, the fact that preemption is not absolute in this context opens a door to clever plaintiffs: They can try to avoid preemption at the motion-to-dismiss stage by (a) making conclusory allegations that the CBE regulation would have allowed the defendant-manufacturer to change the label without FDA approval in the manner that state law supposedly required; and (b) refraining from including in the complaint the information needed to assess that allegation. As this case demonstrates, a plaintiff may have no basis to get past the first preemption question identified above—whether the defendant had any "newly acquired information" relevant to the claim—but nonetheless may allege the contrary in conclusory terms while omitting the fact that the defendant disclosed all relevant information to FDA. Through these pleading tactics, plaintiffs with preempted claims may survive a motion to dismiss, often forcing defendants to endure needless and burdensome discovery.

A. Plaintiffs consistently seek to plead around preemption in the FDCA context.

There is a clear pattern in failure-to-warn cases, like this one, of plaintiffs attempting to plead artfully around FDCA preemption.

As relevant here, Plaintiffs can omit material that would show that alleged "newly acquired information" was not, in fact, new. The Second Circuit, for example, has held that dismissal is appropriate where a complaint alleges certain developments that occurred after a label was approved, but "provides no basis upon which the court could conclude that the … events covered by the alleged 'reports' and 'studies' presented a different type of risk than those the company had discussed with the FDA, or were more severe or more frequent than … events that the government already knew about." *Gibbons*, 919 F.3d at 708. But by the simple expedient of omitting from the

complaint information about what "the company had discussed with the FDA" or what "the government already knew about," *id.*—or, even worse, including incorrect allegations that certain information was *not* submitted to FDA—a plaintiff may make it harder for the court to assess this key question at the pleadings stage.

The Supreme Court has repeatedly discouraged avoidance of preemption through artful pleading. *See, e.g.*, *Aetna Health Inc. v. Davila*, 542 U.S. 200, 214 (2004) ("[D]istinguishing between pre-empted and non-pre-empted claims based on the particular label affixed to them would 'elevate form over substance and allow parties to evade' the pre-emptive scope of ERISA simply 'by relabeling their contract claims as claims for tortious breach of contract.'" (quoting *Allis-Chalmers Corp. v. Lueck*, 471 U.S. 202, 211 (1985))); *Chi. & N.W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 324 (1981) ("[C]ompliance with the intent of Congress cannot be avoided by mere artful pleading."). And some courts, like the Second Circuit in *Gibbons*, have rightly dismissed failure-to-warn claims as preempted at the motion-to-dismiss stage, despite such tactical pleading. *See Gibbons*, 919 F.3d at 708; *see also, e.g.*, *McGrath v. Bayer HealthCare Pharms. Inc.*, 393 F. Supp. 3d 161, 171 (E.D.N.Y. 2019) ("[T]he Complaint fails to state a plausible claim that Bayer could have unilaterally changed its label under the CBE regulation, and Plaintiff's failure-to-warn claim is preempted."); *Gayle*, 452 F. Supp. 3d at 87 ("Plaintiffs' claims here fail at the first step because ... they consist of conclusory and vague allegations and do not plausibly allege the existence of newly acquired information that could have justified Defendants' revising the [Lipitor] label through the CBE regulation." (quoting *Gibbons*, 919 F.3d at 708)). But in far too many cases, these pleading tactics have been successful, with courts recognizing the potential validity of the preemption defense but determining that it is not resolvable at the motion-to-dismiss stage. *See, e.g.*, *Frye v. Novartis Pharms. Corp.*, No. 4:21-cv-1173, 2022 WL 4305656, at *8 (E.D. Ark. Sep.

19, 2022); *Lauderdale v. Organon USA, Inc.*, No. 5:21-CV-5200, 2022 WL 3702113, at *10 (W.D. Ark. Aug. 26, 2022); *In re Suboxone (Buprenorphine/Naloxone) Film Prods. Liab. Litig.*, 761 F. Supp. 3d 1069, 1084–85 (N.D. Ohio 2024); *Stube v. Pfizer Inc.*, 446 F. Supp. 3d 424, 439 (W.D. Ark. 2020). In such cases, the court instead requires defendants to submit to onerous discovery. *See infra* Section I.B.

This phenomenon is not limited to the specific preemption question at issue here, even within the world of FDCA preemption. For claims involving certain medical devices, the FDCA contains an express preemption provision barring any state-law requirement that "is different from, or in addition to, any requirement applicable under [the FDCA] to the device." 21 U.S.C. § 360k(a)(1). In this context, then, "[e]ven if federal law *allowed* [a manufacturer] to provide additional warnings … any state law *imposing* an additional requirement is preempted by § 360k." *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1205 (8th Cir. 2010). In other words, it does not matter if the manufacturer is *permitted* to amend its warnings for the device under a federal-law mechanism like the CBE regulation because, under § 360k, state law cannot *require* the manufacturer to do so. *See id.*

Yet, even in this context where Congress legislated broad express preemption, plaintiffs hoping for a ticket to discovery—and thus to settlement leverage—have a potential out at the pleading stage: They plead that the defendant's device did not conform to its FDA approval specifications, for example because of an alleged "manufacturing defect," and contend that state law imposes a "parallel" duty to adhere to those federal requirements. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) ("§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495

(1996)). Although this is "a narrow gap through which a plaintiff's state-law claim must fit if it is to escape" preemption, *In re Medtronic, Inc.*, 623 F.3d at 1204 (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009)), plaintiffs nonetheless try to fit through it at the pleading stage through conclusory allegations that identify neither what was supposedly defective about the device's manufacture nor what FDA approval specification that (unidentified) manufacturing problem caused the device not to satisfy. Again, while some courts spot this tactic for what it is and dismiss such claims as inadequately pleaded or implausible, *see, e.g., id*. at 1204–07, 1209 (affirming dismissal of failure-to-warn and design and manufacturing defect claims); *Gallego v. Tandem Diabetes Care, Inc.*, 776 F. Supp. 3d 119, 144 (E.D.N.Y. 2025); *Croci v. Zoll Med. Corp.*, No. 24-CV-02137, 2025 WL 2307728, at *8 (S.D.N.Y. Aug. 11, 2025); *Green v. Bayer Corp.*, 522 F. Supp. 3d 492, 503 (E.D. Ark. 2021), too many plaintiffs are able to use thinly pleaded and factually unsupported claims like these to unlock the discovery process, *see, e.g.*, *Riddley v. CooperSurgical, Inc.*, No. 2:24-cv-109, 2024 WL 4557340, at *14 (N.D. Tex. Oct. 23, 2024) (rejecting preemption argument for failure-to-warn claim based on allegation that defendants "breached their common-law duty and violated FDA requirements"); *Armstrong v. ABC Corp.*, No. 1:21-CV-04368, 2023 WL 6063806, at *13 (W.D. La. Aug. 21, 2023) (same, where plaintiffs alleged that defendant "violated its duties to document and report adverse events to the FDA"), *report and recommendation adopted sub nom. Armstrong v. Biotronik, Inc.*, 2023 WL 6247915 (W.D. La. Sep. 25, 2023).

B. Where artfully pled complaints survive the motion-to-dismiss stage, the parties are forced to engage in wasteful discovery for meritless claims.

When plaintiffs manage to plead around preemption and survive a motion to dismiss, they are rewarded with discovery. Given the nature of the preemption question, a narrow and discrete body of evidence can often entitle defendants to judgment—for example, documents showing that

the manufacturer in fact submitted the allegedly new information to FDA. *See supra* pp. 3–6. But plaintiffs typically seek to take full discovery on all potential issues in the case before the defendant has an opportunity to move for summary judgment on this or other narrow, dispositive issues. This is a waste of party and court resources.

Cases portray a cautionary tale of years of discovery ultimately leading to a simple preemption ruling. In one case, for example, a district court determined that "in light of the known issues and the ongoing give-and-take between Boehringer and the FDA on these issues" and "the FDA's continued inaction," certain failure-to-warn claims were preempted. *Ridings v. Maurice*, 444 F. Supp. 3d 973, 998 (W.D. Mo. 2020) (emphasis omitted). But the court did so only after "the parties engaged in a period of extensive pretrial discovery." *Id.* at 978. In another example, the court waited until the conclusion of discovery to rule that "plaintiffs' state law claims based on Merck's failure to upgrade the depression warning to the [warnings and precautions section of the label] are clearly preempted … because the FDA has explicitly declined to require such a warning in its letter response to the September 2017 citizen petition." *Pfaff v. Merck & Co.*, 627 F. Supp. 3d 134, 144 (E.D.N.Y. 2022). More examples abound. *See, e.g.*, *Bueno v. Merck & Co.*, 746 F. Supp. 3d 853, 877, 880 (S.D. Cal. 2024) (granting summary judgment on preemption grounds after over two years of litigation); *R.S.B. ex rel. Hammar v. Merck & Co.*, No. 20-C-1402, 2022 WL 3927868, at *5 (E.D. Wis. Aug. 31, 2022) (granting summary judgment after nearly two years of litigation "[b]ecause Plaintiffs have failed to demonstrate that Merck had newly acquired information to support a CBE label change"); *In re Zofran (Ondansetron) Prods. Liab. Litig.*, 541 F. Supp. 3d 164, 206 (D. Mass. 2021) (concluding—more than two years after initially denying summary judgment—that *Merck Sharp & Dohme* justified summary judgment on preemption grounds because "[t]he FDA was fully informed of the justifications for such a warning and the

FDA, in turn, informed the manufacturer of Zofran that it would not approve a change to the drug's label to include such a warning when it formally approved the new Zofran label"), *aff'd*, 57 F.4th 327 (1st Cir. 2023); *Lyons v. Boehringer Ingelheim Pharms., Inc.*, 491 F. Supp. 3d 1350, 1367 (N.D. Ga. 2020) (granting summary judgment after nearly two years of litigation because "[t]he FDA's repeated refusal to allow Defendant to warn that P-gp inhibitor co-medication is a risk factor for bleeding constitutes clear evidence that the FDA would have rejected the warning the Plaintiff seeks").[2]

One Ninth Circuit case is particularly instructive. In *In re Incretin-Based Therapies Products Liability Litigation*, the district court initially granted defendants summary judgment based on preemption after limited discovery, concluding that "the FDA would have rejected a reference to pancreatic cancer in the product labeling during the time in which Plaintiffs' claims accrued." 142 F. Supp. 3d 1108, 1132 (S.D. Cal. 2015). But the Ninth Circuit remanded for more discovery, without reaching the preemption question. *See In re Incretin-Based Therapies Prods. Liab. Litig.*, 721 F. App'x 580, 581–82, 584 (9th Cir. 2017). Then, "[s]everal years later, and upon completion of supplemental discovery," the district court adhered to its original opinion, concluding that "because Defendants fully informed the FDA of the justifications for a pancreatic cancer warning, and the FDA effectively informed them that it would not approve the label change," the claims were preempted. *In re Incretin-Based Therapies Prods. Liab. Litig.*, 524 F.

[2] While many of these cases did not involve preemption arguments at the motion-to-dismiss stage and so the courts there did not have the opportunity to resolve the preemption question early in the litigation, this Court does have that opportunity. Where, as here, the preemption issue is straightforward, resolving it at the motion-to-dismiss stage avoids the unnecessary discovery and litigation costs that the courts and the parties incurred in many of the cases cited in the text.

Supp. 3d 1007, 1014, 1033 (S.D. Cal. 2021), *aff'd on other grounds*, 2022 WL 898595, at *2 (9th Cir. Mar. 28, 2022).

Greenlighting thinly pleaded claims into full discovery places a serious burden on defendants. One 2012 study found that the median e-discovery cost is $1.8 million. *See* Nicholas M. Pace & Laura Zakaras, RAND Inst. for Civ. J., Where the Money Goes: Understanding Litigant Expenditures for Producing Electronic Discovery 17 (2012). "By some estimates, discovery costs now comprise between 50 and 90 percent of the total litigation costs in a case." John H. Beisner, *Discovering a Better Way: The Need for Effective Civil Litigation Reform*, 60 Duke L.J. 547, 549 (2010). Extensive discovery also imposes serious burdens on courts, which have to referee the inevitable disputes and which see cases linger on their dockets for years. *See Chudasama v. Mazda Motor Corp.*, 123 F.3d 1353, 1367–68 (11th Cir. 1997) ("[D]iscovery imposes burdens on the judicial system; scarce judicial resources must be diverted from other cases to resolve discovery disputes." (footnote omitted)). The FDCA context is no different. Requiring defendants to submit to onerous discovery where the preemption question is easily resolved is wasteful.[3]

Permitting plaintiffs to survive dismissal and unlock discovery by artfully pleading around preemption encourages plaintiffs to bring such claims because defendants may decide it is more cost-effective to settle than face discovery—even with a winning defense. Indeed, the Supreme Court explained in *Bell Atlantic Corp. v. Twombly* that "it is self-evident that the problem of discovery abuse cannot be solved by careful scrutiny of evidence at the summary judgment stage"

[3] Some courts have agreed to limit discovery to only what is needed to decide the preemption question. *See, e.g.*, *In re Gardasil Prods. Liab. Litig.*, 770 F. Supp. 3d 893, 903 (W.D.N.C. 2025) (explaining that "the Court and the Parties agreed to prioritize discovery and dispositive motions on general causation and implied preemption" (quotation marks omitted)); *id.* at 921 (finding failure-to-warn claims preempted because "Merck could not lawfully change the Gardasil label without prior approval from the FDA").

because "the threat of discovery expense will push cost-conscious defendants to settle even anemic cases before reaching those proceedings." 550 U.S. 544, 559 (2007) (quotation marks omitted); *see also id.* at 558 (explaining risk that "a plaintiff with a largely groundless claim be allowed to take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement value" (quotation marks omitted)). Scholars have observed the same phenomenon. *See* Hon. Paul W. Grimm & David S. Yellin, *A Pragmatic Approach to Discovery Reform: How Small Changes Can Make a Big Difference in Civil Discovery*, 64 S.C. L. Rev. 495, 520–21 (2013) ("Many critics of the current discovery rules argue that … the current rules actually create an economic incentive purposely to ask for excessively expensive and burdensome discovery in order to coerce the producing party to seek a settlement purely as a means to avoid excessive discovery costs and not on the basis of the merits of the case."); Linzey Erickson, *Give Us a Break: The (In)equity of Courts Imposing Severe Sanctions for Spoliation Without a Finding of Bad Faith*, 60 Drake L. Rev. 887, 925 (2012) ("In many instances, the cost of litigation may be so high that companies are unwilling to try the case on the merits."); Jack M. Sabatino, *ADR as "Litigation Lite": Procedural and Evidentiary Norms Embedded Within Alternative Dispute Resolution*, 47 Emory L.J. 1289, 1310 n.90 (1998) ("Many lawyers and judges believe that discovery is increasingly used 'as a weapon rather than as an information gathering mechanism.'" (quoting *Interim Report of the Committee on Civility of the Seventh Judicial Circuit*, 143 F.R.D. 371, 387 (1991))).

Lauderdale v. Organon USA, Inc., serves as an example. There, the plaintiff claimed that, following the approval of a label for a certain drug, "new scientific literature, clinical studies, and adverse event reports emerged (1) confirming a causal relationship between [the drug] and [a certain health] risk, and (2) demonstrating the risk … was particularly high among obese women

and African-American women using [the drug]." 2022 WL 3702113, at *9. The defendants countered that the "post-approval claim is preempted because the information cited in the Complaint is neither newly acquired nor capable of supporting strengthened or additional warning." *Id.* But the court refused to reach the defendants' argument that the complaint "overstate[d] the research's significance," concluding that doing so would require "analyz[ing] the evidence." *Id.* at *10. The court thus told the defendants "to conduct discovery, assemble evidence, and present the Court with a factual record that proves as much." *Id.* But rather than pursue this costly endeavor, the defendants appear to have settled the claim. *See Lauderdale v. Organon USA, Inc.*, No. 5:21-cv-5200 (W.D. Ark. Jan. 25, 2023), ECF 78 (joint stipulation of dismissal).

Whether or not one believes that the district court's pleading-stage decision in that case was correct, the case illustrates the incentive for plaintiffs if they are permitted to strategically plead around preemption, survive a motion to dismiss, and obtain full discovery. Even where a plaintiff's claims are preempted, the specter of such discovery may compel defendants to settle. This encourages the sort of strategic pleading present in this case.

The costs of unnecessary discovery are not just felt by pharmaceutical manufacturer-defendants. For one, as noted above, "discovery imposes burdens on the judicial system." *Chudasama*, 123 F.3d at 1367. And in the circumstances here, the public is also harmed by increased and unnecessary litigation costs. Developing drugs is very expensive. *See, e.g.*, Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 25 (2016) (estimated average industry cost of new prescription drug approval, including failures and capital costs, is $2.59 billion). A manufacturer will not invest the vast sums necessary to develop a drug unless it believes it can recoup its investment. Allowing preempted claims to proceed through discovery imposes significant and unpredictable defense and liability

costs on manufacturers and may thereby reduce their willingness to invest in drug development in the first place. *See Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1346–47 (10th Cir. 2015) (Gorsuch, J.) (discussing medical devices). At a minimum, increasing litigation costs lead to higher drug prices, as manufacturers will be forced to recover the costs through their sales. *See* Richard L. Manning, *Products Liability and Prescription Drug Prices in Canada and the United States*, 40 J.L. & Econ. 203, 227 (1997) (finding that "a substantial premium exists in U.S. pharmaceutical prices, strongly related to the prospective costs of litigation, which is absent in the Canadian prices").

II. The complaint in this case illustrates the problem of artfully pleading around preemption.

As argued in Merck's motion to dismiss, Plaintiffs' claims are preempted by the FDCA and should be dismissed on that basis. That is because, among other reasons, (1) Merck submitted much of the purported "newly acquired information" to FDA, *see* Merck Br. 22–24, and (2) the studies Plaintiffs rely on do not demonstrate a causal association between on-label Keytruda use and a different type, severity, or frequency of risk than what FDA already knew about, *see* Merck Br. 24–37.

But Plaintiffs take a page out of the playbook detailed above. They attempt to avoid the inevitable preemption of their lawsuit by invoking the CBE regulation, asserting that "new safety information emerged that should have prompted Defendant to unilaterally change the Keytruda label." *See* Compl. ¶¶ 28–33 (citing 21 C.F.R. § 314.70). While Plaintiffs cite a collection of studies, they fail to clearly define what the "new safety information" was that purportedly triggered the CBE regulation. And they repeatedly—and often incorrectly—allege that Merck did not disclose the identified studies to FDA. *See, e.g.*, Compl. ¶¶ 35, 41, 49, 77, 82. Contrary to that allegation, the information that Merck highlights for the Court shows that the CBE regulation did

not authorize Merck to make the label change that Plaintiffs contend state law required, in part because Merck submitted many of the studies identified by the Complaint to FDA and therefore the information in those studies could not have been "newly acquired." *See* Merck Br. 22–24. This fact is easily verifiable and is outcome-determinative. Yet the Complaint makes no mention of it.

Plaintiffs take a similar approach to the studies that Merck did not submit to FDA. *See id.* at 19–20. A review of those studies demonstrates that they do not contain the sort of information that could justify a unilateral label change under the CBE regulation's terms. *See id.* at 24–37. If those studies were attached as exhibits to the Complaint—or if the Complaint included meaningful information about them—then it would be simple for the Court to review the studies and determine as much. Instead, however, Plaintiffs provide only minimal information about these studies while alleging in a conclusory fashion that the CBE regulation applies. *See* Compl. ¶ 33 (alleging that "new safety information emerged that should have prompted Defendant to unilaterally change the Keytruda label"); *see also id.* ¶¶ 37–40, 43–48, 53–57, 60–64, 67–74 (containing only cursory summaries of the allegedly relevant studies).

For the reasons set forth more fully in Merck's brief, Plaintiffs' attempt to avoid preemption fails. But Plaintiffs will presumably argue that the materials presented by Merck cannot be considered at the motion-to-dismiss stage and ask the Court to punt on the dispositive preemption issue until after full discovery. That would increase both the cost and intrusiveness of this litigation for Merck—and, not coincidentally, increase the odds that Plaintiffs can extract a settlement before the preemption of their claims is decided.

This case thus exemplifies the harmful pattern identified above: Plaintiffs attempt to use tactical pleading to avoid preemption and obtain extensive discovery, even though basic documents before the Court, including the documents of which Merck asks this Court to take judicial notice,

see Merck Br. 22–24, ECF 25, provide a clear answer to the dispositive preemption question. Allowing this lawsuit to move forward to discovery would be wasteful and would encourage more efforts to plead around preemption. Where, as here, it is clear at the outset that claims are preempted, courts should not hesitate to find them preempted. The "just, speedy, and inexpensive determination of every action" is the goal in civil litigation. Fed. R. Civ. P. 1. Unnecessarily postponing a dispositive defense would be contrary to that goal.

CONCLUSION

For the reasons set forth above, the Court should grant Merck's motion to dismiss.

Dated: November 24, 2025

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