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

In re: Suboxone (Buprenorphine/ Naloxone) Film Products Liability Litigation This document relates to: All Actions	Case No. 1:24-md-03092-JPC MDL No. 3092 Hon. J. Philip Calabrese
RYAN BENNETT, *Plaintiff,* v. INDIVIOR INC., *ET AL.*, *Defendants.*	Case No. 1:24-sf-65011 Hon. J. Philip Calabrese

JOINT MEMORANDUM IN SUPPORT OF RULE 12(b)(6) MOTIONS FOR PARTIAL DISMISSAL FOR FAILURE TO STATE A CLAIM UPON WHICH RELIEF CAN BE GRANTED

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I. INTRODUCTION

Plaintiff Ryan Bennett alleges he sustained permanent damage to his teeth from using the prescription medicine Suboxone® Sublingual Film ("Suboxone Film") to treat his opioid dependence. Suboxone Film was approved by the United States Food and Drug Administration ("FDA") in 2010 and remains on the market today. He asserts identical common law failure-to-warn and design defect claims against six defendants whom he alleges indiscriminately were engaged in a laundry list of activities related to Suboxone Film. Plaintiff's allegations show that federal law preempts his claims, and those claims should accordingly be dismissed.

This Court's May 15, 2024 Minutes and Order (PageID #794) requires that Defendants' motions under Federal Rule of Civil Procedure 12(b)(2) and 12(b)(6) be filed at the same time. As stated in the concurrently filed motion, Defendant Indivior PLC moves for relief subject to and without waiver of their motion to dismiss for lack of personal jurisdiction filed on this same date. Pursuant to that same Minutes and Order, this Court ordered that the Plaintiffs' Liaison Counsel ("PLC") file "an exemplar complaint both in the specific case and on the general MDL docket." (PageID #794). On June 21, 2024, the PLC filed its "PLC's Exemplar Complaint." (PageID #102-1). While the exemplar complaint referenced an amended complaint filed on behalf of Maryland Plaintiff Christa Luhman, the PLC has acknowledged that it should have referenced an Ohio Plaintiff pursuant to an agreement memorialized in ECF #62 (PageID #661) where it was stated the "Parties also agree that any such [Rule 12] briefing should be undertaken in relation to a single exemplar

Ohio Plaintiff." On July 1, 2024, the PLC served the Amended Complaint in the *Ryan Bennett* case and acknowledged that the Rule 12 motion and briefing should be brought in reference to that case.[1]

II. BACKGROUND

Defendants note as a preliminary matter that Plaintiff's Amended Complaint includes allegations regarding an antitrust action and criminal proceedings related to Suboxone Film. Those proceedings are not relevant to these product liability/personal injury claims or whether Plaintiff has stated claims on which relief can be granted. *E.g.*, (PageID #124–26). Defendants dispute Plaintiff's characterizations of those unrelated proceedings and facts relevant to those proceedings, but will here address only the issues pertinent to the Rule 12(b)(6) analysis.

The FDA first approved Suboxone® Tablets in 2002 and approved Suboxone Film in 2010. (PageID #120, 123). As set out in the Suboxone Film product label, it is approved to treat opioid dependence and "used as part of a complete treatment plan that includes counseling and psychosocial support." *See* (ECF #121-2, PageID #2282). It remains on the market today for prescription by appropriately-licensed physicians. Defendant Indivior Inc. f/k/a Reckitt Benckiser Pharmaceuticals Inc. ("Indivior")

[1] For ease of reference, Defendants cite the Amended Complaint in *Bennett*, Case No. 1:24-sf-6501, as "ECF #12, PageID #___" because that pleading is not included in the MDL docket.

distributes and holds the New Drug Application ("NDA") for Suboxone Film. (ECF #121-4, PageID #2359–60).[2]

Plaintiff alleges that Suboxone Film can cause dental erosion and decay, and that it caused him to sustain "severe and profound permanent tooth damage and loss." (PageID #113); *see* (*id.* at PageID #168). In addition to Indivior, he has sued five other defendants: Indivior Solutions, Inc., Aquestive Therapeutics, Inc., Indivior PLC, Reckitt Benckiser Healthcare (UK) Ltd., and Reckitt Benckiser LLC. Plaintiff asserts the following identical claims against all six defendants, without distinction: (1) Strict Products Liability, (2) Products Liability—Negligent Failure to Provide Adequate Warnings and Instructions, (3) Strict Products Liability—Defective Design, (4) Products Liability—Negligent Design Defect, and (5) Punitive Damages. (*Id.,* PageID #163–180). Again making no distinction among them, Plaintiff further alleges that all Defendants "were pharmaceutical companies involved in the manufacturing, research, development, marketing, distribution, sale and release" of Suboxone Film. (*Id.*, PageID #115).

Plaintiff alleges that the FDA-approved Suboxone Film label contained inadequate warnings about alleged dental injuries (1) at the time the FDA approved it in 2010, (2) from approval until June 17, 2022, when Defendants added information about dental adverse events to the label, and (3) on and after the June 17, 2022 label

[2] As set out below, Defendants request the Court to take judicial notice of the FDA-approved product label for Suboxone Film and certain other documents discussed herein.

change, which Plaintiff contends was still inadequate. *See*, *e.g.*, (PageID #145). (**At time of approval:** "there is no reason to doubt that the FDA would have approved the initial label for Suboxone Film to warn of the dental risks posed by the product"); (PageID #144) (**Post-approval prior to June 2022 label change:** "Before and during Plaintiff's treatment, the peer-reviewed literature, together with the mounting adverse event reports, required Defendants to implement a CBE warning physicians and consumers of the risk of dental erosion and decay"); (PageID #111–12) (noting June 2022 label and embedding link to label reflecting same); (PageID #152) (**After June 2022 label change:** "Even after the [June 17, 2022] label change, the warning on the label is inadequate to warn healthcare professionals and consumers of the risk of dental injury"). Defendants do not in this motion seek dismissal of Plaintiff's failure to warn claim as it relates to the time period between Suboxone Film approval and the June 2022 label change. *See* discussion *infra* Section B. Thus, if this Motion were granted, Plaintiff's failure to warn claim would be limited to that time period.

In addition, and even though Suboxone Film remains FDA-approved and on the market today, Plaintiff claims that Suboxone Film is "defective in design or formulation in that [it has] limited and unproven effectiveness…" (PageID #174); *see also* (PageID #172) (alleging that Defendants breached a duty "to design a product free from a defective condition" by "designing Suboxone Film in such a way that posed an unreasonable risk of dental injuries and by placing and keeping Suboxone Film on the market despite [its] defective condition").

III. STATEMENT OF ISSUES TO BE DECIDED AND SUMMARY OF ARGUMENT

Issue No. 1 – Design Defect Preemption: In a case involving an FDA-approved prescription drug, is dismissal appropriate based on implied federal preemption when the plaintiff asserts design defect claims that would impose liability on the NDA-holder for (1) seeking FDA approval for the drug (a pre-approval design defect claim), or (2) not withdrawing the drug from the market despite continued FDA approval (a post-approval design defect claim)?

***Response to Issue No. 1*:** Yes, federal law preempts both pre-approval and post-approval design defect claims as a matter of law, making dismissal on the pleadings appropriate. A drug cannot be "re-designed" without turning into another drug requiring separate FDA approval. Thus, both pre- and post-approval design defect claims involving prescription drugs necessarily seek to second-guess and supplant the FDA's determination that the drug is safe and effective when used in accordance with its label and should be available for prescription by licensed healthcare providers. Federal law preempts such tort claims.

Issue No. 2 – Failure to Warn Preemption: In a case involving an FDA-approved prescription drug, is dismissal of certain failure to warn claims appropriate based on implied federal preemption when the plaintiff asserts claims that:

2(a). The drug's label was inadequate when approved by the FDA?

2(b). The drug's label was inadequate after an FDA-approved label change in which the FDA evaluated the then-existing evidence relating to dental adverse events, and the plaintiff has not adequately alleged any "newly acquired information" after that date?

2(c). The non-NDA holder defendants should have taken steps to change the drug label when federal law did not authorize them to do so?

***Response to Issue No. 2*:** Dismissal is appropriate as to all three liability theories.

Issue 2(a): Federal law preempts so-called "pre-approval" warnings claims attacking the adequacy of the as-approved label of a prescription drug. The FDA is the exclusive judge of the safety and efficacy of a prescription drug based on the information available at approval. Underscoring that conclusion, federal regulations permit the NDA-holder to make a unilateral label change (*i.e.*, without prior FDA approval) only through the "changes being effected" ("CBE") regulation, which, on its face, applies only after approval. *See* 21 C.F.R. § 314.70(c)(3).

Issue 2(b): As of the June 2022 label change, in an exercise of its exclusive authority to determine the efficacy and safety of Suboxone, the FDA determined based on all the information available that Suboxone Film was safe and effective, and that the label was adequate. If the NDA-holder cannot unilaterally comply with an ostensible state law duty to change the drug's label without running afoul of federal law, federal law preempts a claim based on the violation of that purported duty. Federal law permits an NDA-holder to make a unilateral label change only via the CBE regulation, which requires "newly acquired information." Plaintiff has failed to allege any 'newly acquired information' since June 17, 2022 that would allow for a label change via the CBE process.

Issue 2(c): Federal law permits only the prospective NDA-holder to seek approval for a prescription drug. Once approved, only the NDA-holder may use the

CBE regulation to make a unilateral label change. Any claim that a non-NDA holder should have changed the Suboxone Film label is thus preempted.

Issue No. 3 – Failure to Adequately Allege that Certain Defendants Manufactured, Distributed, or Sold Suboxone Film. Is dismissal appropriate as to claims of design defect and failure to warn when Plaintiff fails to adequately allege that the Defendants in question manufactured, marketed, or sold the product at issue?

Response to Issue No. 3. Dismissal is appropriate as to all such Defendants. It is a fundamental precept of product liability law that a defendant can only be liable for a product that it manufactures, distributes, or sells.

IV. LEGAL STANDARDS AND GOVERNING LAW

To survive a Rule 12(b)(6) motion to dismiss, a complaint must "contain sufficient factual matter, accepted as true, to state a claim for relief that is plausible on its face" once "measured against the elements of [the] claim." *O.M. Through McConnell v. KLS Martin LP*, 560 F. Supp. 3d 1084, 1087 (N.D. Ohio 2021) (Calabrese, J.) (citing *Darby v. Childvine, Inc.*, 964 F.3d 440, 444 (6th Cir. 2020) and *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)) (internal quotations omitted) (applying Fed. R. Civ. P. 12(b)(6)).[3] A facially plausible claim must allege "factual content that allows the court to draw the reasonable inference that the defendant[s are] liable for the misconduct alleged." *Id.* (citing *Iqbal*, 556 U.S. at 678). While a plaintiff's "well-pled factual allegations," will be construed in the plaintiff's favor, courts do not accept

[3] Unless noted otherwise, all internal citations and punctuation are omitted.

purely "naked assertions" as true. *Id.* at 1088. A complaint must therefore articulate more than "labels and conclusions," "a formulaic recitation of the elements of a cause of action," or "conclusory allegations or legal conclusions masquerading as factual allegations." *Id.* At 1087–88 (cleaned up) (citing *Wilburn v. United States*, 616 F. App'x 848, 852 (6th Cir. 2015); *Iqbal*, 556 U.S. at 678; and *Eidson v. State of Tennessee Dep't of Children's Servs.*, 510 F.3d 631, 634 (6th Cir. 2007)).

A defendant may move to dismiss under Rule 12(b)(6) based on an affirmative defense, such as federal preemption, if "the plaintiff's own allegations show that a defense exists that legally defeats the claim for relief." *Marsh v. Genentech, Inc.*, 693 F.3d 546, 554–55 (6th Cir. 2012); *see In re Ford Motor Co. F-150 & Ranger Truck Fuel Economy Mktg. & Sales Prac. Litig.*, 65 F.4th 851, 859 (6th Cir. 2023) (stating that preemption is an affirmative defense).

Along with the complaint itself, courts faced with a motion to dismiss "may consider exhibits attached to the complaint, public records, items appearing in the record of the case, and exhibits attached to defendant[s]' motion to dismiss, so long as they are referred to in the complaint and are central to the claims contained therein." *Jones v. Lubrizol Advanced Materials, Inc.*, 559 F. Supp. 3d 569, 599 (N.D. Ohio 2021) (Calabrese, J) (citing *DeShetler v. FCA US LLC*, No. 3:18 CV 78, 2018 WL 6257377, at *4 (N.D. Ohio Nov. 30, 2018), *aff'd,* 790 F. App'x 664 (6th Cir. 2019)).

Defendants request that this Court take judicial notice of the prescribing information for Suboxone Film (a/k/a the FDA-approved product label), which is included in Plaintiff's Complaint ¶ 8 in the form of an embedded link and is attached

to the Declaration of Randall L. Christian as Exhibit 1-A (ECF #121-2, PageID #2281–2314) in support hereof. *See, e.g., Sandoval v. PharmaCare US, Inc.*, 145 F. Supp. 3d 986, 992 (S.D. Cal. 2015) ("[c]ourts addressing motion to dismiss product labeling claims routinely take judicial notice of images of the product packaging."); *Yeldo v. MusclePharm Corp.*, 290 F. Supp. 3d 702, 708 (E.D. Mich. 2017) (taking judicial notice of product label).

Pursuant to this same authority Defendants request the Court to take judicial notice of the product label for Sublocade® (hereafter "Sublocade") referenced throughout the Amended Complaint and attached to the Declaration of Randall L. Christian as Exhibit 1-B (ECF #121-3, PageID #2315–57) in support hereof. Defendants also request that this Court take judicial notice of Exhibits 1-C (ECF #121-4, PageID #2358–60) and 1-D (ECF #121-5, PageID #2361–63) to the Declaration of Randall L. Christian in support hereof, documents taken from and accessible via the FDA's government 'Orange Book' website database, which reflect that Indivior Inc. is the exclusive holder of the NDA for Suboxone Film and Suboxone tablets. As stated by an Ohio Southern District Court in the context of a motion to dismiss brought under Rule 12(b)(6):

> "In ruling on a motion to dismiss, the Court 'may consider materials in addition to the complaint if such materials are public records or are otherwise appropriate for the taking of judicial notice.' " *Mories v. Boston Sci. Corp.*, 494 F. Supp. 3d 461, 469 (S.D. Ohio 2020) (quoting *New England Health Care Emps. Pension Fund v. Ernst & Young, LLP*, 336 F.3d 495, 501 (6th Cir. 2003)). Doing so does not convert a motion to dismiss into a motion for summary judgment. *Id.*; *Goryoka v. Quicken Loan, Inc.*, 519 F. App'x 926, 927 (6th Cir. 2013) ("[m]atters of public record may be considered on a motion to dismiss").

Reynolds v. Medtronic, Inc., No. 3:20-CV-403, 2021 WL 1854968, at *4 (S.D. Ohio May 10, 2021) (quotations in original). The *Reynolds* court went on to take judicial notice of the FDA approval listings at issue in that case.

Defendants request that this Court take judicial notice of a document relating to Sublocade incorporated into Plaintiff's Amended Complaint ¶ 161 in the form of an embedded link, available through the FDA database entitled "Center for Drug Evaluation and Research - Application Number 209819Orig1s000 - Clinical Pharmacology and Biopharmaceutics Review(s)." It is attached as Exhibit 1-E to the Declaration of Randall L. Christian (ECF #121-6, PageID #2364–2527) in support hereof. Last, Defendants request that the Court take judicial notice of a document from the FDA website entitled "Drug Review and Development Definitions," attached as Exhibit 1-F to the Declaration of Randall L. Christian (ECF #121-7, PageID #2528–46) in support hereof.

V. ARGUMENT

A. Federal Law Preempts Plaintiff's Design Defect Claims and the Court Should Dismiss Them with Prejudice.

Plaintiff claims to have suffered personal injuries due to alleged defects in the design of the Suboxone Film that he claims to have received. (PageID #172–78). Under Ohio law, a product is defectively designed if, at the time it left the manufacturer's control, the foreseeable risks associated with the product's design or formulation outweighed the design's benefits. *See, e.g.,* Ohio Rev. Code § 2307.75(A). According to Plaintiff, the therapeutic benefits of the Suboxone Film he received were

outweighed by the risk of dental injury he claims is associated with its use. (PageID #174).

Plaintiff acknowledges that Suboxone Film is FDA-approved and contains two active ingredients: buprenorphine and naloxone. (PageID #110, 123). Plaintiff alleges that Suboxone Film is "designed to be acidic to maximize absorption of the buprenorphine and minimize absorption of naloxone" and that "[t]his acidic formulation leads to dental erosion and decay." (PageID #110). Thus, according to Plaintiff, to comply with his claim brought under state law, Defendants were required to alter Suboxone Film's FDA-approved formulation to reduce or eliminate its acidity before selling it to Plaintiff. But, as shown below, federal law prohibited Defendants from changing Suboxone Film's FDA-approved formulation. Thus, the only way Defendants could have complied with both federal law and their ostensible state law tort duty (as alleged by Plaintiff) was to not sell Suboxone Film in Ohio at all. Such claims attempting to override the FDA's expert determination regarding the safety and efficacy of a prescription drug are preempted as a matter of federal law.

1. Impossibility Preemption.

The Supremacy Clause of the United States Constitution makes federal law "the supreme Law of the Land." U.S. Const. art. VI, cl. 2; *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 479–80 (2013). Courts apply this principle under the rubric of preemption. *Bossetti v. Allergan Sales, LLC*, No. 1:22-CV-523, 2023 WL 4030681, at *3 (S.D. Ohio June 15, 2023) (slip copy). Federal law can expressly or impliedly preempt state law. At issue here is "impossibility preemption," a species of implied

preemption that arises when it is "impossible for a private party to comply with both state and federal requirements." *Bartlett*, 570 U.S. at 480.

In assessing whether impossibility preemption applies, "the question is whether the [defendant] could independently do under federal law what state law requires of it." *Pliva v. Mensing*, 564 U.S. 604, 620 (2011) (citing *Wyeth v. Levine*, 555 U.S. 555, 573 (2009)); *Yates v. Ortho-McNeil-Janssen Pharms., Inc.*, 808 F.3d 281, 298 (6th Cir. 2015); *Brashear v. Pacira Pharms., Inc.*, No. 1:21-CV-700, 2023 WL 3075403, at *2 (S.D. Ohio Apr. 25, 2023). To answer this question, the Court begins by identifying the actions the state law at issue would compel the defendant to take. *See Yates*, 808 F.3d at 297; *Bossetti*, 2023 WL 4030681, at *3. If federal law prohibits the defendant from taking the actions required by state law, the state law claim is clearly preempted. *See Yates*, 808 F.3d at 298; *Brashear*, 2023 WL 3075403, at *3; *Bossetti*, 2023 WL 4030681, at *3. But, as both the Supreme Court and the Sixth Circuit have explained, a state law claim is also preempted if it imposes duties the defendant "cannot satisfy … without the Federal Government's special permission and assistance [because the defendant] cannot independently satisfy those state law duties for pre-emption purposes." *Mensing*, 564 U.S. at 623–24; *Yates*, 808 F.3d at 295, 299–300.

2. The FDA is Responsible for Approving the Design (Formulation) of Prescription Drugs.

The FDA has exclusive authority to approve prescription drugs for sale in the United States. 21 U.S.C. § 355(a). The approval process is "onerous and lengthy," *Bartlett*, 570 U.S. at 476. The FDA may only approve a prescription drug if the NDA

provides "***substantial evidence*** that the drug will have the effect it purports or is represented to have." 21 U.S.C. § 355(d)(5) (emphasis added).

The NDA "must include 'full reports of [all clinical] investigations,' … relevant nonclinical studies, and 'any other data or information relevant to an evaluation of the safety and effectiveness of the drug.'" *Bartlett*, 570 U.S. at 476 (alteration in original) (internal citation omitted); *see also* 21 C.F.R. § 314.50(d)(5)(iv) (requiring all "data or information relevant to an evaluation of the safety and effectiveness of the drug" be submitted to the FDA). These studies must be "well-controlled" and conducted "by experts qualified by scientific training and experience to evaluate the effectiveness of the drug." 21 U.S.C. § 355(d)(7). In addition, "FDA is required to exercise its scientific judgment to determine the kind and quantity of data and information an applicant is required to provide for a particular drug to meet the statutory standards." 21 C.F.R. § 314.105(c).

3. Plaintiff's Post-Approval Design Defect Claim is Preempted Because An NDA-Holder Cannot Change the Formulation of a Drug After FDA Approval in the Manner Urged by Plaintiff.

Plaintiff Advocates a "Major Change" that Cannot be Made Without FDA Approval. The only exceptions to the prohibition against qualitative and quantitative changes to an approved drug's formulation are the *very* limited changes the regulation defines as "minor" and "moderate." *See* 21 C.F.R. § 314.70(b)(2)(i). Minor changes include "[t]he deletion or reduction of an ingredient intended to affect only the color of the drug product" and "[a] change in the size and/or shape of a container containing the same number of dosage units." 21 C.F.R. § 314.70(d)(2)(ii),

(iv). A moderate change, for example, would be "[a] change in the container closure system that does not affect the quality of the drug product." 21 C.F.R. § 314.70(c)(2)(i).

Such minor and moderate changes are not at issue here. As discussed, Plaintiff claims Suboxone Film is "designed to be acidic to maximize absorption of the buprenorphine and minimize absorption of naloxone" and that "[t]his acidic formulation leads to dental erosion and decay." (PageID #110). Thus, Plaintiff effectively claims that Ohio law required Defendants to alter the drug's FDA-approved chemical composition in a manner that would affect its acidity level and absorption rates of its two active ingredients. Defendants were prohibited from making such a "major" change without first obtaining FDA approval. *See* 21 C.F.R. § 314.70(b)(1)–(2)(i) (prohibiting changes to the "qualitative or quantitative formulation of the drug product" absent prior approval from FDA); *id.* § 314.3(b) (defining "drug product" as "a finished dosage form" and "dosage form" as including "the way the product is administered"); *see also Yates*, 808 F.3d at 298 (finding that post-approval design defect claim preempted because design change allegedly required by state law constituted a "major" change under FDA regulations); *Bossetti*, 2023 WL 4030681, at *4 (same); *Brashear*, 2023 WL 3075403, at *3, n. 2 (same).

Plaintiff's Post-Approval Design Defect Claim is Preempted. According to Plaintiff's design defect allegations, Ohio law required Defendants to change Suboxone Film's FDA-approved chemical formulation to reduce or eliminate its acidity. But, as the Sixth Circuit has recognized:

> FDA regulations provide that once a drug … is approved, the manufacturer is prohibited from making any major changes to the

> 'qualitative or quantitative formulation of the drug product, including inactive ingredients, or in the specifications provided in the approved application.'

Yates, 808 F.3d at 298 (quoting 21 C.F.R. § 314.70(b)(2)(i)); *Bartlett*, 570 U.S. at 477 (quoting 21 C.F.R. § 314.70(b)(2)(i)). Because this regulation prohibits virtually any change to an approved drug's formulation, courts, including the Sixth Circuit, routinely find "post-approval design defect claim[s] clearly preempted by federal law." *See, e.g., Yates*, 808 F.3d at 298; *Bossetti*, 2023 WL 4030681, at *4 ("[P]ost-approval design-defect claims are clearly preempted."); *Brashear*, 2023 WL 3075403, at *3 ("[A]s the Sixth Circuit has made clear, [plaintiff]'s post-approval design defect claim is preempted by federal law.") (internal quotation marks omitted).

Thus, Plaintiff's post-approval design defect claim is preempted because FDA regulations prohibited Defendants from altering Suboxone Film's FDA-approved formulation as Plaintiff claims Ohio law required. The Court should dismiss this claim with prejudice.

4. Plaintiff's Pre-Approval Design Defect Claims are Preempted.

Plaintiff alleges that Defendants should have discovered the alleged risk of dental injury before seeking the FDA's approval in the first place—and should then have foregone seeking approval of the drug. *See* (PageID #173). Thus, Plaintiff appears to claim that Defendants had a duty under Ohio law to design a less acidic Suboxone Film *before* seeking FDA approval. But, to the extent Plaintiff is asserting any such pre-approval design defect claim, it fails because "the Sixth Circuit has already closed that road." *See Bossetti*, 2023 WL 4030681, at *4 (citing *Yates* at 298).

In *Yates*, the Sixth Circuit addressed whether a plaintiff may recover for injuries relating to a defendant's design choices made before FDA approval. 808 F.3d at 298. The Sixth Circuit rejected the claim as "too attenuated" because it requires an assumption that the FDA would have approved the allegedly safer design. *Id.* at 299. The Sixth Circuit explained that "[d]efendants could not have complied with whatever pre-approval duty might exist without ultimately seeking the FDA's approval prior to marketing [the drug], and certainly prior to [plaintiff's] use of the drug." *Id.* at 299–300 (citing *Mensing*, 564 U.S. at 623–24); *see also e.g., Fleming v. Janssen Pharms., Inc.*, 186 F. Supp. 3d 826, 833 (W.D. Tenn. 2016) (finding pre-approval design defect claims preempted under *Yates*); *Bossetti*, 2023 WL 4030681, at *4–5 (same); *Brashear*, 2023 WL 3075403, at *3 (same).

The same reasoning forecloses any pre-approval design defect claim Plaintiff asserts here. To the extent any such pre-approval duty exists under Ohio law, Defendants could not have complied with it without obtaining the FDA's approval before marketing the hypothetical alternative product. *See Yates*, 808 F.3d at 300. Because Defendants could not have "independently satisfied [such a duty] for preemption purposes," the claim is preempted. *See Mensing*, 564 U.S. at 623–24.

5. Preemption Cannot be Avoided by Claiming Defendants Could Have Complied with Federal and State Law by Removing Suboxone Film from the Market.

Plaintiff claims that "Defendants had a duty to design a product free from a defective condition" and "breached this duty…by ***placing*** and ***keeping*** Suboxone on the market despite Suboxone's defective condition." (PageID #172) (emphasis added).

Plaintiff cannot, however, avoid federal preemption of his design defect claims by contending that Defendants could have complied with both state and federal law by simply removing Suboxone Film from the market.

In *Bartlett*, the Supreme Court explained that if a claim of impossibility preemption fails any time a defendant could comply with state and federal law by ceasing to act, "impossibility pre-emption would be all but meaningless." *Bartlett*, 570 U.S. at 487–88 (internal citations omitted). Thus, the Supreme Court rejected the stop-selling rationale as "incompatible with … pre-emption jurisprudence" which "presume[s] that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability." *Id.* at 488. And in *Yates*, the Sixth Circuit, applying *Bartlett*, found all pre-approval design defect claims preempted because:

> In contending that defendants' pre-approval duty would have resulted in a [drug] with a different formulation, [plaintiff] essentially argues that defendants should never have sold the FDA-approved formulation … in the first place. We reject this never-start selling rationale for the same reasons the Supreme Court [did] in *Bartlett*.

Yates, 808 F.3d at 300.

Consequently, Plaintiff cannot preclude preemption of his design defect claims by claiming that Defendants could have complied with both Ohio and federal law by removing Suboxone Film from the market or by never seeking approval of the formulation in the first place.

6. Preemption Cannot be Avoided by Claiming that a Safer Alternative Design Could Have Been Marketed Instead of Suboxone Film.

Plaintiff repeatedly assails Suboxone Film as being "acidic." (PageID #130). But Plaintiff does not allege an alternative way Suboxone Film could have been designed to mitigate the alleged dental risks. Instead, he references a completely different long-acting ***injectable*** product — Sublocade — with different active ingredients and characterizes it as a "safer alternative" to Suboxone Film. (PageID #156). The claim that an entirely different product can be considered a safer alternative to the one at issue fails as a matter of law. And even if Sublocade could be considered a "safer alternative" design to Suboxone Film (it cannot) these allegations do not allow Plaintiff's design defect claims to escape preemption.

(a) As a matter of law, Sublocade is a product different from Suboxone Film, not an alternative design of Suboxone Film.

Courts have recognized that at the pleadings stage, a 'safer alternative design' allegation can fail as a matter of law when the "alternative" is in reality an entirely different product. *See, e.g., Barnes v. Medtronic, PLC*, No. 2:17-CV-14194, 2019 WL 1353880, at *2 (E.D. Mich. Mar. 26, 2019) (dismissing design defect claim when plaintiff pled "alternative categories of products" as safer alternative design). In surveying cases on this issue, the Alabama Supreme Court reached this conclusion:

> [T]here are necessarily some circumstances where a court ***can*** appropriately hold as a matter of law that a proposed alternative design is sufficiently different from the allegedly defective product that it is more properly viewed as a design for a different product than as an alternative design of the allegedly defective product.

Hosford v. BRK Brands, Inc., 223 So. 3d 199, 205 (Ala. 2016) (emphasis in original). Plaintiff's suggestion that the entirely different injectable product Sublocade is an alternative design presents such a circumstance.

The NDA review for Sublocade, which Plaintiff has incorporated into his complaint in the form of an embedded link at ¶ 161, is attached as Ex. 1-E (ECF #121-6, PageID #2364).[4] It states that this product is a "Solution for injection" and that the route of administration is "[s]ubcutaneous injection." (ECF #121-6, PageID #2366). As a product with buprenorphine as its only active ingredient, it does not have the same active ingredients as Suboxone Film. *Id.* The Sublocade prescribing information reflects in clear terms that it is a product entirely different from Suboxone Film:

- It has a Black Box Warning that states "WARNING: RISK OF SERIOUS HARM OR DEATH WITH INTRAVENOUS ADMINISTRATION."
- Per the Indications, it can only be administered to "patients who have initiated treatment with a buprenorphine-containing product, followed by dose adjustment for a minimum of 7 days.
- It can only be administered by a health care provider.
- It is administered monthly only by subcutaneous injection.
- It contains only one active ingredient—buprenorphine; it does not contain naloxone.

See (ECF #121-3, PageID #2316). Suboxone Film shares none of these characteristics. It includes the active ingredient naloxone, it is self-administered as a daily dose by the patient by placing it under the tongue or inside the cheek, it has no black box

[4] The formal title of this document is Center for Drug Evaluation and Research - Application Number 209819Orig1s000 - Clinical Pharmacology and Biopharmaceutics Review(s).

warning, and initiation of it does not require a prior course of any other medication. (ECF #121-2, PageID #2282).

Persuasive authority instructs that in the pharmaceutical context, a product with a different active ingredient indicated to treat the same symptoms is not a safer alternative design, it is a different product:

> Thus, a safer alternative design must be for the product at issue – here, Prempro…[Plaintiff] does not explain how Prempro could have been modified or improved; she instead argues that progestin should not have been added to estrogen. In essence, [she] argues that the product Prempro should have been a different product: its predecessor Premarin.

Brockert v. Wyeth Pharms., Inc., 287 S.W.3d 760, 770–71 (Tex. App. 2009); *see also Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 385 (Tex. 1995) ("It is not rational…to impose liability in such a way as to eliminate whole categories of useful products from the market.").

Here, Plaintiff proposes a wholly different category of product: an injectable drug with buprenorphine as its sole active ingredient, as an alternative to the category of oral film products that deliver buprenorphine and naloxone. The court in *Barnes* rejected the similar contention that an entire category of polyester hernia mesh products was unsafe compared to alternative *types* of mesh: "Plaintiff's design defect claim cannot succeed by categorically challenging the safety of polyester mesh and pleading only alternative categories of products as alternative production practices." *Barnes*, 2019 WL 1353880, at *2. The *Barnes* court dismissed Plaintiff's design defect claim on this basis, and this Court should likewise hold that Plaintiff's

allegations regarding Sublocade fail as a matter of law to propose a safer alternative design.

(b) Plaintiff's design defect claims are preempted even assuming that Sublocade is a "safer alternative design" under Ohio law.

Plaintiff's claim that Indivior should have marketed Sublocade and should have never started selling Suboxone Film violates the Sixth Circuit's admonition that a design defect claim cannot impose a requirement that the manufacturer "never start selling" the drug at issue. *Yates*, 808 F.3d at 300. This alone is fatal to Plaintiff's attempt to avoid preemption by holding up Sublocade as a purported safer alternative design.

Moreover, even before *Yates,* at least one court in the Northern District of Ohio concluded that the plaintiff's design defect claim was preempted even assuming the truth of the plaintiff's allegation that that another contraceptive product was a "safer alternative design." *See Booker v. Johnson & Johnson*, 54 F. Supp. 3d 868, 874–76 (N.D. Ohio 2014). Notwithstanding that allegation, the court held that "it was impossible for the Defendants to comply with both its state-law duty to alter the composition of the drug, and its federal-law duty not to alter an FDA-approved design." *Id.* at 875. The same reasoning applies here, and the Court should reject Plaintiff's attempt to avoid preemption by referencing Sublocade as a purported safer alternative design.

B. Federal Law Preempts Plaintiff's Claim that the Suboxone Label was Inadequate at the Time of Approval and After the June 2022 Label Change.

1. Plaintiff's Claim that the Suboxone Film Label Should have been Modified Prior to FDA Approval is Preempted.

Plaintiff claims that the Suboxone Film label was inadequate at the time the FDA approved it because it did not address the claimed risk of adverse dental events. (PageID #145). Federal law preempts this claim.

To secure FDA approval for a drug, drug manufacturers must submit its proposed drug label and gain FDA approval for its proposed labeling. 21 U.S.C. § 355(b)(1)(A)(vi); 21 C.F.R. § 314.50(c)(2)(i). The drug label text must be submitted along "with annotations to the information in the summary and technical sections of the NDA that support the inclusion of each statement." 21 C.F.R. § 314.50(c)(2)(i). Before it can approve a new drug, FDA must determine, "based on a fair evaluation of all material facts," that the proposed label is not "false or misleading in any particular." 21 U.S.C. § 355(d)(7); 21 C.F.R. § 314.125(b)(6). "Once the FDA has approved a label, the presumption is that the FDA conducted the necessary vetting and research to confirm that the label accurately communicates the risks with using the drug." *Brashear*, 2023 WL 3075403, at *4 (citing *In re Darvocet, Darvon, & Propoxyphene Prod. Liab. Litig.*, 756 F.3d 917, 922 (6th Cir. 2014)).

Plaintiff's claim that the Suboxone Film label should have been changed prior to approval stands in conflict with this authority. Recognizing this conflict, a Tennessee district court held that such a pre-approval failure-to-warn claim failed as a matter of law:

> 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.

Mitchell v. Boehringer Ingelheim Pharms., Inc., No. 1:16-cv-02384-STA-egb, 2017 WL. 5617473, at *4 (W.D. Tenn. Nov. 21, 2017) (emphasis added).

The First Circuit has similarly held that pre-approval warning claims are preempted because the FDA is "the exclusive judge of safety and efficacy based on information available at the commencement of marketing." *In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 779 F.3d 34, 41 (1st Cir. 2015); *see also Utts v. Bristol-Myers Squibb Co.*, 226 F. Supp. 3d 166, 182 (S.D.N.Y. 2016) (finding pre-approval warnings claims preempted and noting that brand and generic manufacturers share the "same lack of authority to alter a…label's warning at the time the NDA process concludes.").

In sum, Plaintiff's claim that the Suboxone Film label was inadequate as of the time of FDA approval is preempted and should be dismissed.

2. Plaintiff's Claim that the Suboxone Film Label was Inadequate as of or After the June 17, 2022 Label Change is Preempted.

(a) The FDA's determination that the Suboxone Film was adequate as of the June 17, 2022 label change preempts Plaintiff's claim that it was not.

The legal authority cited above likewise demonstrates that Plaintiff's inadequate labeling claim as of the FDA-approved June 17, 2022 label change is preempted. As stated in Plaintiff's complaint, the FDA required information "about the risk of dental problems to be added to the prescribing information and patient

medication guide for all buprenorphine medicines dissolved in the mouth." (PageID #111). In June 2022, Indivior incorporated information regarding dental problems into the Suboxone Film prescribing information. *See* (PageID #111); *see also* (ECF #121-2, PageID #2291, at § 5.13) ("Dental Adverse Events"). The regulations governing this change provide that this change required and received FDA approval via a supplemental NDA ("sNDA"). *See* 21 C.F.R. § 314.70(b)(2)(v)(A); *id.* § (b)(3).

As with initial approval of the NDA, when the FDA approves an sNDA "the presumption is that the FDA conducted the necessary vetting and research to confirm that the label accurately communicates the risks with using the drug." *See Brashear*, 2023 WL 3075403, at *4. This is particularly true where, as here, the focus of the FDA-approved revision addresses the precise risk of injury claimed by Plaintiff. *See In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prod. Liab. Litig.*, 185 F. Supp. 3d 761, 769–70 (D.S.C. 2016) (labeling claim preempted when FDA "specifically approved [a] statement" when plaintiff urged "different statements" regarding the drug's efficacy for "primary prevention in women…").

(b) Plaintiff fails to allege a plausible basis for modifying the Suboxone Film label after the FDA-approved June 17, 2022 label change.

Plaintiff claims that after the June 2022 label change, the Suboxone Film prescribing information still failed to adequately warn of risks regarding dental injuries. (PageID #152). Plaintiff fails to allege how Indivior could have changed the Suboxone Film prescribing information in a manner consistent with applicable

statutory and regulatory authority. His claim alleging labeling inadequacy after the June 2022 label change is accordingly preempted.

"Once the FDA approves an NDA or sNDA, federal law generally prohibits the manufacturer from materially changing the label without submitting an additional sNDA for the FDA's advance approval." *Lauderdale v. Organon USA, Inc.*, No. 5:21-CV-5200, 2022 WL 3702113, at *4 (W.D. Ark. Aug. 26, 2022) (citing 21 C.F.R. § 314.70(b)). "A ***limited exception*** exists under 21 C.F.R. § 314.70(c)(6)(iii), also known as the 'Changes Being Effected' (CBE) regulation, which allows a brand-name drug manufacturer to 'add or strengthen a contraindication, warning, precaution, or adverse reaction' to reflect 'newly acquired information' without advance FDA approval." *Id.* (emphasis added); *see also Brashear*, 2023 WL 3075403, at *4. Federal regulations specify the narrow circumstances under which a drug sponsor can modify warnings via the CBE process. *See* 21 C.F.R. § 314.70(c)(6)(iii). "Outside of the specified CBE circumstances, NDA holders must obtain prior approval from the FDA for any labeling or other changes through the 'prior approval supplement' ('PAS') process." *Patton v. Forest Laboratories, Inc.*, 2018 WL 5269239 at * 3 (C.D. CA Sept. 19, 2018) (citing 21 C.F.R. § 314.70).

Plaintiff does not allege the presence of "newly acquired evidence" following the June 2022 label change as would be necessary to making a label change through the CBE process. Plaintiff's claims that Defendants should have used the CBE process to change the Suboxone Film label after the June 2022 label change are thus preempted by federal law. When claiming a breach of duty based on failure to change

the label via the CBE process, "the plaintiff must plausibly allege information showing that a manufacturer would have been able to use the CBE process to change its drug labeling." *Brashear*, 2023 WL 3075403, at *4 (citing *Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699, 708–09 (2d Cir. 2019) (ruling that "conclusory and vague allegations" cannot plausibly show the existence of newly acquired information); *see also id.* (citing *In re Celexa,* 779 F.3d at 42–43) (dismissing plaintiff's failure-to-warn claims on preemption grounds because plaintiff did not allege any information that would have enabled the manufacturer to use the CBE process).

Plaintiff does not adequately specify a factual basis for the proposition that, after the FDA's June 2022 approval of the Suboxone Film label, there was newly acquired information reflecting evidence of a causal association that would allow a label change under the CBE process. His claim in this regard is accordingly preempted and should be dismissed.

Application of the foregoing arguments would result in Plaintiff's failure to warn claim being limited to the time period between FDA approval of Suboxone Film and the June 17, 2022 label modification.

C. Plaintiff's Claim that All "Defendants" Should have Changed the Suboxone Film Label Conflicts with Federal Law and FDA Regulations which Prohibit Non-NDA Holding Defendants from Changing the Suboxone Film Label.

Plaintiff claims that all of the "Defendants" were required to change "the Suboxone label to include warnings and instructions addressing the risk of [dental] injury associated with the drug as soon as they had notice of adverse events relating to the same." (PageID #148). He specifically asserts that the label change Defendants

had a duty to undertake should have been accomplished through the FDA's CBE provision set out in 21 C.F.R. § 314.70(c)(3). (PageID #144).

Under federal law, however, only the holder of an NDA can use the CBE regulation to make a unilateral change to an approved drug label. Such a label change requires submission of a "supplement" to the NDA. *See* 21 C.F.R. § 314.70(c)(1), (3), (6)(iii). The supplement must set out the proposed label change and must provide a "full explanation of the basis for the change." *Id.* § (c)(1) & (3). FDA regulations make clear that "***only the applicant*** may submit a supplement to an application." 21 C.F.R. § 314.71(a) (emphasis added). Federal regulations define "Applicant" as any person who submits an NDA and any person who owns an approved NDA. 21 C.F.R. § 314.3.

Applying this regulatory framework to a case before it, a court in the Southern District of Ohio observed that the drug "***sponsor*** is permitted to add risk information to the FPI without first obtaining FDA approval via a CBE supplement…" *See Swanson v. Abbott Lab'ys*, No. 2:14-CV-1052, 2017 WL 5903362, at *5 (S.D. Ohio Nov. 28, 2017) (emphasis added) (citing Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922-01). Per the FDA regulatory framework, the terms "applicant" and "drug sponsor" both refer to the NDA holder for the prescription drug. As stated in the FDA's "Drug Development and Review Definitions," an "applicant, or drug sponsor, is the person or entity who assumes responsibility for the marketing of a new drug, including responsibility for compliance with applicable provisions of the ***Federal Food, Drug, and Cosmetic***

Act and related regulations. The 'sponsor' is usually an individual, partnership, corporation, government agency, manufacturer or scientific institution." *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922-01 (emphasis in original), attached as Ex. 1-F (ECF# 121-7, PageID #2528–2546). In this case, only Indivior—the sponsor of Suboxone Film—had the authority to change that product's label.

This Court's discussion of preemption principles in *Hall v. OrthoMidwest, Inc.*, 541 F. Supp. 3d 802 (N.D. Ohio 2021), is instructive. In that case, the plaintiff sought to impose a duty on defendants who distributed a medical device to "inform[] and educat[e]" medical providers" regarding alleged safety issues of a hip replacement device cleared by the FDA through the 510(k) process. *Id.* at 806. Distributor Defendants argued that under the rationale of the Supreme Court's holding in *Mensing*, plaintiff's claims were preempted because they did not manufacture the product. *Id.* at 807; *see also PLIVA, Inc. v. Mensing*, 564 U.S. 604, 613 (2011) (holding that brand name drug manufacturer, *i.e.* the NDA holder, could change drug label via CBE process but generic drug manufacturer could not). This Court agreed with Distributor Defendants' rationale, observing that "[a]s a matter of law, the distributor of a medical device marketed through the 510(k) process has no authority to change the product or its warnings," and stating that "principles of conflict preemption likely bar" these claims against the distributors. *Hall*, 541 F. Supp. 3d at 808. This Court determined that reaching a holding of conflict preemption would extend preemption case law to 510(k) medical devices and that "the [removal] procedural posture of the

case does not provide the appropriate vehicle to take such a step….even though doing so does not involve much, if any, doubt." *Id.*

Here, Indivior Inc., under its current name and its former name Reckitt Benckiser Pharmaceuticals Inc., has at all times been the exclusive holder of the NDA for Suboxone Film and Suboxone tablets. (ECF #121-4, PageID #2359–60). By alleging indiscriminately that "Defendants" should have used the CBE regulation to change the Suboxone Film label, Plaintiff thus seeks to hold the non-NDA-holder Defendants liable under state law for not doing something that federal law prohibits. As a matter of law, Plaintiff's failure-to-warn claims against these Defendants are preempted.

Unlike the circumstance in *Hall,* dismissing Plaintiff's failure to warn claims as to Defendants who do not hold the Suboxone Film NDA does not require an extension of existing preemption principles. Ohio law provides that a product can be defective due to inadequate warning only when, in the presence of other circumstances described by the statute, "[t]he manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk." Ohio Rev. Code § 2307.76 (A)(1)(b). This same requirement applies to post-marketing warning or instruction. *Id.* § 2307.76(A)(2)(b). Put differently, a failure to warn claim imposes a "duty to warn against reasonably foreseeable risks." *Graham v. Am. Cyanamid Co.*, 350 F.3d 496, 514 (6th Cir. 2003). In this case, federal law clearly places the duty to warn of Suboxone Film's risks ***exclusively*** on Indivior Inc., the NDA holder for that drug, and does not allow parties

who do not hold the NDA to change the warning. Plaintiff's claim that those Defendants who do not hold the Suboxone Film NDA should have changed the Suboxone Film warning thus irreconcilably conflicts with federal law and should be dismissed as to those Defendants on that basis.

D. Plaintiff's Claims Should be Dismissed as to Those Defendants for which there is no Well-Pled Allegation that they Manufactured, Distributed, or Sold Suboxone Film.

It is a fundamental precept of product liability law that a defendant cannot be liable for a product it did not manufacture, distribute, or sell. As the Sixth Circuit has recognized, the "threshold requirement of ***any*** products-liability claim is that the plaintiff assert that the defendant's product caused the plaintiff's injury." *Smith v. Wyeth, Inc.*, 657 F.3d 420, 423 (6th Cir. 2011) (emphasis added). As stated in relation to use of generic equivalents, "[t]here is no theory of product liability under which a defendant can be held liable for an injury caused by a product that it did not sell, manufacture, or otherwise supply to the plaintiff. Therefore, in the context of product liability claims, a plaintiff must state sufficient allegations to allow at least the reasonable inference that the product that caused the injury was made, sold, or distributed by the defendant in question." *In re Darvocet, Darvon & Propoxyphene Prod. Liab. Litig.*, 856 F. Supp. 2d 904, 908 (E.D. Ky. 2012), *aff'd sub nom. In re Darvocet, Darvon, & Propoxyphene Prod. Liab. Litig.*, 756 F.3d 917 (6th Cir. 2014).

Applying this well-established principle, a court applying Ohio law dismissed claims against a defendant which did not make, sell or distribute the pharmaceutical product made by the defendant. *Hendricks v. Pharmacia Corp.*, No. 2:12-CV-00613,

2014 WL 2515478, at *6 (S.D. Ohio June 4, 2014), *report and recommendation adopted,* No. 2:12-CV-613, 2014 WL 4961550 (S.D. Ohio Oct. 2, 2014).

Here there is no well-pled allegation that Defendants Indivior PLC (or Reckitt Benckiser Healthcare (UK) Ltd., or Reckitt Benckiser LLC) made, sold, or distributed Suboxone Film. And indeed, the additional materials available for consideration in determining this motion to dismiss make clear that none of these defendants made, sold, or distributed Suboxone Film. Dismissal of Plaintiff's claims as to these Defendants is therefore appropriate.

1. Plaintiff fails to adequately allege that any defendant manufactured, distributed, or sold Suboxone Film.

Plaintiff makes formulaic and non-specific allegations throughout the Amended Complaint (ECF #12) that, for example, "Defendants manufacture, promote, and sell Suboxone Film…." (PageID #110); that "[e]ach Defendant was involved in the development, design, research, testing, licensing, manufacture, marketing, distribution, and/or sale of Suboxone Film" (PageID #114); and that "Defendants were responsible for the sales and marketing in the United States of Suboxone Film" (PageID #115). These are precisely the type of generic "labels and conclusions" and "formulaic recitation of the elements" rejected by the Supreme Court in *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *see also Iqbal*, 556 U.S. at 669. A court supervising a pharmaceutical MDL reached this same conclusion, rejecting an almost identical allegation that defendants had "conducted business and derived substantial revenue from their design, manufacture, testing, marketing, labeling, packaging, handling, distribution, storage and/or sale of [the products]

within each of the States and Territories of the United States." *In re Zantac (Ranitidine) Prod. Liab. Litig.*, No. 20-MD-2924, 2020 WL 6907056, at *4 (S.D. Fla. Nov. 24, 2020). That court characterized these allegations as "no more than conclusions" which in the 12(b)(2) setting were "not entitled to the assumption of truth." *Id.* (quoting *Iqbal*, 556 U.S. at 679).

Here, Plaintiff fails to adequately allege with any factual sufficiency that any of these Defendants were "manufacturers" under the statutory definition. Under the authority of *Twombly* and *Iqbal*, this Court should reject and disregard for purposes of its 12(b)(6) analysis the generic, conclusory, and undifferentiated allegations that "Defendants" manufactured, distributed, or sold Suboxone Film.

2. Information available for the Court's consideration reflects that neither Indivior PLC, Reckitt Benckiser Healthcare (UK) Ltd., nor Reckitt Benckiser LLC manufactured, distributed, or sold Suboxone Film.

In addition to the absence of any well-pled allegations that Indivior PLC, Reckitt Benckiser Healthcare (UK) Ltd., or Reckitt Benckiser LLC manufactured, distributed, or sold Suboxone Film, information available for the Court's consideration of this motion makes clear that they did not. As the only defendant holding the NDA for Suboxone Film, Indivior Inc. had the exclusive authority to distribute Suboxone Film in the United States. *See* (ECF #121-4, PageID #2359–60); *see also* 21 U.S.C. § 355(a) ("[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug"). As stated by the Supreme Court, "to obtain authorization to market a new drug, a drugmaker must

submit a new drug application (NDA), containing "full reports of investigations which have been made to show whether or not [the] drug is safe for use and whether [the] drug is effective in use." *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 196 (2005) (citing 21 U.S.C. § 355(b)(1)).

The Suboxone Film label incorporated into Plaintiff's Amended Complaint clearly states that Suboxone Film is "Distributed by: Indivior Inc. North Chesterfield, VA 23235." (ECF #121-2, PageID #2314). That same label also states: "Manufactured for Indivior Inc. North Chesterfield, VA 23235 by: Aquestive Therapeutics, Warren, NJ 07059." *Id.* Federal regulations require that the prescription product label must "bear conspicuously the name and place of business of the manufacturer, packer, or distributor." 21 C.F.R. § 201.1(a). If it does not, the drug is considered misbranded. *Id.* There is no allegation that the Suboxone Film label is misbranded in this regard, nor is any basis alleged for such claim.

Because Plaintiff fails to adequately allege that Indivior PLC, Reckitt Benckiser Healthcare (UK) Ltd., or Reckitt Benckiser LLC manufactured, distributed, or sold Suboxone Film, his claims as to those Defendants should be dismissed in their entirety.

VI. CONCLUSION

As set out by the foregoing argument and authorities, Plaintiff's design defect claims are preempted by federal law as to all Defendants. Federal law preempts Plaintiff's claims that the Suboxone Film label was inadequate when Suboxone was approved, and it also preempts the claim that the label was inadequate as of and after

the FDA approved the label modification on June 17, 2022. Plaintiff's claim that Defendants who did not hold the NDA for Suboxone Film should have modified its prescribing information is flatly prohibited by federal law and regulation and is preempted. Last, Plaintiff fails to adequately allege that Indivior PLC, Reckitt Benckiser Healthcare (UK) Ltd., or Reckitt Benckiser LLC manufactured, marketed, or distributed Suboxone Film as would be necessary to attach liability under design defect and failure to warn theories. Further, the information available for consideration reflects that they did not.

All of the claims as outlined above should be dismissed for the reasons stated.

Dated: July 26, 2024

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Local Rule 7.1(f) and 9.a.i of the Court's Civil Standing Order, I certify that the foregoing document complies with the word count limitations set out in 9.a.i of the Court's Civil Standing Order. It contains 8,905 Words, excluding any parts exempted by Local Rule 7.1(f). This case is on the mass tort track, which allows for a word limit of 15,000. In making this certificate of compliance, I am relying on the word count provided by Microsoft Word, which was used to create and prepare this document.

CERTIFICATE OF SERVICE

I hereby certify that on July 26, 2024, the foregoing *Joint Memorandum in Support of Rule 12(b)(6) Motions for Partial Dismissal for Failure to State a Claim Upon Which Relief Can be Granted* was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

/s/ Randall L. Christian
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