UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE SUBOXONE (BUPRENORPHINE/ NALOXONE) FILM PRODUCTS LIABILITY LITIGATION	)	Case No. 1:24-md-03092-JPC
	)	MDL 3092
	)	Judge J. Philip Calabrese
This Document Applies to *Bennett v. Indivior Inc., et al.*, 1:24-sf-65011	)	

PLC'S Response to Partial Motion to Dismiss for Failure to State a Claim (ECF No. 126)

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INTRODUCTION

Plaintiff Ryan Bennett sues Defendant Indivior Inc. for failure to warn of the risk of dental injury. He sues Defendants Indivior Inc., Indivior Solutions, Inc., and Aquestive Therapeutics for pre-approval design-defect claims. The parties stipulated to dismissal of Defendants Indivior PLC, Reckitt Benckiser LLC, and Reckitt Benckiser Healthcare (UK) Ltd. (Case No. 1:24-sf-65011, ECF No. 14.)

Defendants moved to partially dismiss Mr. Bennett's claims, contending certain aspects of his failure-to-warn claims are preempted and his design-defect claims are entirely preempted. (ECF No. 126-1.) Defendants concede that Mr. Bennett states claims for failure to warn against Indivior Inc. from the launch of Suboxone film in 2010 through the label change on June 17, 2022. (*Id.*, PageID #2765, 2787.)

Defendants argue Mr. Bennett's "pre-approval" warning claim is preempted because an approved label is adequate as a matter of law. (*Id.*, PageID #2783–84.) It is not altogether clear what Defendants mean by this assertion. Mr. Bennett is not seeking recovery for injuries occurring *before* FDA approved the product predicated on failure to warn; obviously no one used Suboxone before it was approved by FDA.

What they likely mean, given the accompanying citations, is that a plaintiff may not rely on "newly acquired information" (NAI) that predates a label change. If so, then they—and the case law they cite—are clearly wrong because *Wyeth v. Levine*, made clear two fundamental tenets: (1) the *manufacturer* is responsible for its label *at all times*; and (2) NAI data includes "previously submitted data" *including* data

that predates the label. 555 U.S. 555, 569 (2009). In short, nothing precludes a plaintiff from relying on data that predates FDA's approval of a label to either evade preemption or prove an element of his claim.

Nor is Indivior's post-label-change argument impactful. A "central premise of federal drug regulation [is] that the manufacturer bears responsibility for the content of its label at all times." *PLIVA, Inc. v. Mensing,* 564 U.S. 604, 616 (2011) (internal quotations omitted). As such, a manufacturer *always* operates under an obligation to satisfy FDA's "Changes Being Effected" (CBE) regulations to add or strengthen a warning. Thus, where NAI could support a label change, the plaintiff's claim is not preempted. *Id.* And because NAI can come from *any* source, including a *reanalysis of previously submitted data*, the mere fact FDA approved an updated label does not change the preemption analysis.

Put another way, the issue is, as it is in every other preemption setting: does NAI exist that, taken cumulatively with all other relevant information, could lead to a label change? The mere fact an intervening label change occurred is insufficient to establish a claim is preempted.

Defendants' design-defect preemption argument fares no better. Though in *Yates v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.* the Sixth Circuit held that plaintiff's pre-approval design-defect claim was preempted, the sole basis for that conclusion was predicated upon the notion that speculating what action FDA may, or may not, take with respect to a safer alternative drug *that was not FDA approved* was "too attenuated." 808 F.3d 281, 299 (6th Cir. 2015). Here, no such "attenuation"

exists. The safer alternative Mr. Bennett pleads is extended-release injectable buprenorphine (Sublocade), which the FDA already approved.

Notwithstanding Defendants' contention to the contrary, Mr. Bennett's pre-approval design-defect claim is about the *delivery system for buprenorphine*. So the issue for this Court under *Yates* is: would FDA approve a safer alternative buprenorphine-delivery system? The answer is yes. The FDA approved Sublocade in 2017. And because Mr. Bennett alleges that alternative design was available before Defendants launched Suboxone film in 2010, his pre-approval design-defect claim is not preempted.

Finally, to the extent that the Court finds any aspect of Mr. Bennett's claims are impliedly preempted, he challenges the constitutionality of that judicially created doctrine as an intrusion on the dual sovereignty of the State of Ohio and its authority to protect the health and safety of its citizens.

FACTS

Plaintiff Ryan Bennett was prescribed opioids for pain management and Suboxone film to treat the resulting opioid use disorder. (*Id.*, ¶¶ 13–14.)[1] Before he was prescribed the film, he and his physicians received no warning that the film was dangerous for his teeth, instructions on how to minimize such dangers, or the importance of tapering off the product to avoid long-term exposure to its acidic formulation. (*Id.*, ¶¶ 15, 123–24, 186–89, 203, 217.) As a result of using Suboxone film, he suffers from severe and profound permanent tooth loss. (*Id.*, ¶ 16.)

[1] All citations are to his amended complaint, filed July 1, 2024, in Case No. 1:24-sf-65011, ECF No. 12.

Suboxone film is an oral dissolvable form of buprenorphine used to treat opioid use disorder. (*Id.*, ¶ 3.) Indivior Inc.'s predecessor (thrice removed) is Reckitt & Colman, which secured orphan-drug designation for buprenorphine in 1994. (*Id.* at ¶¶ 19, 43, 60.) Its successor company, Reckitt Benckiser Pharmaceuticals, received FDA approval for their first buprenorphine-containing products to treat opioid addiction in 2002: Subutex (buprenorphine) and Suboxone (buprenorphine/naloxone), both of which were in tablet form. (*Id.*, ¶ 54.)

Because buprenorphine was designated an orphan drug, approval of the Subutex and Suboxone tablets provided a seven-year exclusivity period during which no competitors could enter the market. (*Id.*, ¶ 64.) To avoid generic competition as the exclusivity period was expiring, Defendants developed Suboxone film as a bioequivalent to tablets (meaning the same amount of buprenorphine would be released into the patient's bloodstream), but that was not A-B rated to tablets (and thus did not qualify for generic substitution at the pharmacy). (*Id.*, ¶ 66.) The patent application affirms that the film has the "same active" as the tablets, *i.e.*, buprenorphine. (*Id.*, ¶ 69.) Defendants relied on the same studies to secure approval of the film and tablets, including two studies testing a "buprenorphine solution" not in tablet or film form. (*Id.*, ¶¶ 57–58, 67.)

The product hop from the tablet to the film was a monopolistic strategy designed to avoid generic competition: by substituting one buprenorphine-delivery system for another, Defendants secured a path to brand-name profits that did not improve the safety or efficacy of the product. (*Id.*, ¶¶ 72–73.) Though Defendants

pulled Suboxone tablets from the market in the United States in 2013, the tablets remain available in international markets, and generic tablet competitors remain available in the United States. (*Id.*, ¶ 72.)

In the wake of the successful product hop, various antitrust claims as well as criminal actions began. (*Id.*, ¶¶ 74–76.) To date, over a billion dollars in corporate profits have been disgorged, two senior executives were convicted of misbranding Suboxone film, and the CEO of Indivior Inc. went to prison. (*Id.*)

I. Facts specifically relevant to Mr. Bennett's failure-to-warn claim

In early 2022, the FDA announced that it would require a warning on all "medicines containing buprenorphine that are dissolved in the mouth." (*Id.*, ¶ 6.) On June 17, 2022, the Suboxone film prescribing information was revised to include the following language:

5.13 Dental Adverse Events

Cases of dental caries, some severe (i.e., tooth fracture, tooth loss), have been reported following the use of transmucosal buprenorphine-containing products. Reported events include cavities, tooth decay, dental abscesses/infection, rampant caries, tooth erosion, fillings falling out, and, in some cases, total tooth loss. Treatment for these events included tooth extraction, root canal, dental surgery, as well as other restorative procedures (i.e., fillings, crowns, implants, dentures). Multiple cases were reported in individuals without any prior history of dental problems.

Refer patients to dental care services and encourage them to have regular dental checkups while taking SUBOXONE. Educate patients to seek dental care and strategies to maintain or improve oral health while being treated with transmucosal buprenorphine-containing products. Strategies include, but are not limited to, gently rinsing the teeth and gums with water and then swallowing after SUBOXONE has been completely dissolved in the oral mucosa. Advise patients to wait for at least one hour after taking SUBOXONE before brushing teeth *[see Dosing and Administration (2.5), Information for Patients (17), Medication Guide].*

(ECF No. 121-2, PageID #2291.)[2] Indivior acknowledges that Mr. Bennett has adequately pled his claim for failure to warn before June 17, 2022. (ECF No. 126-1, PageID #2787.)

Mr. Bennett alleges, however, that the updated language remained insufficient to adequately inform the public and prescribing physicians of the true risks of dental injuries or provide adequate instructions to minimize those risks. (*Id.*, ¶¶ 9, 121, 203, 217.) As detailed in Section I.B below, in analyzing newly acquired information for purposes of invoking a CBE, the Court must consider the accumulated information over time (including reanalysis of that information), not just what happened after the label change. Mr. Bennett therefore details the cumulative body of information on which Indivior Inc. must presently base its warning obligations.

Suboxone film was approved in 2010 and the film and tablets were available during the 2010–13 time period. (*Id.*, ¶¶ 68, 73.) In 2012, Harvard Medical School

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[2] Mr. Bennett does not object to the Court taking judicial notice of Defendants' Exhibits 1-A (Suboxone film prescribing information) (ECF No. 121-2) or 1-B (Sublocade prescribing information) (ECF No. 121-3) as both are matters of public record not reasonably subject to dispute. *Stafford v. Jewelers Mut. Ins. Co.*, 554 F. App'x 360, 369 (6th Cir. 2014).

He acknowledges that Indivior Inc. is the exclusive NDA holder for Suboxone film and tablets, so the Court need not take judicial notice of Defendants' Exhibits 1-C, 1-D, and 1-F (ECF Nos. 121-4, 121-5, and 121-7), which all address Indivior Inc.'s NDA-holder status.

Mr. Bennett does object to the Court taking what can be described as partial judicial notice (at most) of Defendants' Exhibit 1-E (ECF No. 121-6). That exhibit does not appear to be a publicly available document—the link reportedly used to access the document does not lead to a valid webpage—and the exhibit is partially redacted. It is outside of the pleadings, not cited by Mr. Bennett, and therefore is not properly before the Court on a Rule 12(b)(6) motion. *See Thomas v. Noder-Love*, 621 F. App'x 825, 829 (6th Cir. 2015) ("Documents outside of the pleadings that may typically be incorporated without converting the motion to dismiss into a motion for summary judgment are 'public records, matters of which a court may take judicial notice, and letter decisions of governmental agencies.'"). *See also Passa v. City of Columbus*, 123 F. App'x 694, 698 (6th Cir. 2005).

professors published a case report concluding "'the possibility that chronic use of sublingual buprenorphine/naloxone may have played a role'" in the affected patient's dental injuries. (*Id.*, ¶ 79 (citing Suzuki J and Park EM, *Buprenorphine/naloxone and dental caries: a case report.* AM J. ADDICT. 2012 Sep–Oct;21(5):494–5).)

The following year, a case series of 11 patients reported worsening dental health, including extractions, fillings, caries, and root canals, noting that these injuries "occur when teeth are exposed to an environment that has low pH." (*Id.*, ¶¶ 80–82 (citing Suzuki J., et al, *Sublingual buprenorphine and dental problems: a case series*, PRIM CARE COMPANION CNS Diord. 2013;15(5) (Oct. 3, 2013), in turn citing letter from Reckitt Benckiser Pharmaceutical's chief medical officer asserting that the Suboxone tablet had a pH of 3.4).) The authors concluded that "prolonged contact between tooth surfaces with buprenorphine/naloxone, therefore, may be a contributing factor in the alteration of the tooth microbial profile and/or the pH to promote dental caries, similar to what has been previously reported in patients who use methamphetamine." (*Id.*) Mr. Bennett further alleges that Defendants knew that the film was acidic: the patent (US Patent 8,475,832 B2) indicates a target pH range of 2–4 with the "ideal" pH being 3.5. (*Id.*, ¶ 88.)

Meanwhile, adverse-event reports for "Suboxone" mounted in the FAERS database. (*Id.*, ¶¶ 89–103.) "The FAERS database does not distinguish between the tablet and film forms of Suboxone in reporting adverse events" because they contain the same active ingredient (buprenorphine). (*Id.*, ¶ 87.) Mr. Bennett alleges that 136 reports of dental adverse events are documented in FAERS from the launch of the

tablet through the end of 2021. (*Id.*, ¶¶ 90–103.) After FDA issued its Safety Communication in January 2022, another ten dental adverse events were reported before the June 17, 2022 label update. (*Id.*, ¶ 104.)

In addition, more than 100 adverse-event reports of dry mouth/xerostomia coincident with the use of Suboxone were reported. (*Id.*, ¶ 175.) This is significant because xerostomia, "'is associated with a low pH of the saliva and a decreased buffering capacity'" and is "'strongly associated with dental erosion.'" (*Id.*, ¶ 174 (citing Ana Carolina Magalhaes, et al., *Insights into preventative measures for dental erosion*, 17 J. APPLIED ORAL SCI. 75, 79 (2009)). Mr. Bennett alleges that the dry-mouth side effect "worsens the risk of dental erosion that Suboxone film already poses." (*Id.*)

Mr. Bennett alleges that Indivior Inc. should have known that the adverse events were being underreported due to (1) the fact that published literature reports that only a slim fraction of AEs are actually reported to FDA; (2) the dentists who treat the injuries caused by Suboxone film are not the doctors who prescribed it and may not even know a patient is on the drug; and (3) the patient population has a high risk of being lost to follow-up. (*Id.*, ¶¶ 107–10.) Mr. Bennett alleges that Indivior Inc. should have afforded greater significance to the AEs that were reported in light of the practical realities of existence for this patient population. (*Id.*, ¶ 110.)

Six months after the June 2022 label change, a research letter published in the Journal of the American Medical Association reported on increased risk for dental adverse events with use of sublingual buprenorphine dissolvables compared with

transdermal buprenorphine and oral naltrexone. (*Id.*, ¶ 117.) Mr. Bennett does not allege that Indivior Inc. provided this information to the FDA. The Court may take judicial notice of its own docket. *Chase v. MaCauley*, 971 F.3d 582, 587 n.1 (6th Cir. 2020). This would include the ~11,000 individuals who have filed individual cases or who are included on Schedule A. (ECF No. 100-1, 101-1.) Construing the facts in Mr. Bennett's favor, these constitute thousands of additional adverse-event reports of dental injuries. Mr. Bennett does not allege that Indivior Inc. provided this information to the FDA.[3]

Mr. Bennett contends that the Suboxone film label remains inadequate following the June 17, 2022 additions because the language does not adequately inform patients and physicians that permanent dental erosion and decay are associated with Suboxone film usage. (*Id.*, ¶ 123.) It merely asserts that "cases…have been reported." (ECF No. 121-2, PageID #2291.) Nor does it inform physicians or patients that "indefinite" use of the drug (which its prescribing information indicates may be the duration of maintenance treatment) increases that risk. (*Id.*, ¶ 124; ECF No. 121-2, PageID #2285.) Mr. Bennett alleges that Indivior failed and continues to fail to provide warnings that, *e.g.*,

- "accurately reflect the symptoms, scope, severity, and permanence of the side effects and health risks;"

[3] Indeed, it is impossible that Indivior Inc. provided this information to FDA. Attached as Exhibit 1 to the Declaration of Ashlie Case Sletvold (ECF No. 134) is a spreadsheet of the FAERS adverse-event reports on "Suboxone" for the years 2023–24 for the reaction group "Musculoskeletal and Connective Tissue Disorders" (in which dental injuries appear). (ECF No. 134-1.) It lists a total of 36 adverse events sent to FDA during that time period; only 11 reference dental adverse reactions.

- provide the "proper or adequate rate of incidence or prevalence of dental-related injuries;"
- "warn of the consequences that might result from failure to follow the instructions related to dental health;"
- "provide instructions on ways to safely use Suboxone film to avoid injury (including as to duration of use);"
- "instruct providers to conduct saliva quality, pH, and buffering capacity testing before and during Suboxone film usage;"
- "explain the mechanism, mode, and types of adverse events associated with Suboxone film;" and
- "advise patients and/or physicians that there existed safer and more or equally effective alternative products, treatment options, and/or delivery mechanisms that do not carry the risks posted by Suboxone film."

(*Id*. at ¶ 217.)

II. Facts specifically relevant to Mr. Bennett's pre-approval design-defect claims

Mr. Bennett alleges that "[r]ecovering from an opioid addiction often involves medication-assisted therapy. Such medications include methadone, naltrexone, or buprenorphine, each of which reduce cravings and the risk of relapse." (*Id*., ¶ 41.) He alleges that "[o]ral absorption is not the only way to administer buprenorphine for opioid use disorder," (*id*., ¶ 149) and identifies various delivery modes: "subdermal or subcutaneous implant, intravenous or intramuscular injection, transdermal patch, and oral forms including tablets and films dissolved in the mouth." (*Id*., ¶ 48.)

Mr. Bennett alleges that "[p]olymer extended-release injections for drug delivery have been technologically feasible since the 1990s." (*Id*., ¶ 153 (citation omitted).) "The FDA approved a polymer extended-release injectable naltrexone

(trade name Vivitrol) for treating alcohol dependence nearly two decades ago." (*Id.*, ¶ 154 (citations omitted).)

Mr. Bennett further alleges that "[b]y 2004, it was established that buprenorphine injections using polymer microcapsule depot sustained-release technology are safe and effective for treating opioid use disorder." (*Id.*, ¶ 158 (citations omitted.)) In 2006—before Suboxone film was designed—a company called Biotek, Inc. was awarded a patent for an extended-release monthly buprenorphine injection (called Norvex). (*Id.*, ¶¶ 156–57, 159.)

Mr. Bennett alleges that Sublocade is an alternative delivery mechanism for buprenorphine: "[t]he buprenorphine is incorporated into a polymer solution, becomes incorporated within the polymer matrix, and is slowly released in the body as the polymer biodegrades." (*Id.*, ¶ 161.) Indivior Inc. sought approval for Sublocade on May 30, 2017 and FDA approved it just six months later. (*Id.*)

Mr. Bennett alleges that Suboxone film and Sublocade are two of the possible delivery mechanisms for buprenorphine. He alleges that "[b]ecause Sublocade is injected subcutaneously, it does not create an acidic environment in the mouth." (*Id.*, ¶ 172.) Mr. Bennett alleges that "Defendants knew the safer injection was less likely to cause dental damage than Suboxone film" (*id.*, ¶ 180), and the "FDA would have approved Sublocade earlier had Defendants sought approval of this safer technology for delivering buprenorphine that does not require multiple daily acid baths for patients' teeth" (*id.*, ¶ 163). Finally, Mr. Bennett alleges that he would have taken Sublocade and avoided dental injuries if Defendants had not withheld it. (*Id.*, ¶ 179.).

ARGUMENT

The standards for motions under Rules 12(b)(6) and (c) are well known and the same:[4] "all well-pleaded material allegations of the pleadings of the opposing party must be taken as true, and the motion may be granted only if the moving party is nevertheless clearly entitled to judgment" as a matter of law. *JPMorgan Chase Bank, N.A. v. Winget*, 510 F.3d 577, 581 (6th Cir. 2007). A complaint merely need contain such factual matter—accepted as true—that states a facially plausible claim. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556, 570 (2007). The factual content pleaded by the plaintiff must allow the court to draw the reasonable inference that the defendant is liable for the alleged misconduct. *Hindel v. Husted*, 875 F.3d 344, 346–47 (6th Cir. 2017). The plausibility standard "does not impose a probability requirement at the pleading stage; it simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of illegal [conduct]." *Twombly*, 550 U.S. at 556.

I. Plaintiff's claim for failure to warn is not preempted.

The doctrine of preemption derives from the Supremacy Clause, which provides that federal law "shall be the supreme Law of the Land; … any Thing in the Constitution of Laws of any State to the Contrary notwithstanding." US CONST., art. 6, cl. 2. Indivior Inc. does not argue that federal law expressly preempts Mr. Bennett's claims. It relies instead on the affirmative defense of implied preemption, asserting the affirmative defense that it was "impossible" to comply with both State and federal law. (ECF No. 126-1.)

[4] Defendants answered Mr. Bennett's complaint, (ECF Nos. 127, 129), so their motion to dismiss is a motion for judgment on the pleadings under Rule 12(c).

Impossibility preemption is a demanding defense that "[a] drug manufacturer will not ordinarily" be able to prove. *See Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1679 (2019); *Merrick v. Diageo Americas Supply, Inc.*, 805 F.3d 685, 694 (6th Cir. 2015) (noting there is a "strong presumption" against preemption); *Torres v. Precision Indus., Inc.*, 995 F.3d 485, 491 (6th Cir. 2021) (same). To establish impossibility preemption, a manufacturer must establish that the underlying State law "irreconcilably conflicts" with federal law. So if Mr. Bennett alleges that data existed tending to show "some basis to believe there is a causal relationship between" Suboxone film and dental injuries, then Indivior Inc. was required to submit a CBE to change the label without FDA approval, and the defense fails.

A. An overview of preemption in failure-to-warn cases

1. The CBE process requires a manufacturer to amend its label where data exists establishing "some basis" there is a "causal relationship" between exposure to the drug and harm.

The FDCA grants FDA the authority to regulate drug labeling. 21 U.S.C. § 355(b)(1)(F). In 2007, Congress amended the FDCA to "require a manufacturer to change its drug label based on safety information that becomes available after a drug's initial approval." *Wyeth v. Levine*, 555 U.S. 555, 567 (2009). This obligation is continuous, requiring the manufacturer to evaluate the sufficiency of its label at all times. *Id.* Based on this amendment, *Wyeth* recognized that it is the drug manufacturer, as opposed to FDA, that bears ultimate responsibility for the label's contents. *Id.* at 568. As such, the FDCA affords a manufacturer the right to alert FDA of "Changes Being Effected" (CBE) to the label.

The CBE regulations, in turn, allow a manufacturer to change a drug's label without prior FDA approval, "if the change is designed to 'add or strengthen a . . . warning where there is 'newly acquired information' about the 'evidence of a causal association between the drug and a risk of harm.'" *Albrecht*, 139 S. Ct. at 1673 (quoting 21 C.F.R. § 314.70(c)(6)(iii)(A)). "Newly acquired information" is defined as

> [D]ata, analyses, or other information not previously submitted to the [FDA], which may include (but is not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events, or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA.

21 C.F.R. § 314.3(b).

Discussing the scope of NAI, the Supreme Court reiterated that it includes data triggering any one of the four warning categories subsumed within 21 C.F.R. § 201.57(c). *See Albrecht*, 139 S. Ct. at 1673. This includes data evidencing "*some basis* to believe there is a *causal relationship* between the drug and the occurrence of the adverse event." 21 C.F.R. § 201.57(c)(7) (emphasis supplied). In short, where NAI exists evidencing "some basis" of a causal relationship, the manufacturer must use the CBE process to make an appropriate label change. Failure to do so violates the manufacturer's obligation to "continuously" monitor its label "at all times." *Wyeth*, 555 U.S. at 569.

For purposes of this motion, Mr. Bennett merely need plead what information Indivior Inc. could have "acquired"—cumulatively—but did not send to FDA to evade its motion to dismiss. Put another way, the plaintiff only needs to plead that data exists establishing "some basis" of a "causal relationship." *See* 21 C.F.R. §

201.57(c)(7).[5] Here, that means that to evade a Rule 12 motion, Mr. Bennett must merely plead what "newly acquired information" existed triggering the manufacturer's obligation to use the CBE process.[6] Where the plaintiff satisfies this standard—as Mr. Bennett has here—a defendant's preemption defense fails.

2. Once a plaintiff establishes that he adequately pled the existence of NAI requiring a CBE, the burden shifts to the defendant to *prove*—on a motion for summary judgment—that FDA would reject the proposed label.

Although not directly related to Defendants' motion, the preemption analysis includes an additional step. Specifically, preemption is an affirmative defense. *See In re Taxotere (Docetaxel) Prod. Liab. Litig.,* 508 F. Supp. 3d 71, 79 (E.D. La. 2020) (citation omitted). As such, it is the *manufacturer's* burden to establish the information it supplied, or could have supplied, FDA was not "newly acquired." *Id.* *Albrecht* confirmed as much, indicating it is the defendant's obligation to show federal law "prohibited" it from adding a warning. *Albrecht*, 139 S. Ct. at 1678. As the proponent of a preemption defense, a defendant bears the burden of *proving* it. *See e.g., Rayes v. Novartis Pharms. Corp.,* No. 21-55723, 2022 WL 822195, at *1–2 (9th Cir. Mar. 18, 2022); *Silverstein v. Boehringer Ingelheim Pharm., Inc.*, No. 19-CIV-81188, 2020 WL 6110909, at *11 (S.D. Fla. Oct. 7, 2020); *In re Zofran (Ondansetron)*

[5] Importantly, a label may include warnings that *do not* rise to the level of a confirmed causal association. *See* 21 C.F.R. § 201.57(c)(7). Even assuming a plaintiff bears some burden beyond a burden of alleging "newly acquired information," that burden only extends to alleging the data provides "some basis" of a "causal relationship."

[6] *Gibbons v. Bristol Myers Squibb*, 919 F.3d 699 (2nd Cir. 2019); *Goodell v. Bayer Healthcare Pharm. Inc.*, No. 18-cv-10694, 2019 WL 4771136 (D. Mass. Sept. 30, 2019); *Mahnke v. Bayer Healthcare Pharm. Inc.*, No. 2:19-cv-07271, 2019 WL 8621437 (C.D. Cal. Dec. 10, 2019).

Prod. Liab. Litig., 368 F. Supp. 3d 94, 115 (D. Mass. 2019), *vacated in part on other grounds* (July 15, 2019).

The difficulty with this straightforward tenet arises in pharmaceutical litigation vis-à-vis the shifting burdens associated with preemption. As noted above, on a Rule 12 motion the plaintiff bears the burden of alleging NAI existed to require a CBE. Upon satisfying this pleading threshold, the burden shifts to the manufacturer *to prove*—at summary judgment—with "clear evidence" that: (1) it "fully informed" FDA of the data; and (2) FDA acted to deny a proposed label change under its "congressionally delegated authority." *Albrecht*, 139 S. Ct. at 1678; *see also Hardeman v. Monsanto Co.*, 997 F.3d 941, 958 (9th Cir. 2021); *In re Avandia Mktg., Sales Practices, and Prods. Liab. Litig.,* 945 F.3d 749, 759 (3d Cir. 2019) (holding manufacturer is "not the arbiter" of which data are sufficient to trigger a label change).

Establishing the manufacturer "fully informed" FDA is a daunting task requiring not only that the manufacturer provided FDA the data, but also that it analyzed the data for FDA to justify its position. *Wyeth*, 555 U.S. at 559–67. A manufacturer who fails to do so cannot establish it "fully informed" FDA.

In re Taxotere is instructive. In the *Taxotere* MDL, the court evaluated the "fully informed" element in connection with the defendant's summary-judgment motion. 508 F. Supp. 3d at 85–87. *Taxotere* involved product-liability claims alleging that defendant failed to warn of the risk of permanent alopecia from its chemotherapy drug. In 2004, FDA approved Sanofi's NDA for use of Taxotere with two combination

drugs. In doing so, Sanofi supplied FDA with a proposed label identifying alopecia as a risk, the interim results of two clinical trials, and two articles evaluating Taxotere's safety profile, which, it argued, "clearly disclosed" the risk of alopecia to FDA. *Id.* at 83.

The court found, however, that in supplying these data Sanofi failed to analyze them for FDA or alert FDA regarding an uptick in reported adverse events (data FDA ostensibly possessed through FAERS). *Id.* FDA ultimately approved the label striking any reference to alopecia as a potential risk. *Id.* at 84. Sanofi argued it provided "clear evidence" that it "fully informed" FDA of the risk of alopecia—which it claimed FDA rejected (*i.e.*, because FDA struck the language from the warning, Sanofi argued that the plaintiff's claim that the label failed to include an alopecia warning was preempted). The court disagreed.

Commenting on the "clear evidence" prong, the *Taxotere* court made two observations. First, citing *Wyeth*, it made clear the "a manufacturer must analyze the accumulating data—including any pertinent data that predated supplemental applications—for the FDA." *Id.* at 82 (citing 555 U.S. at 559–67). Second, it noted a manufacturer cannot "shift the responsibility of analyzing these reports to the FDA." *Id*. at 85. Based on these observations the Court held:

> To show "clear evidence," a manufacturer must show that it "fully informed the FDA of the justifications for the warning required by state law and that 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."

Id. (quoting *Albrecht*, 139 S. Ct. at 1672). In other words, it is not remotely enough to claim, as Indivior does here, that simply because FDA "approved" a label and/or "possessed" certain data that a claim is preempted. (ECF No. 126-1, PageID #2783–85.) That is particularly true on a Rule 12 motion given the absence of a fully developed record. The point, for purposes of this motion, is that bald assertions FDA "approved" a label do nothing to advance a defendant's preemption defense. It is against this backdrop that Mr. Bennett turns to Indivior's argument.

B. Indivior Inc.'s pre-approval preemption theory is simply wrong given the Supreme Court, and scores of cases, recognize a plaintiff may evade a preemption defense based on data that pre-dates the label or label change, such as clinical trials.

Indivior initially advances the novel proposition that a plaintiff may not rely on data that pre-dates the label change because the "approved" label is sufficient as a matter of law. (ECF No. 126-1, PageID #2783–84.) At the same time, Indivior concedes that *no claim* from "[t]he time period between FDA approval of Suboxone Film and the June 17, 2022 label modification" is preempted. (*Id.*, PageID #2787.) As it relates to the pre-approval argument, the Court need not decide this issue given Indivior's agreement that no claim during the time period from approval through June 2022 is preempted and no plaintiff used the drug (and hence was not properly warned) before FDA approval.[7]

[7] The Court will need to address an offshoot of this issue with respect to Defendants' claim a plaintiff cannot use data that pre-dates a label modification to establish NAI. (ECF No. 126-1, PageID #2785.)

Based on the cases it cites, Defendant likely meant to argue that a plaintiff may not rely on NAI that predates the label. But *Wyeth* considered *and rejected* the very argument Indivior makes here: "that it could have changed [the] label only in response to new information that the FDA had not considered." *Wyeth*, 555 U.S. at 568. Simply stated, an argument (or holding) that acceptance of a manufacturer's label by FDA precludes the use of data that predates the label so as to establish NAI is fundamentally flawed.

Not surprisingly, given the Supreme Court's holding in *Wyeth* establishing the manufacturer's continuous duty to monitor and update its label, scores of cases (correctly) hold that data that predates a drug's launch may establish NAI and lead to a conclusion the label was inadequate *on Day 1*.[8] In a series of cases evaluating the scope of NAI, the Ninth Circuit—following *Wyeth*—unequivocally established a plaintiff may rely on pre-launch data to allege the original label was inadequate. Starting with *In re Incretins-Based Therapies Products Liability Litigation*, the

[8] The Ninth Circuit's holdings are not unique. Cases spanning numerous districts reach the same conclusion. *See McGee v. Novartis Pharm. Corp.,* No. 22-cv-00024, 2022 WL 17454521 at * 2 (D. Colo. Dec. 6, 2022) (considering allegation that reanalysis of previous clinical-trial data evidenced increased risk of harm); *Harris v. Novartis Pharm. Corp.*, No. 4:21-CV-3013, 2021 WL 5506808, *2 (D. Neb. Sept. 8, 2021) (same); *Davison v. Novartis Pharm. Corp.*, No. 8:21-cv-1782, 2021 WL 4340412, *3 (M.D. Fla. Sept. 23, 2021) (same); *Holley v. Gilead Scis., Inc.*, 379 F. Supp. 3d 809, 826 (N.D. Cal. 2019) (denying preemption of pre-approval failure-to-warn claims and noting defendant "cited no federal law that would prevent a drug manufacturer from submitting a different warning label to the FDA prior to initial approval of a drug"); *Stube v. Pfizer, Inc.*, 446 F. Supp. 3d 424, 437 (W.D. Ark. 2020) (plaintiffs' pre-approval failure-to-warn claim alleging defendant could and should have submitted a stronger initial label for FDA consideration not preempted); *In re Actos (Pioglitazone) Prod. Liab. Litig.*, No. 12-cv-00064, 2014 WL 60298, at *7 (W.D. La. Jan. 7, 2014) (holding federal law did not preempt a failure-to-warn claim where plaintiffs alleged the defendant should have proposed a stronger original label); *Eve v. Sandoz Pharm. Corp.*, No. IP 98-1429-C-Y/S, 2002 WL 181972, at *3 (S.D. Ind. Jan. 28, 2002) ("evidence of [defendant's] interaction with the FDA may be pertinent to proving [plaintiffs'] claim").

district court refused to allow discovery into the manufacturers' pre-approval clinical-trial data contending the use of such data was precluded in the preemption analysis. The Ninth Circuit reversed and required defendants to produce the pre-approval data, stating,

> whether it would have been possible for the defendants to comply with both their common law duty to warn and the federally imposed reporting obligations is a separate issue that cannot be resolved without knowing what information was available to the defendants.

721 F. App'x 580, 583 (9th Cir. 2017). Similarly, in *Rayes v. Novartis Pharmaceuticals Corp.*, the Ninth Circuit again reversed the district court's conclusion that a plaintiff could not rely upon clinical-trial data to evade a preemption defense. 2022 WL 822195 (9th Cir. Mar. 18, 2022). Indeed, one of the *Rayes* plaintiff's allegations was that Novartis's label "stated that only 1% of patients experienced [the claimed injuries] in the clinical trials, but the real number was 3.3%." *Id.* at *2. What patients experienced during the clinical trials obviously occurred pre-approval.

Read collectively, these cases stand for the proposition—which *Wyeth* endorsed long ago—that a plaintiff may rely on pre-approval data to establish NAI existed, triggering a manufacturer's CBE obligation.

Based on this clear—and binding—precedent, Indivior's reliance on cases like *Mitchell v. Boehringer Ingelheim Pharmaceuticals*, No. 1:16-cv-02384, 2017 WL 5617473 (W.D. Tenn. Nov. 21, 2017) is misplaced. (ECF No. 126-1, PageID #2783–84) (precluding use of pre-approval data to evade preemption for failure to warn as to initial label). But *Mitchell is relevant* for a wholly unrelated reason. Specifically, in

Mitchell the Court denied Boehringer's motion to dismiss, concluding the plaintiff's reliance on little more than limited post-approval adverse events and case reports was sufficient to establish NAI triggering the defendant's CBE obligations. *Id*. at *6. Equally important, given the motion arose under Rule 12, the court quickly dispatched defendant's claim that adverse-event reports were inadequate noting, "[t]his is an argument that is more appropriately made in a motion for summary judgment after discovery." *Id*. *Mitchell's* holding is the exact outcome Mr. Bennett advances here: that resolution of the sufficiency of alleged NAI is "more appropriately made at summary judgment."

C. Indivior Inc.'s post-label preemption argument fails: Defendant could have complied with State law by strengthening the warning—as federal law expressly permits.

While Indivior concedes that Mr. Bennett's claims are not preempted from the date of approval to the June 2022 label change (ECF No. 126-1, PageID #2783–87), it seeks to dismiss his post-June 2022 claims contending he must point to NAI *following* the label change to survive preemption. (*Id.*, PageID #2786.). Implicit in Indivior Inc.'s argument for impossibility preemption is that it was "impossible" to change the label beyond what FDA approved. Indivior cites no authority for the proposition that a label change wipes the slate clean in terms of risk information, and *Wyeth* and *Albrecht* foreclose such as contention. As such, the issue, for purposes of this motion, is whether or not Mr. Bennett adequately pled the existence of NAI sufficient to establish the June 2022 revision to the label remains inadequate based on Indivior Inc.'s perpetual duty of continuous monitoring.

1. A label modification does not alter the status of NAI or limit the temporal scope of the NAI the plaintiff may rely upon to defeat preemption.

Implicit in any NAI analysis is the concept that the manufacturer maintains an obligation, "at all times" to monitor, evaluate and update its label. *PLIVA, Inc. v. Mensing,* 564 U.S. at 616. This obligation extends to *any* label change and requires the manufacturer to continuously monitor data—including data that pre-dates the label change—for changes in the safety profile of the drug. *Krantz v. Regeneron Pharm., Inc.*, No. 2:23-cv-08034, 2024 WL 1792769 at *6 (C.D. Cal. Apr. 24, 2024) (citing *Wyeth*, 555 U.S. at 570–71). From this perspective, the *only* issue for this Court is: did Mr. Bennett's complaint (or the accompanying public documents) present sufficient allegations of NAI.

It is for this reason that courts routinely allow sufficiency-of-the-label claims to proceed past a motion to dismiss. *See Krantz*, 2024 WL 1792769, at *8 (denying defendants' preemption motion following a label change given defendant withheld NAI from FDA); *see also In re Actos (Pioglitazone) Prods. Liab. Litig.*, No. 12-CV-00064, 2014 WL 60298, at *7 (W.D. La. Jan. 7, 2014) (noting FDA approval of labeling language does "not offer conclusive proof of preemption" even after a label change). As such, approval of new labeling language does "not offer conclusive proof of preemption." *Stube v. Pfizer Inc.*, 446 F. Supp. 3d 424, 437 (W.D. Ark. 2020); *Batoh v. McNeil-PPC, Inc.*, 167 F. Supp. 3d 296, 317–20 (D. Conn. 2016). Accordingly, a plaintiff may point to *any* data, including data that pre-dates the label change, to establish the manufacturer possessed NAI.

Krantz v. Regeneron is instructive. In *Krantz*, the plaintiff sued Regeneron claiming its cancer treatment drug inadequately warned about the risk of Stephen-Johnson Syndrome (SJD) and toxic epidermal necrolysis (TEN). FDA originally approved the drug in September of 2018. Three years later, *before* Krantz used the product, Regeneron amended the label to include a Section V warning for SJD and TEN. Notwithstanding this amendment, plaintiff sued contending the *amended label* was insufficient. Defendant moved to dismiss arguing the plaintiff's claim was preempted given FDA's acceptance of the 2021 label.

The court denied the motion making two observations. First, the Court rejected the same post-label argument Indivior makes here noting, "'[t]he manufacturer bears responsibility for the content of its label *at all times*' including 'for the accuracy of adequacy of its label *as long as* the drug is on the market.'" *Id.* at *6 (quoting *Wyeth*, 555 U.S. at 570–71) (emphasis supplied). Second, the court reiterated that NAI "is not limited to new data, but 'also encompasses new analyses of *previously submitted data*.'" *Id.* at *7 (citing *Wyeth,* 555 U.S. at 571 (quoting 73 Fed. Reg. 49603, 49604 (Aug. 22, 2008)) (emphasis supplied). Based on this analysis, the court rejected the defendant's argument that the alleged NAI was: (a) previously supplied to FDA; and (b) pre-dated the label change—the exact defense Indivior Inc. raises here. As such, Mr. Bennett may rely on NAI that predates the June 2022 label.

2. Indivior's contention FDA approval of the June 2022 label update somehow requires preemption is both irrelevant and premature given it is the manufacturer's burden to *prove* it fully informed FDA of all NAI.

Nor is Indivior's contention that the Court can simply presume FDA conducted the necessary vetting to confirm that the label was accurate proper. (ECF No. 126-1, PageID #2783.) Such a suggestion presupposes that Defendant did, in fact, supply FDA all data encompassing the NAI Mr. Bennett claims justified a CBE *and* FDA rejected it—a fact pattern that Mr. Bennett did not allege and that seems a tad premature at the Rule 12 stage. *Weiss v. Fujisawa Pharm. Co.*, 464 F. Supp. 2d 666, 676 (E.D. Ky. 2006) ("In addition, [defendant] could conceivably have possessed information not available to the FDA that they could have communicated to the FDA, to healthcare providers, or to patients, consistent with FDA regulations.").

Beyond that, a manufacturer is not the "arbiter" of what information is or is not relevant to acceptance of a CBE. *In re Avandia*, 945 F.3d at 759. It is up to the FDA alone to determine whether there is sufficient NAI to approve a CBE. C.F.R. § 314.70(c)(7). And even to the extent Indivior's argument is relevant, it is entirely premature at this point given it is Indivior's burden to establish—*with evidence*—that it "fully informed" FDA of *all* available NAI *and* that FDA rejected (or would reject) the label plaintiff seeks. *Id.* at 758–59; *Krantz*, 2024 WL 1792769 at *6–7. In other words, the *only* consideration for the Court at this point is whether the complaint, together with the facts of which the Court may properly take judicial notice, establishes the existence of NAI data that triggered Indivior's CBE

obligations. As set forth below, it most certainly did, and Mr. Bennett's post-June 2022 label claim is not preempted.

D. Mr. Bennett adequately pleads newly acquired information.

Mr. Bennett satisfies the nominal plausibility pleading standard. He alleges that Indivior Inc. failed to strengthen the warnings and precautions for Suboxone film after they were amended in June of 2022, even though it was permitted to do so unilaterally and without FDA approval under the CBE supplement. (Compl., at ¶¶ 111–115, citing 21 C.F.R. § 314.70(c)(3).) The facts below readily establish he adequately pled NAI existed triggering Defendant's CBE obligations.

In his complaint, Mr. Bennett pled the post-June 2022 label was deficient. *(Id.,* ¶ 217). Specifically, to this day, the label fails to provide warnings that alert patients and physicians that: (1) certain health risks associated with Suboxone use can exacerbate tooth decay (*i.e.*, xerostomia) (*id.*, ¶¶ 174–75, 217(f)); (2) failing to provide instructions on how to safely use Suboxone film to avoid injury (specifically relating to duration of use, *i.e.*, that patients should not stay on Suboxone film "indefinitely" (as the prescribing information claims (ECF No. 121-2, PageID #2285)) (Compl. ¶¶ 124, 213, 217(k)); and (3) physicians should conduct saliva quality, pH, and buffering capacity testing before and during Suboxone film usage (*id.* at ¶¶ 121, 203(d), 217(i)). Evidence of the need for these precautions was well documented throughout the peer-reviewed literature and pled by Mr. Bennett. (*Id.* at ¶¶ 84, 174.) Mr. Bennett does not allege that Defendant made any effort to alert FDA of these facts or include this information in the label.

Nothing in the label contains any statement directing health care providers to conduct "saliva quality, pH, and buffering capacity testing before and during Suboxone film usage," that dry mouth can exacerbate tooth damage, or that sustained prolonged use can lead to tooth erosion or decay. (ECF No. 121-2.) Yet, Defendant clearly possessed, or had access to, information that triggered its CBE obligations. For example, Mr. Bennett alleges the following:

- Hundreds of adverse events reporting serious tooth decay and erosion spanning more than a decade, including those stemming from dry mouth (Compl., ¶¶ 90–104);
- That the class of persons for whom the drug was directed often experience xerostomia (dry mouth) that can exacerbate tooth decay (*id.* ¶¶ 174–75);
- That prolonged use can exacerbate tooth damage (*id.*, ¶¶ 124, 213); and
- Decades of peer-reviewed literature discussing the roll diminished saliva plays in promoting tooth decay (*id.*, ¶ 84).

In addition to his complaint's allegations, the docket contains four peer-reviewed articles establishing that xerostomia/dry mouth leads to accelerated enamel erosion and decay. (ECF No. 86, PageID #911–13, 915; ECF No. 86-4 (Jenkins); ECF No. 86-9 (Sheridan); ECF No. 86-15 (Dawes); and ECF No. 86-28 (Farooq et al.).)[9] Mr. Bennett does not allege that Indivior provided this information to FDA or warned him or his physicians about these risks or the need to conduct saliva quality, pH, and buffering capacity testing before and during Suboxone film usage. These data were readily available to Indivior before amending the Suboxone label in June of 2022.

[9] The Court may take judicial notice of its own docket. *Chase v. MaCauley*, 971 F.3d 582, 587 n.1 (6th Cir. 2020).

The record at this stage of proceedings is devoid of any indication that Indivior made any effort to compile, analyze, and submit the data to FDA. Had Defendant done so, the revised label would have advised prescribers to actively monitor risks of dental decay for their patients, alerted patients and prescribers that dry mouth can accelerate tooth decay, and cautioned against long-term use of Suboxone film as maintenance treatment. At the pleadings stage, these allegations are more than enough to establish a plausible claim that the June 2022 label is deficient.

II. Plaintiff's design-defect claims are not preempted.

A. The Sixth Circuit does not preclude pre-approval design-defect claims as a matter of law.

Defendants argue Mr. Bennett's pre- and post-approval design defect claims are preempted. Defendants are partially correct. Specifically, post-approval claims predicated on a "stop selling" theory are, in fact, preempted. *Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472, 479–80 (2013). That is why Mr. Bennett did not plead such a claim. But the pre-approval design-defect claims he does allege are not preempted.

The reason for this is two-fold: First, *Bartlett* dealt exclusively with generic pharmaceuticals. Because the FDCA *prohibits* generic manufacturers from redesigning a brand-name formula, the generic entrant—who must rely on a formulation that is the biological equivalent of the branded drug—may not alter the product's formulation. 570 U.S. at 472. As such, a claim contending the generic should change its design in the form of a state tort, "irreconcilably conflicts" with the federal regulatory regime. Second, *Bartlett* did not address whether a *brand-name* manufacturer may be sued for design defect. The vast majority of courts evaluating

this issue conclude that it may because there is no "conflict" between federal and State law unless and until the manufacturer subjects itself to the FDCA's regulatory framework.[10]

The authority in this circuit is consistent. In *Tobin v. Astra Pharmaceutical Products, Inc.*, the court "reject[ed] the argument that FDA approval preempts state product liability claims based on design defect" and upheld a verdict in plaintiff's favor on that claim. 993 F.2d 528, 537 (6th Cir. 1993). Similarly, in both *Wimbush v. Wyeth*, 619 F.3d 632 (6th Cir. 2010) and *Yates v. Ortho-McNeil*, 808 F.3d 281 (6th Cir. 2015), the Sixth Circuit outlined when a pre-approval design-defect claim is not

[10] *See generally Kaiser v. Johnson & Johnson*, 947 F.3d 996, 1009–10 (7th Cir. 2020) ("the federal regulatory regime did not make it impossible for [defendant] to comply with its state-law duties before it sought § 510(k) clearance . . ."); *In re Tepezza Mktg., Sales Practices, and Prods. Liab. Litig.,* No. 23 C 3568, 2023 WL 7281665, *3 (N.D. Ill. Nov. 3, 2023) (noting the pre-approval theory "does not argue that a manufacturer should have stopped acting, just that it should have acted differently"); *Gaetano v. Gilead Sciences, Inc.,* 529 F. Supp. 3d 333, 342 (D.N.J. 2021) ("Federal law does not dictate the manner in which a manufacturer must design a drug in the first place . . . there are no federal requirements dictating which compositions . . . a manufacturer must submit for approval"); *In re Zostavax Prod. Liab. Litig*., No. 18-20114, 2021 WL 5235225, *4 (E.D. Pa. Nov. 10, 2021) ("There is nothing in federal law to prohibit a drug manufacturer from originally submitting to the FDA for approval an application for a brand-name drug with a safer design required by state law."); *Estate of Cassel v. ALZA Corp*., No. 12-cv-771-WMC, 2014 WL 856023, *5 (W.D. Wisc. Mar. 5, 2014) ("None of the impossibility preemption cases to date contemplates this wholesale preemption of state product liability claims, at least in the drug context."); *Guidry v. Janssen Pharm., Inc*., 206 F. Supp. 3d 1187, 1208 (S.D. La. 2016) ("Indeed, the raison d'être of products liability litigation is to penalize manufacturers who design unreasonably dangerous products in hopes that they never start selling them. State products liability law functions as a compliment to federal drug regulations to keep unreasonably dangerous drugs off the market."); *In re Xarelto Prods. Liab. Litig*., 2017 WL 3188456 (E.D. La. July 21, 2017) (alleging defendant should have designed an assay or antidote for bleeding events pre-approval); *Holley v. Gilead Scis., Inc*. 379 F. Supp. 3d 809 (N.D. Cal. 2019) (same); *Crockett v. Luitpold Pharm., Inc.*, No. 19-276, 2020 WL 433367 (E.D. Pa. Jan. 28, 2020) (same); *Young v. Bristol-Myers Squibb Co.*, No. 4:16-cv-00108, 2017 WL 706320 (N.D. Miss. Feb. 22, 2017) (same).

preempted. Read collectively, thesesuttom precedents lead to the conclusion that Mr. Bennett's pre-approval design-defect claims are not preempted.[11]

Starting with *Wimbush*, the Sixth Circuit faced the same question the Court confronts here: namely, whether a pre-approval design-defect claim is preempted. Noting Wimbush was "entitled to [a] presumption that Congress did not intend to preempt state law" tort claims, the court outlined the limited context where conflict preemption (*i.e.*, an irreconcilable conflict between a State tort and federal law) applies. *Wimbush*, 619 F.3d at 642. In denying summary judgment to the defendant on the plaintiff's pre-approval design-defect claim, the court held, "[s]imply because tort liability 'parallel[s] federal safety requirements' does not mean that liability is preempted." *Id.* at 644 (citing *Verizon North Inc. v. Strand*, 309 F.3d 935, 940 (6th Cir. 2002)). As such, *unless and until* a manufacturer subjects itself to federal law by seeking approval for its product under the FDCA, no "conflict" can exist. *Id.* at 644–45. Put another way, before a manufacturer subjects itself to regulatory scrutiny, there is no federal law that "conflicts" with parallel State tort claims.

Five years later, the Sixth Circuit revisited pre-approval design-defect claims in *Yates*. Yates sued Ortho-McNeil under New York's products-liability law that requires the plaintiff prove a safer alternative design to prevail.[12] Ultimately, the

[11] Defendants rely almost exclusively on *Yates* as the sole basis to support their preemption argument. To the extent the Court is inclined to look to law beyond this Circuit, the far better reasoned and clear majority rule, is that pre-approval design-defect claims are not preempted. *Supra*, Section I.B.

[12] Importantly, *Yates's* entire analysis and rationale for concluding preemption applied was predicated on the underlying state statute that *required* Yates prove a safer alternative design. But *Yates* said nothing about statutory and common-law regimes that *do not* impose

Sixth Circuit held Yates's claims were preempted. In doing so, however, the court noted, "[a] brand-name manufacturer is not restricted to the 'sameness' requirement, which prohibits generic manufacturers from redesigning the drug either prior to or after seeking FDA approval." *Yates*, 808 F.3d at 299 (citing *Mensing,* 564 U.S. at 613). In short, nothing in either *Mensing* or *Bartlett* held that pre-approval claims against a brand-name manufacturer are preempted as a matter of law. Second, *Yates* expressly held, "*Wimbush* is still good law," signaling that it did not hold that *all* pre-approval design claims are preempted. *Id*. at 300.[13] Nor did it call *Tobin*'s holding into question.

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this requirement. Twenty-eight states either do not require the plaintiff to prove a safer alternative design or have yet to address the issue. *See, e.g., Boerner v. Brown & Williamson Tobacco Corp.,* 260 F.3d 837, 846 (8th Cir. 2001) ("our case law makes clear that defective design can be established under Arkansas law without proof of a safer alternative design"); *Kaiser v. Johnson & Johnson*, 947 F.3d 996, 1013 (7th Cir. 2020) ("the [Indiana Products Liability Act] does *not* require evidence of a reasonable alternative design to establish design-defect liability") (citation omitted) (emphasis in original); *Izzarelli v. R.J. Reynolds Tobacco Co.*, 136 A.3d 1232, 1241–42 (Conn. 2016) ("an absolute requirement of proof of a feasible alternative design [would] impose an undue burden on plaintiffs"); *Liggett Grp., Inc. v. Davis*, 973 So. 2d 467, 475 (Fla. Dist. Ct. App. 2007) ("We find no case which holds that a plaintiff is **required** to show a safer alternative design in order to prevail on a strict liability design defect claim.") (emphasis in original); *Ford Motor Co. v. Trejo*, 402 P.3d 649, 651 (Nev. 2017) ("this court strongly disagrees with the notion that a plaintiff in a strict product liability design defect action must present proof of an alternative design"). Because those states do not require *any* consideration of what FDA may, or may not, have done, the analysis in *Yates*—which was predicated on New York law requiring proof of a safer alternative design—is wholly irrelevant. As such, to the extent this Court applies *Yates*'s holding to Mr. Bennett's claims under Ohio law, that outcome has no bearing on whether a plaintiff may proceed with a claim that emanates from a State which does not require proof of a safer alternative.

[13] Defendants cite *Fleming v. Janssen Pharms., Inc.*, 186 F. Supp. 3d 826 (W.D. Tenn. 2016) for the proposition Plaintiff's pre-approval design defect claim is preempted. *Fleming* is easily distinguished. First, *Fleming* appears to indicate *Yates* preempted design-defect claims as a matter of law. *Id.* at 833. That reading is wrong, given *Yates* did not overrule *Wimbush*. Equally important, there is nothing in the record, unlike here, that established Fleming pled facts sufficient to satisfy the *Yates* factors. *Bossetti v. Allergan Sales, LLC*, No. 1:22-cv-523, 2023 WL 4030681 at *5 (S.D. Ohio June 15, 2023) is likewise distinguishable. Like *Fleming*,

Instead, and following development of a full evidentiary record, the Sixth Circuit declined to allow Yates's claims to proceed because:

> To imagine such a pre-approval duty exists, we would have to speculate that had defendants designed ORTHO EVRA® differently, the FDA would have approved the alternate design. Next, we would have to assume that Yates would have selected this method of birth control. Further yet, we would have to suppose that this alternate design would not have caused Yates to suffer a stroke.

Id. at 299. In short, the Sixth Circuit rejected Yates's pre-approval design-defect claim *not* because it was preempted as a matter of law, but because the ability to prove FDA would approve a safer alternative was "too attenuated." *Id.* Leaving aside the Sixth Circuit "too attenuated" construct finds no support under federal law or Supreme Court precedent—a different argument for a different day[14]—the takeaway from the Court's holding is that a plaintiff's claim is not preempted if he can prove (or, at the Rule 12 stage, allege) the following: (1) FDA would approve the design; (2) plaintiff would have used the alternative design; and (3) plaintiff would have avoided the injury. Mr. Bennett readily satisfies this threshold under Rule 12.

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the court "tacitly" endorsed the notion *Yates* decided the issue as a matter of law—a conclusion *Yates* itself rejected. *Id.* at *4. More important, unlike here, Bossetti was unable to "explain 'what a pre-approval claim would look like in her case'" and appears to have not even tried. *Id.* at *5 (quoting *Yates*, 808 F.3d at 300). Here, Mr. Bennett specifically pled "what a pre-approval claim would look like"—the immediate launch of the technologically feasible Sublocade. Finally, like *Fleming* and *Bossetti*, the court in *Brashear v. Pacira Pharm., Inc.,* No. 1:21-cv-700, 2023 WL 3075403 (S.D. Ohio Apr. 25, 2023) dismissed the plaintiff's design-defect claim. And as in the two prior cases, the court's recitation implies the plaintiff failed to plead (or perhaps even try) to satisfy the three *Yates* factors—a fact readily distinguishing the case from what Mr. Bennett plead here.

[14] *See In re Tepezza*, No. 23 C 3568, 2023 WL 7281665, *3 (N.D. Ill. Nov. 3, 2023) (declining to follow *Yates* on Rule 12 motion because "a lack of proof at this stage does not warrant dismissal on preemption grounds").

B. Mr. Bennett readily clears bar the Sixth Circuit established in *Yates*: he alleges a safer alternative design that the FDA already approved that does not erode teeth with daily acid baths.

Mr. Bennett alleges Suboxone film delivers the active ingredient buprenorphine for the treatment of opioid dependence, including maintenance treatment. (Compl., ¶186; Suboxone prescribing information, ECF No. 121-2, PageID #2285 (§ 2.4 Maintenance: "There is no maximum recommended duration of maintenance treatment. Patients may require treatment indefinitely…").) He alleges that alternative delivery methods for buprenorphine are available. (Compl., ¶ 48.) One such method is an extended-release injectable. (*Id.*, ¶ 142.) In 2017, FDA approved an extended-release injectable—Sublocade—for the maintenance treatment of opioid dependence. (*Id.*, ¶ 161; ECF No. 121-3.) Mr. Bennett alleges that the extended-release injectable has similar efficacy to the film without the risk of dental damage, which he would have used to avoid his dental injuries. (Compl., ¶¶ 142, 179.) And he alleges that the technology existed for extended-release injectable buprenorphine before Defendants sought approval of Suboxone film. (*Id.*, ¶¶ 150–158.) These facts establish the three factors *Yates* outlined as necessary to evade preemption.

C. Defendants' efforts to cast injectable buprenorphine as ineligible to be a safer alternative design for Suboxone film fail.

Notwithstanding Defendants' contentions to the contrary, this case involves administration of buprenorphine and its delivery system. Mr. Bennett alleges that a route other than oral administration—*e.g.*, the extended-release injectable Sublocade—would not have led to dental harm. (Compl., ¶¶ 176, 179).

Under Ohio law, an alternative formulation of a drug may be proposed as a safer alternative design. *See Younce v. Glaxosmithkline, LLC*, No. N21C-11-055, 2022 WL 18359405, *7 (Del. 2022) ("Under O.R.C. § 2307.75(F), a plaintiff has the burden to prove a feasible alternative design that would have prevented the alleged injury. Here, Plaintiffs have pled that there were safer, alternative designs available to treat depression. Plaintiffs have also pled that alternative formulations for other medications were available. As a result, at this stage in litigation, Plaintiffs have adequately pled a feasible alternative design.").[15]

[15] Other jurisdictions have held similarly. *See, e.g.*, *Frazier v. Mylan, Inc.*, 911 F. Supp. 2d 1285, 1297 (N.D. Ga. 2012) ("Pfizer contends that these alternatives suggested by plaintiff are completely different products, and therefore, plaintiff has failed to allege a feasible alternative design to phenytoin. Assuming that the alternatives pled by plaintiff are completely different products from phenytoin, the risk-utility analysis for design defect cases recognizes that when considering whether an alternative safer design existed, the factfinder may consider the feasibility of an alternative design as well as the 'availability of an effective substitute for the product which meets the same need but is safer.'"); *Newman by Newman v. McNeil Consumer Healthcare*, No. 10 C 1541, 2013 WL 7217197, *12 (N.D. Ill. Mar. 29, 2013) ("Defendants contend that acetaminophen fails to qualify as an 'alternative design' because it is an entirely different product with different chemical composition and different pharmacodynamic and pharmacokinetic properties, different indications, efficacy properties, safety profile and tolerability... While the Court is somewhat sympathetic to Defendants' argument, it is based on an interpretation of Texas' state law, which is not applicable here; Defendants do not suggest that the courts of Illinois have adopted similar reasoning."); *Keffer v. Wyeth*, 791 F. Supp. 2d 539, 549 (S.D.W.V. 2011) ("Defendants next assert that OMP is not a true 'alternative design' but a different product altogether. They note that (1) OMP has a different chemical makeup than synthetic progestin; (2) substituting OMP for synthetic progestin in a hormone therapy regimen may require drastic changes in dosage and methods of administration; and (3) the FDA has approved OMP as a separate drug (under the brand name Prometrium). Defendants are correct that an 'alternative design must not be an altogether essentially different product.'... Stated differently, 'an alternative design is not reasonable if it alters a fundamental and necessary characteristic of the product.'... However, the reasonableness of an alternative design is generally a question of fact for the jury... The plaintiff in this case has presented evidence regarding the comparability of OMP and synthetic progestin in treating menopausal symptoms."); *Torkie-Tork v. Wyeth*, 739 F. Supp. 2d 895, 900 (E.D. Va. 2010) ("If Wyeth could have used a natural progesterone instead of synthetic progestin and accomplished a similar positive therapeutic effect, a jury may reasonably decide that the refusal to employ such a design was negligent.").

Still, Defendants insist, relying only on non-binding cases from non-Ohio jurisdictions, that the products are entirely different and essentially incomparable. But the presence of naloxone in Suboxone film does not render it so different from Sublocade that the two cannot be compared. Mr. Bennett does not allege that naloxone is an "active" ingredient in Suboxone film: he alleges that "[t]he formulation of Suboxone film is designed to be acidic to maximize absorption of the buprenorphine while minimizing absorption of the naloxone." (*Id.*, ¶ 3.) The Suboxone film prescribing information confirms that "[n]aloxone had no clinically significant effect when administered by the sublingual route…" (ECF No. 121-2, PageID #2307.) Instead, it is intended to prevent diversion and abuse of buprenorphine. (ECF No. 121-2, PageID #2307 ("the naloxone in buprenorphine/naloxone tablets may deter injection of buprenorphine/naloxone tablets by persons with active substantial heroin or other full mu-opioid receptors").) Much like The Club prevents unauthorized driving of a car, naloxone in tablets or film prevents the unauthorized use of buprenorphine, *e.g.*, by dissolving it in water and injecting it intravenously; such a feature is unnecessary when the buprenorphine is administered by a healthcare professional as with Sublocade.

That Suboxone film and Sublocade are both delivery methods for administering buprenorphine is exhaustively underscored by the prescribing information. (ECF No. 121-2 (film); ECF No. 121-3 (injectable).) The Court does not need to draw any inferences in Mr. Bennett's favor to conclude that, in drafting the prescribing information, Defendants viewed the film and the injection as similar

products. A full comparison of the similarities detailed in their respective prescribing information would exceed the word limit for this memorandum. Some key examples are detailed in the following table:

Label Section	Suboxone film	Sublocade injection
INDICATIONS AND USAGE	"indicated for the treatment of opioid dependence" (ECF No. 121-2, PageID #2282.)	"indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a buprenorphine-containing product, followed by dose adjustment for a minimum of 7 days" (ECF No. 121-3, PageID #2316.)
WARNINGS AND PRECAUTIONS	"Addiction, Abuse, and Misuse: Buprenorphine can be abused in a similar manner to other opioids. Monitor patients for conditions indicative of diversion or progression of opioid dependence and addictive behaviors." (ECF No. 121-2, PageID #2282.)	"Addiction, Abuse, and Misuse: Buprenorphine can be abused in a similar manner to other opioids. Monitor patients for conditions indicative of diversion or progression of opioid dependence and addictive behaviors." (ECF No. 121-3, PageID #2316.)
USE IN SPECIFIC POPULATIONS	"Lactation: Buprenorphine passes into mother's milk." (ECF No. 121-2, PageID #2282.)	"Lactation: Buprenorphine passes into mother's milk." (ECF No. 121-3, PageID #2316.)
Patient Access to Naloxone for the Emergency Treatment of Opioid Overdose	(advising prescribers to "strongly consider prescribing naloxone" with film) (ECF No. 121-2, PageID #2288.)	(same) (ECF No. 121-3, PageID #2326.)
Managing Risks from Concomitant Use of Benzodiazepines or Other CNS Depressants	"For patients in buprenorphine treatment, benzodiazepines are not the treatment of choice for anxiety or insomnia." (ECF No. 121-2, PageID #2289.)	"For patients in buprenorphine treatment, benzodiazepines are not the treatment of choice for anxiety or insomnia." (ECF No. 121-3, PageID #2327.)

QTc Prolongation	"Thorough QT studies with buprenorphine products have demonstrated QT prolongation ≤ 15 msec." (ECF No. 121-2, PageID #2291.)	"Thorough QT studies with buprenorphine products have demonstrated QT prolongation ≤ 15 msec." (ECF No. 121-3, PageID #2330.)
DRUG INTERACTIONS	(identifying "Clinically Significant Drug Interactions" as "Benzodiazepines and Other Central Nervous System (CNS) Depressants," "Inhibitors of CYP3A4," "CYP3A4 Inducers," "Antiretrovirals: (NNRTIs)" "Antiretrovirals: (PIs)," "Antiretrovirals: (NRTIs)," Serotonergic Drugs," "MAOIs," "Muscle Relaxants," "Diuretics," and "Anticholinergic Drugs") (ECF No. 121-2, PageID #2296–2300.)	(identifying "Clinically Significant Drug Interactions" as "Benzodiazepines and Other Central Nervous System (CNS) Depressants," "Inhibitors of CYP3A4," "CYP3A4 Inducers," "Antiretrovirals: (PIs)," "Antiretrovirals: (NRTIs)," Serotonergic Drugs," "MAOIs," "Muscle Relaxants," "Diuretics," and "Anticholinergic Drugs") (ECF No. 121-3, PageID #2335–2338.)
Clinical Considerations	"Fetal/maternal adverse reactions Neonatal opioid withdrawal syndrome may occur in newborn infants of mothers who are receiving treatment with SUBOXONE sublingual film." (ECF No. 121-2, PageID #2301.)	"Fetal/maternal adverse reactions Neonatal opioid withdrawal syndrome may occur in newborn infants of mothers who are receiving treatment with SUBLOCADE." (ECF No. 121-3, PageID #2339.)
Lactation: Clinical Considerations	"Advise breastfeeding women taking buprenorphine products to monitor the infant for increased drowsiness and breathing difficulties." (ECF No. 121-2, PageID #2303.)	"Advise breastfeeding women taking buprenorphine products to monitor the infant for increased drowsiness and breathing difficulties." (ECF No. 121-3, PageID #2341.)

CONTROLLED SUBSTANCE	"SUBOXONE sublingual film contains buprenorphine, a Schedule III controlled substance under the Controlled Substances Act." (ECF No. 121-2, PageID #2304.)	"SUBLOCADE contains buprenorphine, a Schedule III controlled substance under the Controlled Substances Act." (ECF No. 121-3, PageID #2342.)
Distribution	"Buprenorphine is approximately 96% protein bound, primarily to alpha and beta globulin." (ECF No. 121-2, PageID #2309.)	"Buprenorphine is approximately 96% protein bound, primarily to alpha and beta globulin." (ECF No. 121-3, PageID #2348.)

The respective prescribing information for these two drugs cite the same study regarding women exposed to buprenorphine during pregnancy. (ECF No. 121-2, PageID #2301; ECF No. 121-3, PageID #2339.) Both cite to a study in 13 lactating women "on buprenorphine treatment" regarding the presence of buprenorphine's metabolite in human milk and infant urine. (ECF No. 121-2, PageID #2303; ECF No. 121-3, PageID #2340.) The Sublocade prescribing information uses sublingual buprenorphine data where the injectable has not been studied, *e.g.*, the pharmacokinetics of hepatic impairment (ECF No. 121-3, PageID #2342, 2349), the co-effects of CYP3A4 inhibitors and inducers (*id.*), and mutagenicity studies (*id.* at 2350).

The Suboxone film prescribing information acknowledges that patients can transition between buprenorphine/naloxone and buprenorphine products. (ECF No. 121-2, PageID #2287.) The Sublocade prescribing information indicates that "Patients established on long-term treatment with transmucosal buprenorphine (8-24 mg/day) and whose disease symptoms are controlled may be transitioned directly to SUBLOCADE." (ECF No. 121-3, PageID #2319.) This indicates that Sublocade is

indicated for patients who have been stabilized on Suboxone film, meaning Mr. Bennett, after just one week on Suboxone film (or other transmucosal buprenorphine-containing product), could have transitioned to Sublocade and avoided his injuries. Indeed, a notable difference between the Suboxone film and Sublocade prescribing information is that only the film's contains any reference to potential dental harm.

The prescribing information for Sublocade indicates that—at least when crafting the label—Indivior Inc. viewed Sublocade as Mr. Bennett does: as a "buprenorphine-containing product:" "Cases of hypersensitivity to **buprenorphine-containing products** have been reported in both clinical trials and in the postmarketing experience." (ECF No. 121-3, PageID #2329.)

Because buprenorphine is the *only* active ingredient to treat opioid dependence in both products, the issue for this Court is does Mr. Bennett allege: (1) that FDA would (or did) approve a different buprenorphine-delivery system; (2) that buprenorphine is anticipated for continued use; and (3) that the new delivery system does not cause the same or similar injury. Mr. Bennett's complaint clearly alleges each of these factors, which are confirmed by the prescribing information for Suboxone film and Sublocade.

The cases Defendants muster in support of their "different product" argument do not apply to Mr. Bennett's claims under Ohio law.[16] He alleges that Sublocade is

[16] *Barnes v. Medtronic*, PLC, No. 2:17-cv-14194, 2019 WL 1353880 (E.D. Mich. Mar. 26, 2019) (applying Michigan law) (plaintiff proposed as alternative designs a different treatment technique for hernias or a mesh manufactured from a different material); *Hosford v. BRK Brands, Inc.*, 223 So. 3d 199 (Ala. 2016) (applying Alabama law) (at trial plaintiff proposed a dual-sensor smoke alarm that used both ionic and photoelectric technology, at considerably

a safer alternative for maintenance treatment of opioid dependence with buprenorphine. And at the pleading stage, this meets his burden. The Court cannot conclude otherwise—as a matter of law—based on decisions applying Michigan, Texas, or Alabama law.

D. That Aquestive Therapeutics, Inc., is not the NDA holder is of no moment; Aquestive is a "manufacturer" under Ohio's Product Liability Act and may be held liable for manufacturing a defectively designed product.

Finally, Defendant Aquestive argues that it is not subject to any liability in this case because it is not the NDA holder. Mr. Bennett does not dispute that only the NDA holder may submit a CBE to strengthen the label. That obligation, however, relates only to failure-to-warn claims. That same law does *not* preclude a plaintiff from seeking recovery against a non-NDA holder for design defect and strict liability.

1. Mr. Bennett may sue Aquestive for manufacturing a defectively designed product.

As noted above, Mr. Bennett properly pled a design-defect claim. *Supra* at Section II.B. That analysis applies to any defendant that falls within Ohio's product-liability laws. As such, the only issue for this Court is whether Mr. Bennett stated a claim for relief under Ohio's product liability-law.

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higher cost); *Brockert v. Wyeth Pharma., Inc.*, 287 S.W.3d 760 (Tex App. 2009) (applying Texas law) (plaintiff alleged that an estrogen-only birth-control pill was safer alternative design to the estrogen-progesterone combination pill that injured her); *Caterpillar, Inc. v. Shears,* 911 S.W.2d 379, 384 (Tex. 1995) (also applying Texas law) (reversing jury verdict for plaintiff as "expert did not testify, and there is no evidence elsewhere in the record, of a safer alternative design for a front-end loader that could fulfill the multi-purpose role of Caterpillar's model 920 with a removable ROPS.").

2. Ohio's product-liability law extends to those who manufacture a defective product. The Suboxone film prescribing information confirms Aquestive "manufactured" the product.

Under Ohio law, a product is defective in design if at the time it left the manufacturer's control there was a foreseeable risk associated with the design or formulation. Ohio Rev. Code § 2307.75(A) (2001). Ohio's product-liability act defines a manufacturer as: "a person engaged in a business to design, formulate, produce, create, make, construct, assemble, or rebuild a product or a component of a product." Ohio Rev. Code. § 2307.71(A)(9) (2001). The Act expressly extends liability to any manufacturer that "produced" or "assembled" the product. Here, it is undisputed that Aquestive manufactures Suboxone film. (ECF No. 121-2, PageID #2287 (indicating that the drug is "manufactured for Indivior Inc." "by: Aquestive Therapeutics").)

Finally, a plaintiff must also show there was a "practical and technical feasible alternative design that...that would have prevented the harm for which the claimant seeks to recover..." *Rheinfrank v. Abbott Lab'ys, Inc.*, 119 F. Supp. 3d 749, 786 (S.D. Ohio 2015), *aff'd*, 680 F. App'x 369 (6th Cir. 2017) (cleaned up). At the pleading stage, Mr. Bennett must plead only that the defendant is a manufacturer as defined by the Act and that there was a safer alternative that would have avoided injuries, which he has done. *Allstate Ins. Co. v. Electrolux Home Prods., Inc.*, 2012-Ohio-90, ¶ 11; Compl. ¶ 153; *supra* Section II.B. As such, Mr. Bennett's claim against Aquestive should proceed.

III. Implied preemption is an unconstitutional intrusion into the dual sovereignty of the States.

As demonstrated above, Mr. Bennett adequately pled his claims and they are not impliedly preempted. If the Court concludes otherwise, Mr. Bennett argues that implied preemption is a judicially created doctrine that unconstitutionally intrudes on the sovereignty of the States. Under the Tenth Amendment, Congressional silence cannot serve as a basis to invalidate State laws under the Supremacy Clause.

"In splitting the atom of sovereignty, the Framers created American federalism, a unique way of dividing governmental power and a unique way of aggregating it." Hon. Jeffrey S. Sutton, 51 IMPERFECT SOLUTIONS, 11 Oxford University Press (2018). "The horizontal separations of power among the three branches of the national government, together with the vertical separation of powers between the national government and the States, provide the soundest protection of liberty any people has known." *Id.*

That dual protection of Americans' rights is on display in the context of laws governing products liability for pharmaceuticals. The FDCA and State products laws were enacted to serve the same purpose: protecting consumers from dangerous products. Taken together, these protective enactments give consumers the dual protections of requirements on the front end—through the FDA regulatory scheme—to attempt to prevent the sale of dangerous drugs, and on the back end—through State products-liability laws—to give injured people a remedy to redress harm the federal scheme failed to prevent. The FDCA does not include a private right of action, nor does it indicate any intention to displace the State laws that do.

To the contrary, the Supreme Court recognized in *Wyeth* that the federal legislation and regulatory scheme complements State law. 555 U.S. at 578. FDCA's precursor—The Federal Food and Drugs Act (enacted in 1903)—was the nation's "first significant public health law." *Id.* at 566. It "prohibited the manufacture or interstate shipment of adulterated or misbranded drugs, [and] supplemented the protection for consumers already provided by state regulation and common-law liability." *Id.* Congress increased consumer protection in 1938 with the enactment of the FDCA, which required pre-market approval of drugs. *Id.* And as the Supreme Court in *Wyeth* recognized, "as it enlarged the FDA's powers to 'protect the public health' and 'assure the safety, effectiveness, and reliability of drugs,'… Congress took care to preserve state law." *Id.* at 567. *Wyeth*, accordingly, rejected the manufacturer's contention that FDA regulations created both a ceiling and floor so that FDA approval of labeling preempts conflicting State law. *Id.* at 576.

But in interpreting plaintiffs' claims in the context of pharmaceutical products, some courts have been quick to displace State laws by putting too much emphasis on the federal component of dual sovereignty without an adequate statutory basis for that displacement.[17] In short, absent express preemption by Congress, State failure-

[17] *See, e.g., In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 41 (1st Cir. 2015) (finding that the possibility that the FDA would have agreed to a label change did not preclude the court from concluding that compliance with both State and federal branding requirements was impossible); *Booker v. Johnson & Johnson*, 54 F. Supp. 3d 868, 875 (N.D. Ohio 2014) ("Creating an alternative design would, by its very essence, require changing the composition of the drug, which is prohibited by federal law."); *Utts v. Bristol-Myers Squibb Co.*, 226 F. Supp. 3d 166, 185–86 (S.D.N.Y. 2016) ("To imagine such a pre-approval duty exists, the Court would have to speculate that had the defendants designed Eliquis differently, the FDA would have approved the alternate design"); *In re Lipitor (Atorvastatin*

to-warn and design-defect claims may not be rejected under an implied notion of "impossibility" when those provisions augment the protection of a State citizen: requiring manufacturers to do *more* than the FDCA requires may be inconvenient, but it is not "impossible" such that the Supremacy Clause can be used as a hammer to invalidate the protections State legislatures have enacted for their citizens.

The Supreme Court elucidated the contours of judicial deference and statutory construction in *Loper Bright v. Raimondo*, 144 S. Ct. 2244 (2024). A reading of *Wyeth* in the framework of *Loper Bright*, together with deference to the police powers of the States recognized in both *Wyeth* and *Dobbs v. Jackson Women's Health Organization*,

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Calcium) Mktg., Sales Practices & Prod. Liab. Litig., 185 F. Supp. 3d 761, 770–71 (D.S.C. 2016) ("To hold otherwise would mean that *any* new information regarding a drug would allow a drug manufacturer, under the CBE regulation, to wholly re-write a drug label, completely divorced from the FDA-approved label, regardless of whether the new information was relevant to particular statements being changed or not. Such an interpretation is contrary to the regulatory scheme of the FDCA and contrary to the CBE regulation itself"); *Fleming v. Janssen Pharms., Inc.*, 186 F. Supp. 3d 826, 833 (W.D. Tenn. 2016) (claims that defendants should have designed the drug differently pre-approval were preempted); *Mitchell v. Boehringer Ingelheim Pharms., Inc.*, No. 116CV02384STAEGB, 2017 WL 5617473, at *4–5 (W.D. Tenn. Nov. 21, 2017) ("In the present case, any claim that Plaintiff has made against Defendant based on the alleged inadequacy of the initial FDA approved label fails as a matter of law because Defendant was required to use that label when it first marketed Jardiance and could not have changed the label after FDA approval based on alleged pre-launch data that was known to the FDA at the time of the approval"); *Patton v. Forest Lab'ys, Inc.*, No. EDCV17922MWFDTBX, 2018 WL 5269239, at *11 (C.D. Cal. Sept. 19, 2018), *aff'd*, 793 F. App'x 608 (9th Cir. 2020) ("While it is obvious that the FDA, in approving the relevant Lexapro initial labeling and not yet requiring Defendants to change their label, disagreed with Plaintiffs, even if the FDA were wrong, only the government (*i.e.*, not Plaintiffs) may bring suit to enforce the FDCA and the FDA's regulations requiring Defendants to change their label"); *Brashear v. Pacira Pharms., Inc.*, No. 1:21-CV-700, 2023 WL 3075403, at *2 (S.D. Ohio Apr. 25, 2023) ("Federal law impliedly preempts state law … in at least two circumstances: when Congress intends federal law to occupy the field, or when state law conflicts with a federal statute") (citation omitted); *Bossetti v. Allergan Sales, LLC*, No. 1:22-CV-523, 2023 WL 4030681, at *3 (S.D. Ohio June 15, 2023) (in the absence of express preemption, is there clear evidence that a federal agency would prohibited the defendant from taking the necessary steps under state law).

affirms Mr. Bennett's position: if Congress wants to make a law, or to displace a State law, it must explicitly say so.

A. *Loper Bright* reaffirmed the judiciary's crucial role in interpreting the law as it is enacted by Congress.

Recently, the Supreme Court addressed implicit delegations of power and the contours of judicial deference to other branches of government in *Loper Bright*. 144 S. Ct. 2244. It described the judiciary's Constitutional obligations, traditional statutory construction, and the limits of judicial deference to the political branches. *Id*. at 2257. In overturning *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), *Loper Bright* signaled a full embrace of the Framers' understanding of the judicial function: to interpret acts of Congress to ascertain the parties' rights. *Id*. These are foundational principles of the Republic, not restrained to cases involving administrative agencies.

The Constitution vests the federal judiciary with the "responsibility and power to adjudicate 'Cases' and 'Controversies.'" *Id*. Interpretation of the laws is the "proper and peculiar province of the courts." FEDERALIST NO. 78 at 525 (A. Hamilton). The Constitution requires judges to exercise their judgment "independent of influence from the political branches." *Loper Bright*, 144 S. Ct. at 2257. Where a court's judgment "differ[s] from that of other high functionaries" the court is "not at liberty to surrender, or waive it." *Id*. at 2258. Courts need not—and cannot—sacrifice their own judgments in deference to the political branches. The Court in *Loper Bright* articulated the "traditional understanding"—even outside of the APA—"that courts must decide all relevant questions of law." *Id*. at 2260 (internal citation omitted).

Chief Justice Marshall famously declared that "[i]t is emphatically the province and duty of the judicial department to say what the law is, the role of the judiciary has been to "interpret the act of Congress, in order to ascertain the rights of the parties." *Id.* at 2257 (quoting *Marbury v. Madison*, 1 Cranch 137, 177 (1803)). Interpretation necessarily begins with an act of Congress, not an absence of one, and requires the reviewing court to determine "whether Congress ha[s] directly spoken to the precise question at issue." *Id.* at 2247. If the intent of Congress is clear, "that is the end of the matter." *Id.* at 2264. Such interpretation requires the court to find the best meaning, which "is fixed at the time of enactment" and without regard to policy preferences "that had not made it into the statute." *Id.* at 2266, 2268 (cleaned up).

Where a question is of "deep economic and political significance" the Supreme Court expects Congress to delegate authority "expressly, if at all." *Id.* at 2269. Modest, vague, or subtle words will not suffice, just as words that did "not make it into the statute" cannot dictate judicial interpretation. *Id.* at 2268–69. *See also* Hon. Raymond M. Kethledge, *Ambiguities and Agency Cases: Reflections After (Almost) Ten Years on the Bench*, 70 VAND. L. REC. EN BANC 315, 320 (2017) (emphasizing the importance of relying on text rather than "purposes" in interpreting law to "maintain our constitutional separation of powers").

Preemption of State laws is suspect because of the risk to "the sovereignty States enjoy under the Constitution." *Id.* at 2286 n.5. If a Congressional grant of authority to an administrative agency to determine who pays the monitors on Atlantic herring vessels (*i.e.*, the underlying facts of *Loper Bright*) is a question of

"deep economic and political significance," the usurpation of a State's police power imperiling the dual sovereignty on which our federalist system is based is also a question of deep economic and political significance. If Congress has not provided an express preemption clause in a statute, that must be the end of the matter, particularly where it is clear that Congress chose not to. For example, when Congress amended the FDCA in 1976 and enacted an express preemption provision for medical devices, it declined to do so for prescription drugs. *Wyeth,* 555 U.S. at 567. The Congressional decision not to enact an express preemption provision for pharmaceuticals cannot be read as anything other than a desire *not to preempt* State laws.

The *Chevron* court presumed that statutory ambiguity indicated an intention for the executive to fill in the gaps rather than the judiciary in its traditional role. Under *Chevron*, where a statute was "silent or ambiguous," including because Congress simply failed to consider a question, a reviewing court could not construe the statute without deferring to another branch, even though an "ambiguity is not a delegation to anybody, and a court is not somehow relieved of its obligation to independently interpret the statute." *Loper Bright*, 144 S. Ct. at 2266. As the *Loper Bright* Court pointed out, if Congress intended such a deferential standard to questions of law in departure from the traditional rule that courts interpret statutes and the Constitution, it would have said so. *Id*. at 2261.

As *Loper Bright* confirms, in the absence of an express delegation, the role of the reviewing court is to independently interpret the statute and effectuate the will

of Congress subject to constitutional limits. *Id.* at 2263. *Loper Bright* demands that Congressional actions, whether to preempt or delegate, be expressly taken. It is the judiciary's job to interpret those actions using its own judgment, without deference to the political branches outside of its obligation to interpret the words of the Congress.

B. Implied preemption jurisprudence does not honor the judiciary's proper role in interpreting the law as Congress has enacted it.

The role of the judiciary, as held in *Loper Bright*, is inconsistent with the accumulated implied preemption jurisprudence interpreting the FDCA and FDA regulations. As the Supreme Court has held, Congress knows how to preempt State laws, and it is settled that the powers of the States are "not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Wyeth*. 555 U.S. at 565.

But some interpretive case law goes beyond what Congress actually did and puts courts in the role of divining what Congress meant to do and why. Following the statutory-construction dictates of *Loper Bright* requires, as Justice Thomas points out in his concurrence in *Wyeth*, preemptive effect should "be given only to those federal standards and policies that are set forth in, or necessarily follow from, the statutory text that was produced through the constitutionally required bicameral and presentment procedures." 555 U.S. at 586 (Thomas, J. concurring). In other words, "'[e]vidence of pre-emptive purpose [must be] sought in the text and structure of the [provision] at issue' to comply with the Constitution." *Id.* at 588. The "manifest purpose" of Congress is clearest when it has explicitly declared its intentions. Courts cannot fill a blank space with anything other than the assumption that the silence

was intentional. Efforts to displace the duly enacted legislation of the States in service of unstated Congressional "purposes" or through excessive deference to administrative decisions transgresses the proper role of the judiciary as held in *Loper Bright* and *Wyeth*.

C. Implied preemption infringes on the States' historical authority to regulate the health and safety of its citizenry when Congress has not expressly preempted that authority under the Supremacy Clause.

In *Dobbs v. Jackson Women's Health Organization,* the Supreme Court recognized the primacy of State police power in the absence of Congressional action or Constitutional provisions 597 U.S. 215 (2022). Inquiries into legislative motives rather than legislative language "are a hazardous matter." *Id*. at 253 (cleaned up). The *Dobbs* Court noted that where there is nothing in the federal law governing a right, it is left to "the people's elected representatives." *Id*. at 256. Congress is free to act, but where it has not it is not for a court to substitute its preferences. *Id*. at 240. Nor are courts free to substitute Congress's unenacted "purposes" for the expressed will of "the people's elected representatives" who enact State laws.

The *Dobbs* Court explains that courts must ground decisions in "text, history, or precedent." *Id*. at 270. Implied preemption is not grounded in text, because it cannot be. It is not grounded in history, because the tenets of federalism have historically preserved the dominion of State police powers to regulate the health and safety of State citizens, including State product-liability laws. Following *Loper Bright*, implied preemption is not grounded in precedent to the extent courts have interpreted actions Congress has not expressly taken as preempting State laws. The

relevant precedents are now *Loper Bright* and *Dobbs*. If courts must view rights not "grounded in text, history, or precedent" with suspicion, they must view implied preemption with equal suspicion as it is ungrounded in Congressional text. It is grounded only in its absence.

For the first 185 years after the adoption of the Constitution, each State was permitted to address the question of abortion in accordance with the views of its citizens. *Dobbs*, 597 U.S. at 225. In overturning *Roe v. Wade,* 410 U.S. 113 (1973), the *Dobbs* Court found that the Constitution conferred a right to an abortion even though it was not specifically mentioned. 597 U.S. at 225. The Court canvassed State laws at the time *Roe* was decided, finding that pre-*Roe* "it was firmly established that laws prohibiting abortion like the Texas law at issue in *Roe* were permissible exercises of state regulatory authority," and most states exercised that authority. *Id.* at 261. The Court observed that *Roe* "effectively struck down the laws of every single State." *Id*. at 228–29.

Every State has product-liability laws enacted to protect the health and safety of its citizens. It is accepted that product-liability laws are, just as pre-*Roe* State abortion laws were, exercises of "state police power regulations." *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 518 (1992). Many pre-date the FDCA. A finding of implied preemption is an "exercise of raw judicial power" that effectively strikes down the laws of all 50 states. *See Dobbs*, 597 U.S. 228–29. But our understanding of ordered liberty allows "the people's elected representatives" to decide how rights are regulated. *Id*. at 256.

D. Efforts to displace State product-liability law beyond *express* preemption by Congress are an improper application of the Supremacy Clause.

The Framers anticipated that conflicts may arise between federal laws and State laws. The Supremacy Clause of the Constitution is intended to address those conflicts: "[t]his 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." US CONST., art. 6, cl. 2. There is nothing in the Supremacy Clause that abrogates the dual sovereignty of the States where Congress is silent. To the contrary, the Tenth Amendment specifically reserves State powers not expressly delegated to the federal government. U.S. CONST. am. 10 ("The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people."). States maintain concurrent sovereignty, subject only to the limits of the Supremacy Clause. *Wyeth*, 555 U.S. at 584.

The Supremacy Clause, however, requires Congress to actually make a law to be elevated above an actual law of a State. The Supremacy Clause, moreover, provides that only laws duly enacted by Congress may displace State law. Only when Congress is acting—and, under *Loper Bright*, acting *expressly*—within its enumerated powers can it preempt State law. To allow anything beyond a duly enacted federal law to displace a State's law is to impinge on the "federalist structure of joint sovereigns." *Wyeth,* 555 U.S. at 584 (Thomas, J., concurring). Though the Supremacy Clause gives the federal government the right to preempt State laws,

where Congress is silent it remains the State's province to fill the gap. This was the Framers' intention.

Where Congress has not expressly provided for preemption of State law, principles of federalism and statutory construction recognized in *Dobbs* and *Loper Bright* preclude a finding of implied preemption. Where Congress has not acted expressly through a statute, what it has not said cannot restrict States in their traditional exercise of police power. Implied preemption converts what should be a statutory inquiry into whether Congress intended to preempt State law into a metaphysical one whose conclusion lies in the shadows of what Congress did not say or what an administrative agency has decided. No Congressional enactment suggests that Congress intended to preempt Ohio product-liability law that the General Assembly enacted to protect the health and safety of its citizens, like Mr. Bennett, from dangerous drugs. As Mr. Bennett has detailed above, his well-pleaded allegations situate his claims squarely within the framework of what Defendants had the power, ability, and obligation to do. Should the Court conclude that any aspect of his claims are preempted, it must address the constitutionality of impliedly preempting State law.

CONCLUSION

For the foregoing reasons, the Court should deny the motion to dismiss and allow Mr. Bennett's failure-to-warn and design-defect claims to proceed.

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Respectfully submitted,

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RULE 7.1(F) CERTIFICATION

Under L.R. 7.1(f) and ¶¶ 9.A and 9.A.i of the Court's Civil Standing Order, I certify that, according to the word count provided by Microsoft Word, this document contains 14,387 words in compliance with the 15,000-word limit for cases assigned to the mass-tort track.

/s/ Ashlie Case Sletvold
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