UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE SUBOXONE (BUPRENORPHINE/NALOXONE) FILM PRODUCTS LIABILITY LITIGATION	)	Case No. 1:24-md-3092 MDL No. 3092 Judge J. Philip Calabrese Magistrate Judge Jennifer Dowdell Armstrong
RYAN BENNETT, Plaintiff, v. INDIVIOR INC., *et al.*, Defendants.	)	Case No. 1:24-sf-65011

OPINION AND ORDER

Plaintiff Ryan Bennett alleges that he sustained personal injuries from his use of Suboxone film to treat opioid use disorder and brings claims against Defendants Indivior Inc., Indivior Solutions Inc., and Aquestive Therapeutics, Inc. under State law. Generally arguing that federal law preempts Plaintiff's claims, Defendants move to dismiss. For the following reasons, the Court **GRANTS IN PART** and **DENIES IN PART** Defendants' motion.

THRESHOLD PROCEDURAL ISSUE—JUDICIAL NOTICE

In their motion to dismiss, Defendants ask the Court to take judicial notice of: (1) the approved label for Suboxone film (MDL ECF No. 121-2); (2) the approved label

for Sublocade (MDL ECF No. 121-3), a monthly injection of buprenorphine which FDA approved in 2017 and which Plaintiff contends constitutes a safer alternative design (*see Bennett* ECF No. 12, ¶¶ 161 & 162, PageID #156); (3) certain documents publicly available through the Food and Drug Administration's website (MDL ECF No. 121-4; MDL ECF No. 121-5); and (4) an additional Sublocade document (MDL ECF No. 126-6).

Plaintiff seeks judicial notice of: (1) the thousands of individuals who filed individual cases or are included on Schedule A (MDL ECF No. 135, PageID #3215); (2) a summary of adverse events from the years 2023 and 2024 for potentially relevant injuries (MDL ECF No. 134-1); and (3) four peer-reviewed published articles (MDL ECF No. 135, PageID #3232 & n.9).

On a Rule 12(b)(6) motion, a court may generally consider matters of public record, orders, items appearing in the record of the case, and exhibits attached to or made part of the complaint. *Amini v. Oberlin Coll.*, 259 F.3d 493, 502 (6th Cir. 2001) (citing *Nieman v. NLO, Inc.*, 108 F.3d 1546, 1554 (6th Cir. 1997)). Considering "materials in addition to the complaint if such materials are public records or are otherwise appropriate for the taking of judicial notice" does not convert a motion to dismiss into a motion for summary judgment. *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)).

Many of the items the parties seek to notice are incorporated or referenced in the amended complaint; others are publicly available and not reasonably subject to

dispute. For these reasons, the parties do not object to judicial notice of them—with two exceptions. (MDL ECF No. 135, PageID #3212 n.2; ECF No. 145, PageID #3318, n.1.) The items at issue are Defendants' document regarding Sublocade (MDL ECF No. 121-6) and Plaintiff's summary of adverse events (MDL ECF No. 134-1). The Court considers each in turn.

First, regarding the Sublocade document, Plaintiff's complaint references the document. (*See Bennett* ECF No. 12, ¶ 161, PageID #156.) In fact, it includes a hyperlink to the document. (*Id.*) Therefore, the Court overrules Plaintiff's objection and takes judicial notice the Sublocade document and considers it on this motion to dismiss without converting the motion to one for summary judgment. (MDL ECF No. 121-6.)

Second, as for Plaintiff's summary of adverse events, such a summary may be admissible as substantive evidence, *see* Fed. R. Evid. 1006, but it is not referenced in the pleadings. As extrinsic evidence, the Court may not consider it without converting the motion to dismiss into one for summary judgment, which the Court declines to do. Therefore, the Court sustains Defendants' objection to consideration of the summary (MDL ECF No. 134-1) and does not consider it on this motion to dismiss.

In so ruling, the Court notes that Plaintiff briefly references the summary a single time, in a footnote, to support an argument that Indivior Inc. did not provide information about dental adverse events from 2023 and 2024 to FDA. (*See* MDL ECF No. 135, PageID #3215 n.3.) Nonetheless, the amended complaint details many

adverse events involving dentition or oral health from 2007 to 2022. (*See Bennett* ECF No. 12, ¶¶ 90–104, PageID #130–42.) In the present procedural posture, these allegations support an inference that similar adverse events continued beyond 2022. Further, the amended complaint alleges that Defendants failed to advise regulators and the medical community "that serious dental injuries might be a side effect of Suboxone film" and that these serious dental injuries "should or could be reported as an adverse event." (*Id.*, ¶ 206, PageID #166; *see also id.*, ¶¶ 217(h) & (m), PageID #169–70.)

At oral argument on the motion to dismiss, Plaintiff used various slides, some containing information that goes beyond the pleadings and the record in the case. In ruling on the motion to dismiss, the Court has not considered that information.

STATEMENT OF FACTS

On Defendants' motion to dismiss, the Court takes the following allegations as true and construes them in favor of Plaintiff as the non-moving party. Citations to the specific allegations in the *Bennett* case reference the amended complaint (docketed as ECF No. 12 in that specific case, No. 1:24-sf-65011), and citations to the parties' briefs and arguments reference the docket in MDL No. 3092 (Case No. 1:24-md-3092).

A. Approval of Suboxone Film in 2010

In 2010, the Food and Drug Administration approved Suboxone film as safe and effective for treatment of opioid dependence. (*Bennett* ECF No. 12, ¶¶ 14 & 68, PageID #112 & #123.) Suboxone film contains a combination of buprenorphine (a synthetic opioid used to treat pain and opioid use disorder) and naloxone (also known

as Narcan, which blocks the effect of opioids); Suboxone film releases this combination of drugs through oral absorption by placing it under the tongue. (*Id.*, ¶¶ 3 & 43, PageID #110 & #118.) Suboxone film is intended to reduce the symptoms of withdrawal from opioid abuse. (*Id.*) According to the amended complaint, it does so by reducing the highs and lows associated with misuse of opioids and is "designed to be acidic to maximize absorption of the buprenorphine while minimizing absorption of naloxone." (*Id.*, ¶ 3, PageID #111.) According to the label for Suboxone film, the drug "should be used as part of a complete treatment plan that includes counseling and psychosocial support." (MDL ECF No. 121-2, PageID #2282.)

B. The Corporate Parties

Defendant Indivior Inc., formerly known as Reckitt Benckiser Pharmaceuticals Inc., distributes and holds the new drug application for Suboxone film. (MDL ECF No. 121-4, PageID #2359–60.)

Plaintiff alleges that Aquestive Therapeutrics is the exclusive global manufacturer of Suboxone film. (*Bennett*, ECF No. 12, ¶ 21, PageID #114.) The label for Suboxone film identifies Aquestive Therapeutics as the manufacturer of the product. (MDL ECF No. 121-2, PageID #2314.)

The amended complaint provides little substantive information about Indivior Solutions other than the fact that it is a subsidiary of Indivior Inc. (*Bennett* ECF No. 12, ¶ 20, PageID #114), but Defendants' answer avers that Indivior Solutions previously promoted Suboxone film and was involved in the marketing and sale of the drug (MDL ECF No. 127, ¶¶ 3 & 24, PageID #2799–2800 & PageID #2808; *see also* MDL ECF No. 171, PageID #4145–46 & #4151).

According to the amended complaint, "[e]ach Defendant was involved in the development, design, research, testing, licensing, manufacturing, marketing, distribution, and/or sale of Suboxone film," and "Defendants were responsible for the sales and marketing in the United States of Suboxone film." (*Bennett* ECF No. 12, ¶¶ 24 & 26, PageID #114–15.)

C. The Label and Adverse-Event Reports

Plaintiff's amended complaint avers that the initial Suboxone film label "contained no warning regarding the risk of damage to the teeth." (*Id.*, ¶ 78, PageID #127.) Further, according to the amended complaint, Defendants knew in 2011 that "the mean dissolution time for the 8 mg and 2 mg doses was between 5 and 6.6 minutes rather than the 3 minutes listed in its patent for Suboxone film." (*Id.*, ¶ 52, PageID #120.) The amended complaint identifies published case reports from 2012 and 2013 purportedly linking chronic use of Suboxone film to adverse dental effects, due to the product's acidity. (*Id.*, ¶¶ 79–80, PageID #127–28; *see also id.*, ¶ 82, PageID #128 (referencing a 2013 publication positing that Suboxone film's acidity may promote dental caries).)

Additionally, the amended complaint contains a lengthy list of adverse-event reports (relating either to Suboxone film or Suboxone tablets because of the way FDA maintains the data). (*See id.*, ¶¶ 92–96, PageID #131–35.) These adverse event reports allegedly continued through 2022 after Suboxone tablets were no longer marketed. (*Id.*, ¶¶ 98–102 & ¶ 104, PageID #135–42.) As noted above, although the amended complaint lists adverse events through 2022, the number and continuing nature of the adverse events alleged entitle Plaintiff to an inference at the pleading

stage that these reports continue past 2022. Of the adverse events listed in the amended complaint, 48 specifically report dental issues between 2010 and 2014. (*Id.*, ¶¶ 92–94 & ¶ 96, PageID #131–35.) Another 75 date to the period between 2015 and 2022. (*Id.*, ¶¶ 98–103, PageID #135–41.)

D. Mr. Bennett's Use of Suboxone Film

Plaintiff Ryan Bennett was prescribed Suboxone film to treat opioid use disorder. (*Id.*, ¶ 14, PageID #112.) Plaintiff alleges that the "acidic formulation" of Suboxone film "leads to dental erosion and decay." (*Id.*, ¶ 3, PageID #111.) As a result of his use of Suboxone film, Plaintiff claims that he "suffers from severe and profound permanent tooth damage and loss." (*Id.*, ¶ 16, PageID #113.)

E. The Label Change in June 2022

In January 2022, FDA issued a drug safety communication "warning that dental problems have been reported with medicines containing buprenorphine that are dissolved in the mouth. The dental problems, including tooth decay, cavities, oral infections, and loss of teeth, can be serious and have been reported even in patients with no history of dental issues." (*Id.*, ¶¶ 6 & 103, PageID #111 & #141.)

On June 17, 2022, FDA required Defendants to change the label for Suboxone film to add information about dental adverse events. (*Id.*, ¶¶ 8 & 114, PageID #111–12 & 144; MDL ECF No. 121-2, § 5.13, PageID #2291.) Specifically, the warnings and precautions section of the label advises that some severe cases of dental adverse events, including tooth fracture and loss, have been reported following use of Suboxone film. (MDL ECF No. 121-2, § 5.13, PageID #2291.) Treatment for such events includes a root canal, extraction, dental surgery, and other procedures

including fillings, crowns, implants, and dentures. (*Id.*) These adverse events occurred even in individuals without any prior history of dental problems. (*Id.*) Even with this additional information, Plaintiff alleges that the label fails to provide an adequate warning. (*See, e.g.*, *Bennett* ECF No. 12, ¶¶ 148 & 244, PageID #152 & 174.)

The amended complaint lists more adverse events reported after the label change. (*Id.*, ¶ 104, PageID #141–42.) Suboxone film remains on the market today.

STATEMENT OF THE CASE

Based on these facts, Plaintiff Ryan Bennett filed suit on November 2, 2023. (*Bennett* ECF No. 1.) He asserts product liability claims under State law on theories of failure to warn and design defect against Defendants Indivior Inc., Indivior Solutions and Aquestive Therapeutics. (*See generally Bennett* ECF No. 12.) Specifically, Plaintiff claims that Defendants knew or should have known that, "when used as prescribed and intended," Suboxone film "causes harmful damage to the teeth due to the drug's acidity" and that Suboxone film "caus[ed] permanent damage to Plaintiff's teeth." (*Id.* at ¶¶ 4–5, PageID #111.)

Although Plaintiff initially sued other defendants as well, only these three Defendants remain in the case at this point. (*See* MDL ECF No. 144, PageID #3311.) (A company called MonoSol RX remains a party, but it became Aquestive. (*See* ECF No. 171, PageID #4187.)) Defendants contend that federal law preempts Plaintiff's failure-to-warn and design defect claims. They do not seek dismissal of Plaintiff's failure-to-warn claims for the time period between FDA approval of Suboxone film in

2010 and the date of the label change on June 17, 2022. (MDL ECF No. 126, PageID #2765.)

At oral argument, Plaintiff represented that Mr. Bennett stopped taking Suboxone film before the label change in 2022. (ECF No. 171, PageID #4161.) Therefore, his case does not raise any question about the preemptive effect of the label change in June 2022, even though the parties briefed it. One purpose of the motion to dismiss in this MDL was to address this threshold question. To achieve this goal, the Court will address that issue in the context of the *Powell* case, No. 1:24-sf-65787 (which was referenced at argument). Because the parties briefed that issue in the context of the amended complaint in *Bennett*, and counsel had the opportunity to argue the issue, there is no prejudice from considering preemption based on the label change. Because the *Powell* complaint contains different allegations than *Bennett* in this regard (*see* ECF No. 171, PageID #4161; *see also id.*, PageID #4177), and those differences might bear on the analysis at the pleading stage, the Court limits consideration of the issue (raised through *Powell* or any number of other cases in this MDL) based on the allegations in the amended complaint in *Bennett*.

MOTION TO DISMISS STANDARD

Under Rule 12(b)(6), a court may dismiss a complaint if it fails to state a claim for relief. A Rule 12(b)(6) motion tests "the plaintiff's cause of action as stated in the complaint"; it is "not a challenge to the plaintiff's factual allegations." *Golden v. City of Columbus*, 404 F.3d 950, 958–59 (6th Cir. 2005). A complaint must "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible

on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is plausible where "the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). To survive a motion to dismiss, a complaint must "raise a right to relief above the speculative level" into the "realm of plausible liability." *Twombly*, 550 U.S. at 555, 557 n.5.

Under a Rule 12(b)(6) analysis, the Court construes factual allegations in the light most favorable to the plaintiff, accepts them as true, and draws all reasonable inferences in the plaintiff's favor. *Wilburn v. United States*, 616 F. App'x 848, 852 (6th Cir. 2015) (citing *Directv, Inc. v. Treesh*, 487 F.3d 471, 476 (6th Cir. 2007)). But a pleading must offer more than mere "labels and conclusions," because "a formulaic recitation of the elements of a cause of action will not do." *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 555). Nor is a court required to accept "[c]onclusory allegations or legal conclusions masquerading as factual allegations." *Eidson v. Tennessee Dep't of Child.'s Servs.*, 510 F.3d 631, 634 (6th Cir. 2007) (citing *Twombly*, 550 U.S. at 544).

Therefore, courts must distinguish between "well-pled factual allegations," which must be treated as true, and "naked assertions," which need not be. *Iqbal*, 556 U.S. at 678 ("Nor does a complaint suffice if it tenders naked assertions devoid of further factual enhancement.") (cleaned up). In other words, courts do not accept as true "[c]onclusory allegations or legal conclusions masquerading as factual

allegations[.]" *Eidson v. Tennessee Dep't of Children's Servs.*, 510 F.3d 631, 634 (6th Cir. 2007). Rule 8 "does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." *Iqbal*, 556 U.S. at 678–79.

PREEMPTION

Under the Constitution's Supremacy Clause, "the Laws of the United States . . . shall be the supreme Law of the Land." U.S. Const. art. VI, § 2. Accordingly, any State law that conflicts with federal law is without effect. *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981); *McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 316, 427 (1819).

A. Statutory and Regulatory Framework

In the Food, Drug, and Cosmetic Act, codified at 21 U.S.C. § 301 *et seq.*, Congress enacted a system for the approval and regulation of drugs and has amended this regime over time to protect the public health and assure the safety of drugs, *see generally Wyeth v. Levine*, 555 U.S. 555, 566–68 (2009). In short, as relevant here, a person must obtain approval from FDA before marketing any drug through a new drug application (also known as an NDA). *See* 21 U.S.C. §§ 355(a) & (b)(1)(A). That application must include "the labeling proposed to be used for such drug." *Id.* § 355(b)(1)(F); *see also* 21 C.F.R. § 314.50(c)(2)(i). FDA may approve the drug only if it determines that the drug is "safe for use" under "the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. § 355(d). This determination requires that the drug's "probable therapeutic benefits must outweigh its risk of harm." *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 140 (2000). Following approval, FDA regulations provide that the sponsor may not make changes to the label regarding the "qualitative or quantitative formulation of

the drug product, including active ingredients, or in the specifications provided in the approved application." 21 C.F.R. § 314.70(b)(2)(i).

Drug labels—or, more accurately, the information accompanying a prescription drug—must contain particular information in a certain order and format. 21 C.F.R. § 201.57. This level of particularity and regulation guards against overwarning, so that less important information does not overshadow more important information. 73 Fed. Reg. 49,603, 49,605–06 (Aug. 22, 2008). Also, the label presents information in a certain order to avoid "exaggeration of risk, or inclusion of speculative or hypothetical risks," that "could discourage appropriate use of a beneficial drug." 73 Fed. Reg. 2848, 2851 (Jan. 16, 2008).

In the "warnings and precautions" section, a drug manufacturer "must describe clinically significant adverse reactions[,] including any that are potentially fatal, are serious even if infrequent, or can be prevented or mitigated through appropriate use of the drug[.]" 21 C.F.R. § 201.57(c)(6)(i). This section "must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug[.]" *Id.* But a causal relationship "need not have been definitely established" before a label change. *Id.* In the "adverse reaction" section of a label, a drug manufacturer must "describe the overall adverse reaction profile of the drug." *Id.* § 201.57(c)(7). Adverse reactions mean "an undesirable effect, reasonably associated with use of a drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence." *Id.* This definition "does not include all adverse events observed during use of a drug,

only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event." *Id.*

In 2007, Congress amended the statute to give FDA authority to require changes to a drug's label based on information that becomes available after its initial approval. *See* 21 U.S.C. § 355(o). Generally, drug manufacturers work with FDA to obtain approval to make label changes as safety information changes. *See* 21 C.F.R. §§ 314.80(c) & 314.81(b)(2)(i). To carry out this statutory directive, FDA adopted a regulation known as the "changes being effected" regime permitting certain changes to a label before receiving the agency's approval. However, "major changes" to the "qualitative or quantitative formulation of the drug product, including inactive ingredients, or in the specifications provided in the approved application" require a prior approval supplement to the new drug application and FDA approval before the change. *Id.* § 314.70(b)(2)(i).

Under the agency's rules, a change in labeling to reflect "newly acquired information" to strengthen a label constitutes a "moderate change," not a major one. *Id.* § 314.70(c)(6)(iii). That is, a drug's sponsor may "add or strengthen a contraindication, warning, precaution, or adverse reaction" or "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product," so long as the newly acquired information prompting the change satisfies the standard of a causal association for inclusion in the label, then seek FDA approval. 21 C.F.R. §§ 314.70(c)(6)(iii)(A) & (C). Still, Congress did not require FDA

to approve all post-marketing label changes, instead making clear that a drug's sponsor remains responsible for updating its label. 21 U.S.C. § 355(o)(4)(I).

B. The Presumption Against Preemption

Historically and traditionally, the States have great power and latitude to protect the health, safety, and happiness of their residents. *See, e.g.*, *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996). In enacting the statutory framework for regulation of drugs, Congress "took care to preserve state law." *Wyeth*, 555 U.S. at 567. For example, Congress included a provision in a 1962 amendment to the Food Drug and Cosmetic Act that "[n]othing in the amendments . . .shall be construed as invalidating any provision of State law . . . unless there is a direct and positive conflict" between State and federal law. Pub. L. No. 87-781, § 202, 76 Stat. 781, 793 (1962). Consistent with this provision, lawsuits asserting State-law causes of action "continued unabated despite . . . FDA regulation." *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312, 340 (2008) (Ginsburg, J., dissenting); see *also id.* at 340 n.11 (collecting cases). When Congress expressly preempted State laws respecting medical devices in 1976, it declined to enact a similar provision for prescription drugs. Pub. L. No. 94-295, § 2, 90 Stat. 539, 574 (1976); 21 U.S.C. § 360k(a).

In every preemption case, "the purpose of Congress is the ultimate touchstone." *Lohr*, 518 U.S. at 485 (internal quotation marks omitted). Because the States are independent sovereigns, "in all pre-emption cases, and particularly in those in which Congress has legislated . . . in a field which the States have traditionally occupied," such as tort law, courts "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and

manifest purpose of Congress." *Id.* at 485 (cleaned up). In other words, "Congress does not cavalierly pre-empt state-law causes of action." *Id.* For this reason, there is a strong presumption against preemption of State-law causes of action. *Torres v. Precision Indus., Inc.*, 995 F.3d 485, 491 (6th Cir. 2021); *Merrick v. Diageo Americas Supply, Inc.*, 805 F.3d 685, 694 (6th Cir. 2015). And "[i]mpossibility preemption is a demanding defense." *Wyeth*, 555 U.S. at 573.

ANALYSIS

Against this statutory and regulatory backdrop, the Supreme Court has decided four seminal cases that illustrate the interplay between the Food, Drug, and Cosmetic Act and State tort claims. These decisions frame the parties' arguments on this motion to dismiss.

First, in *Wyeth v. Levine*, 555 U.S. 555 (2009), the plaintiff was administered a brand-name drug through a method known as IV-push instead of IV-drip. After she developed gangrene, her arm had to be amputated, and a jury returned a verdict against the drug's manufacturer for failing to provide an adequate warning regarding the dangers of using the IV-push method of administration. The Supreme Court determined that it was not *impossible* for the defendant to comply with both federal law regarding drug labeling and State tort law's warning requirements. *Id.* at 573. The defendant could have used the changes-being-effected regulation to provide the safety information that the jury found was required. *Id.* at 572–73. Also, the defendant failed to make a clear showing that FDA would have prohibited the change that State tort law required. *Id.* at 571. Further, the Supreme Court held that a

State-law requirement for a stronger warning did not *obstruct* the purposes and objectives of federal drug labeling regulations. *Id.* at 581.

Second, in *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), two patients claimed personal injuries from a generic drug and brought failure-to-warn claims under State law. Applying impossibility preemption, the Supreme Court held that the generic manufacturer could not comply with both its labeling obligations under federal law and change the label to cure any defect a finder of fact found under State law. *Id.* at 613. Notably, federal law requires the manufacturer of a generic drug to use the same warning approved for the brand-name equivalent. *See* 21 U.S.C. §§ 355(j)(2)(A) & (j)(4)(G). For impossibility preemption, the question is "whether the private party could independently do under federal law what state law requires of it." *Mensing*, 564 U.S. at 620 (citing *Wyeth*, 555 U.S. at 573). Because the changes-being-effected regime is not available for a generic drug, its manufacturer cannot change the label without FDA approval. *Id.* at 615–16.

Third, in *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013), a plaintiff recovered damages at trial under State tort law from the manufacturer of a generic nonsteroidal anti-inflammatory drug on a design-defect claim. Because the manufacturer of the generic drug at issue could not change the chemical composition of the product or revise the label independent of the sponsor of the brand name drug, the Supreme Court held that the defendant could not comply with both federal law and State tort law. *Id.* at 475–76. In doing so, the Court rejected the argument that

the defendant could stop selling the drug as incompatible with preemption jurisprudence. *Id.* at 488.

Fourth, in *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299 (2019), the plaintiffs in multi-district litigation alleged that the manufacturer of a brand-name drug used to treat osteoporosis in post-menopausal women failed to provide an adequate warning of certain types of bone fractures. The plaintiffs took the drug before the label was updated to warn of these risks. In the pre-market approval process, the defendant provided FDA with information about potential bone fractures, which the agency rejected as theoretical. Nearly a decade later, three years before the label change, the defendant sought FDA's approval for these warnings, and FDA approved some but not all proposed revisions to the label. One year before the label change, FDA issued a drug safety communication finding no clear connection between the drug and certain types of bone fractures. The following year, FDA agreed to a label change that warned of the fractures at issue. On this record, developed on a motion for summary judgment, the Supreme Court ruled that a judge—not a jury—makes the determination whether, in analyzing impossibility preemption, clear evidence shows that FDA would not have approved a particular warning. *Id.* at 310 & 316–17. Further, it clarified that the standard does not present an evidentiary issue, but a question of law within the context of the agency's discharge of congressionally delegated authority. *Id.* at 315. Because of the changes-being-effected regime, the Supreme Court recognized that "a drug manufacturer will not

ordinarily be able to show that there is an actual conflict between state and federal law such that it was impossible to comply with both." *Id.*

In these decisions, the Supreme Court determined that federal law preempts State-law claims for design defect and failure to warn against manufacturers of generic drugs because of their obligations to formulate and label generic drugs like their brand-name counterparts. *Bartlett*, 570 U.S. at 475–76; *Mensing*, 564 U.S. at 613. In the cases involving brand-name drugs, the Supreme Court ruled that failure-to warn claims could proceed but did not consider design defect claims. *Wyeth*, 555 U.S. at 573–75; *see also Albrecht*, 587 U.S. at 315. Three of these cases arose after the development of a record on summary judgment (*Albrecht*) or at trial (*Wyeth*, *Barlett*), not the pleading stage. In *Mensing*, the Supreme Court took up the failure-to-warn claims against the manufacturer of a generic drug in two consolidated appeals from rulings on motions to dismiss.

I. Design Defect

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* Ohio Rev. Code § 2307.75(A). Plaintiff claims that the risk of adverse effects from Suboxone film in the form of serious dental injuries outweigh the product's benefits. His amended complaint presents claims relating to two different time periods: before FDA's approval of Suboxone film and after it was on the market.

I.A. Pre-Market Approval

Because FDA approved Suboxone film, it made an independent determination that the drug is safe and effective for its intended use and that the proposed labeling is accurate and adequate. *See* 21 U.S.C. §§ 355(b)(1) & (d). The approval process is "onerous and lengthy," *Bartlett*, 570 U.S. at 476, and requires "substantial evidence that the drug will have the effect it purports or is represented to have," 21 U.S.C. § 355(d)(5). A drug's sponsor must submit all "data or information relevant to an evaluation of the safety and effectiveness of the drug." 21 C.F.R. § 314.50(d)(5)(iv). "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." *Id.* § 314.105(c).

To the extent Defendants argue that the fact of FDA approval bars any State-law tort claim, that argument fails. Generally, as the Supreme Court makes clear, plaintiffs retain State-law tort remedies against the manufacturer or sponsor of brand-name drugs, so long as it is not impossible to comply with both State and federal law. *Levine*, 555 U.S. at 573 (addressing a State-law failure-to-warn claim).

At the other end of the spectrum, the Supreme Court also rejects the argument that State law may require a defendant simply to stop selling a drug. *Bartlett*, 570 U.S. at 488. Plaintiff appears to pursue such a theory here. (*See Bennett* ECF No. 12, ¶ 232, PageID #173.) Such a basis for liability is not consistent with preemption analysis, 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." *Bartlett*, 570 U.S. at 488. Indeed, Plaintiff concedes that such claims are preempted as a matter of law. (MDL ECF No. 135, PageID #3233.)

Between these two poles, the parties join their arguments. Plaintiff alleges that Defendants failed to exercise due care in the development of Suboxone film before its approval (*Bennett* ECF No. 12, ¶ 255, PageID #176–77) and designed a defective product (*id.*, ¶¶ 233–38, PageID #173). Defendants counter that they could not have complied with State law without obtaining FDA's approval for a differently designed product, foreclosing their liability as a matter of law. (MDL ECF No. 126, PageID #2776–77.) Although the Supreme Court has not spoken to such a claim involving the manufacturer or sponsor of a brand-name drug, the Sixth Circuit has. Therefore, the Court begins its analysis there.

I.A.1. Sixth Circuit Precedent

In *Yates v. Ortho-McNeil-Janssen Pharmaceuticals., Inc.*, 808 F.3d 281 (6th Cir. 2015), a case arising out of multi-district litigation, the district court granted summary judgment in favor of the designers and manufacturers of a birth control patch that allegedly caused a stroke. Notably, the label of the product at issue warned of heart attacks and strokes. Under New York law, the plaintiff brought claims for failure to warn, manufacturing defect, negligence, and breach of express and implied warranties. Regarding the pre-approval design defect claim, the plaintiff argued on appeal that nothing in federal law prevented the defendants from designing a different drug in the first instance before obtaining FDA approval. *Id.* at 299. Further, the plaintiff pointed to an alternative design (on the market in other

countries), and the defendants offered no evidence suggesting that FDA would not have approved an alternative design. *Id.*

The Sixth Circuit did not read the Supreme Court's decisions (not including *Albrecht*, which it did not decide until 2019) as materially distinguishing between generic and brand-name drugs. Instead, the court took those decisions as generally applying principles of federal preemption jurisprudence in the context of drug regulation. *See id.* at 295–96. With that understanding, the court held that the plaintiff's pre-approval design defect claim was "too attenuated." *Id.* at 299. To the Sixth Circuit, where the label warned of strokes and the plaintiff suffered a stroke, such a pre-approval duty depends on speculation that the defendants would have designed the birth control patch at issue differently and obtained FDA approval for that alternate design, then that the plaintiff would have used that hypothetical product and not suffered a stroke. "This is several steps too far." *Id.*

In so holding, the *Yates* Court analogized the plaintiff's argument to *Mensing*, where the generic manufacturer could have worked with FDA and the brand-name manufacturer to change a label, which would then have allowed the generic manufacturer to give the warning the plaintiff contended State law required. *Id.* (quoting *Mensing*, 564 U.S. at 620). In the Supreme Court's view, that action—a generic manufacturer requesting FDA's assistance that might ultimately result in a label change—does not present a matter of concern under State tort law. *Mensing*, 564 U.S. at 624. Because FDA would ultimately have to approve an alternative design, the Sixth Circuit in *Yates* (involving a brand-name drug) relied on *Mensing*

(addressing a generic) to hold that federal law preempted the plaintiff's pre-approval design defect claim. 808 F.3d at 300.

Although this reasoning might appear to foreclose *any* pre-approval design defect claim as a matter of law, *Yates* does not extend that far for at least two reasons. First, the Sixth Circuit itself rejected that position. *Id.* at 296. Instead, the court read *Bartlett* and *Mensing* (each involving generic drugs) as applying the general test for impossibility preemption, while recognizing that the results of this analysis for brand name drugs and generics might differ "in some circumstances." *Id.*

Second, in *Yates*, the Sixth Circuit let stand a prior precedent regarding the viability of pre-approval design defect claims. In *Tobin v. Astra Pharmaceutical Products, Inc.*, 993 F.2d 528, 537 (6th Cir. 1993) (applying Kentucky law), the court upheld a jury verdict in plaintiff's favor and "reject[ed] the argument that FDA approval [of a brand-name drug] preempts state product liability claims based on design defect." In so holding, the court followed the Fifth Circuit, which ruled that the Food, Drug, and Cosmetic Act does not preempt State-law claims for design defect. *Id.* at 537–38 (citing *Hurley v. Lederle Lab. Div. of Am. Cyanamid Co.*, 863 F.2d 1173, 1176–77 (5th Cir. 1989)).

After *Tobin*, the Sixth Circuit returned to the issue in *Wimbush v. Wyeth*, 619 F.3d 632 (6th Cir. 2010). In *Wimbush*, the plaintiff developed pulmonary hypertension after ingesting a diet drug that the defendants marketed for less than two years before removing it from the market and brought a claim for design defect, among other causes of action, under Ohio law. The district court granted summary

judgment on the ground that FDA's approval of the drug preempted any claims about the defendants' pre-approval conduct. *Id.* at 641–42. Applying the presumption against preemption of preexisting State-law causes of action, the court held that, "as a general proposition, we can discern no physical impossibility between complying with a state law duty to exercise reasonable care in the process leading up to placing a drug on the market and complying with the federal government's process for approving drugs." *Id.* at 643. The court went on to discuss various preemption principles and arguments and concluded that "the case law supports the conclusion that Congress did not intend to preempt state tort law claims when it passed the" Food, Drug, and Cosmetic Act. *Id.* at 644. Under preemption doctrine, the *Wimbush* Court limited its ruling to situations involving no direct conflict between State and federal law: "This is not to say that such a physical impossibility could never exist, for instance if a state duty required that the manufacturer do something that the FDA forbade or vice versa." *Id.* at 643.

Rather than contradict *Wimbush*, a precedent by which it was bound, the *Yates* Court reaffirmed its holding by noting that the plaintiff in *Yates* "has not explained precisely what a pre-approval claim would look like in her case." *Yates*, 808 F.3d at 300. Nor could the court "conceive of any coherent pre-approval duty that defendants would have owed to Yates when it was developing" the drug at issue. *Id.* Further, it viewed the pre-approval claim at issue in *Yates* as different from the one in *Wimbush*. *Id.* In the end, *Yates* confirmed that "*Wimbush* is still good law." *Id.*

Finally, no other circuit has followed *Yates*. Indeed, despite its exhaustive analysis, the Fourth Circuit's recent decision in *In re Fosamax (Alendronate Sodium) Products Liability Litigation*, 118 F.4th 322 (3d Cir. 2024), does not mention it. One Circuit clarified a fine point of *Yates*—that application of the stop-selling argument from *Bartlett* depends on a finding that such a rationale cannot harmonize otherwise conflicting federal and State laws. *Kaiser v. Johnson & Johnson*, 947 F.3d 996, 1011 (7th Cir. 2020). And the Sixth Circuit itself has cited *Yates* only for basic propositions of law not implicated in the substantive analysis here.

I.A.2. Preemption of the Pre-Approval Design-Defect Claim

For two reasons, the Court determines at the pleading stage that federal law does not preempt Plaintiff's pre-approval design defect claim. First, Congress has not preempted such claims. One searches the text of the Food, Drug, and Cosmetic Act in vain for language expressly preempting State-law causes of action or for any provision similar to the preemption provision that applies to medical devices. 21 U.S.C. § 360k(a). Put simply, Congress knows how to preempt State-law claims, and there is no evidence that it did so here.

Second, for that reason, preemption depends on judicial construction or judicial extension of the law beyond the bounds that Congress set. But the Supreme Court has not addressed preemption of a design defect claim involving a brand-name drug. Nor do its decisions lead inexorably to preemption of such claims.

That leaves the law of this Circuit. Put simply, in *Tobin*, the Sixth Circuit "reject[ed] the argument that FDA approval [of a brand-name drug] preempts state product liability claims based on design defect." 993 F.2d at 537. In *Wimbush*, the

Sixth Circuit held that there is "no physical impossibility between complying with a state law duty to exercise reasonable care in the process leading up to placing a drug on the market and complying with the federal government's process for approving drugs." 619 F.3d at 643. And in *Yates*, the Sixth Circuit confirmed that this decision "is still good law." 808 F.3d at 300. Nothing about the Supreme Court's subsequent decision in *Albrecht* calls *Yates* into question. If it did, it is the Sixth Circuit's prerogative and responsibility to say so, and the Court does not presume to make such a pronouncement.

Applying *Yates* on its own terms, a design-defect claim based on pre-approval conduct would require that Defendants design a differently formulated product, which FDA approves, which Mr. Bennett alleges he would have used as prescribed, and which does not result in the serious dental injuries alleged. *Yates*, 808 F.3d at 299. In contrast to *Yates*, where the label warned of the injury the plaintiff suffered, the label for Suboxone film did not warn of dental injuries until June 2022. Also, Plaintiff identifies a specific alternative design to deliver buprenorphine and points to FDA's approval of Sublocade in 2017 to support his position that the agency would have approved a differently formulated product all along. Moreover, in 2006, even before FDA's approval of Suboxone film in 2010, other companies developed injectable buprenorphine products, and Reckitt Benckiser Pharmaceuticals apparently did so in 2011. (*See Bennett* ECF No. 12, ¶¶ 157 & 165, PageID #154–55 & #157.) Mr. Bennett alleges that he would have taken Sublocade or a product like it to avoid the risk of dental injuries. (*Bennett* ECF No. 12, ¶ 179, PageID #161.) According to

the the amended complaint, this alternative form of delivering buprenorphine does not result in dental injuries. (*See, e.g.*, *id.*, ¶¶ 3, 7, 172 & 180, PageID #110–11, #159 & #161.) All of these matters remain to be proved. But at the pleading stage they suffice to state a design-defect claim.

Defendants contend that an injectable like Sublocade constitutes a different product as a matter of law, bringing this case into line with the attenuation *Yates* disallows. Nothing in the record at the pleading stage supports such a conclusion. And Defendants cite no supporting authority. Perhaps a fully developed record will allow the Court to make such a determination. *See Albrecht*, 587 U.S. at 310 & 315–17. In *Yates*, the Sixth Circuit expressly did not close the door to all design-defect claims for branded drugs. Here, the facts alleged do not suffer from the same infirmities as in *Yates* or the other district court cases on which Defendants rely. *See Bossetti v. Allergan Sales, LLC*, No. 1:22-cv-523, 2023 WL 4030681, 2023 U.S. Dist. LEXIS 104827, at *12–13 (S.D. Ohio June 15, 2023) (dismissing general claim that the drug at issue could have been designed better from the start); *Brashear v. Pacira Pharms., Inc.*, No. 1:21-cv-700, 2023 WL 3075403, 2023 U.S. Dist. LEXIS 72456, at *7–8 (S.D. Ohio Apr. 25, 2023) ("[Plaintiff] has not specifically alleged facts that support the hypothetical scenario in which the FDA would have approved a differently formulated [drug]."); *Fleming v. Janssen Pharms. Inc.*, 186 F. Supp. 2d 826, 833 (W.D. Tenn. 2016) (dismissing design-defect claim).

In short, unlike in *Yates* itself, or in the various district court cases following it on which Defendants rely (MDL ECF No. 145, PageID #3320), Plaintiff's amended

complaint narrowly threads the needle at the pleading stage to state a pre-approval design-defect claim. To the extent the Sixth Circuit's case law leaves any doubt about the matter, applying the presumption against preemption at the pleading stage weighs in favor of making any such determination with the benefit of a more complete record.

I.B. Post-Approval

Once approved, FDA's regulations require a drug's sponsor to obtain the agency's approval before making "changes in the qualitative or quantitative formulation of the drug product, including inactive ingredients, or in the specifications provided in the approved [new drug application]." 21 C.F.R. § 314.70(b)(2)(i); *see also id.* § 314.70(b)(3). Because of this requirement, the Sixth Circuit recognizes that federal law preempts State-law design-defect claims following the approval of a new drug application except in certain narrow circumstances. *Yates*, 808 F.3d at 298–99. Because none of those circumstances might apply here, Plaintiff essentially asks Defendants to stop selling Suboxone film—something that preemption doctrine does not allow. *Bartlett*, 570 U.S. at 488. Therefore, the Court concludes that federal law preempts Plaintiff's design-defect claim to the extent that claim relates to the period after FDA's approval of Suboxone film in 2010.

II. Failure to Warn

Ohio law imposes liability on a product's manufacturer or supplier which, at the time of marketing, knows of a risk associated with the product that causes a plaintiff's harm and failed to provide an adequate warning of that risk. *See* Ohio Rev. Code § 2307.76(A)(1). The duty of a manufacturer or supplier to warn continues after

the product is on the market. *Id.* § 2307.76(A)(2). Defendants argue that FDA's approval of the product label along with Suboxone film in 2010 forecloses Plaintiff's pre-approval failure-to-warn claim and any claim following the June 2022 label change, which the agency approved. (MDL ECF No. 126-1, PageID #2782.) As noted, they make no preemption argument for the period between approval of Suboxone film in 2010 and the June 2022 label change. (*Id.*, PageID #2765.)

The Supreme Court has repeatedly underscored that "it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times." *Albrecht*, 587 U.S. at 312; *Wyeth*, 555 U.S. at 570–71. FDA regulations charge a drug's sponsor with creating an adequate label and ensuring that the product's warnings remain adequate while the drug remains on the market. *See, e.g.*, 21 C.F.R. §§ 201.80(e) & 314.80(b); 73 Fed. Reg. 49,603, 49,605 (Aug. 22, 2008). Further, they acknowledge that a drug's safety information may change over time, requiring changes to the label. *Id.* §§ 314.80(c) & 314.81(b)(2)(i).

Absent "clear evidence that the FDA would not have approved a change to [the drug] label," the Supreme Court has declined to conclude that it is impossible to comply with both federal and State requirements for warnings. *Wyeth*, 555 U.S. at 571; *see also In re Fosamax Prods. Liab. Litig.*, 118 F.4th at 332. "[N]othing within [the] history" of federal regulation of drugs and drug labeling indicates "that the FDA's power to approve or to disapprove labeling changes, by itself, pre-empts state law." *Albrecht*, 587 U.S. at 311. Instead, in its most recent statement on the issue, the Supreme Court emphasized a congressional "reluctance to displace state laws

that would penalize drug manufacturers for failing to warn consumers of the risks associated with their drugs[.]" *Id.* at 312.

II.A. Pre-Approval

Under Ohio law, a product is not defective if it contains an adequate warning at the time of marketing. Ohio Rev. Code § 2307.76(A)(1). Part of the process for FDA approval of a new drug requires a drug's sponsor to submit the proposed label to the agency for its approval. 21 U.S.C. § 355(b)(1)(A)(vi); *id.* § 314.50(c)(2)(i). The sponsor must support each statement in the summary and technical sections of the proposed label. *Id.* § 314.50(c)(2)(i). Because the label for Suboxone film at the time of approval did not warn of adverse dental effects (MDL ECF No. 121-2, PageID #2282), Plaintiff's failure-to-warn claim collapses to some degree into his design-defect claim. In any event, Plaintiff did not use Suboxone film before its approval. Therefore, the Court need not address whether FDA approval of the label forecloses any warning claim arising before then.

To the extent Plaintiff intends to rely on studies or information pre-dating FDA approval as part of his post-approval warning claim as newly acquired information within the changes-being-effected regulations, such a question is hypothetical at the moment and not squarely presented. Indeed, Defendants do not move to dismiss Plaintiff's failure-to-warn claim following Suboxone's approval in 2010. Therefore, the Court declines to address the issue now.

II.B. Following the Label Change in June 2022

Defendants contend that the label change that FDA approved in June 2022 preempts Plaintiff's claim that it was not adequate after that date. (MDL ECF

No. 126-1, PageID #2784.) Under the changes-being-effected regulation, a drug sponsor may strengthen a label, without prior FDA approval, to reflect newly acquired information. 21 C.F.R. § 314.70(c)(6)(iii). In the *Bennett* amended complaint, raised through *Powell* for purposes of resolving the issue on this motion as discussed above, Plaintiff points to a research letter published in December 2022 in the Journal of the American Medical Association as newly acquired information requiring a label change under the changes-being-effected regulation. (*Bennett* ECF No. 12, ¶ 117, PageID #145–46.) According to the amended complaint, this study found "an increase in the risk of adverse dental outcomes associated with sublingual buprenorphine/naloxone compared with transdermal buprenorphine or oral naltrexone." (*Id.*, PageID #145.)

> FDA regulations define "newly acquired information" as:
>
> > [D]ata, analyses, or other information not previously submitted to the Agency, 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). At the pleading stage, this December 2022 study may present newly acquired information. It appears to involve data from clinical studies of a cohort of patients from (2006 to 2020) showing a heightened risk of serious adverse dental reactions from use of Suboxone film, ones that FDA thought sufficiently serious to require additional warnings on the label a few months earlier. And there is no suggestion in the pleadings that any Defendant presented this study or the data contained within it to FDA in connection with the June 2022 label change.

Defendants focus on the last clause of the definition, that the study reveal a risk of a different type or greater severity or frequency than previous submissions to the agency. While the study at issue might or might not satisfy this portion of the definition of newly acquired information, at the pleading stage in this case, it is difficult to make such a determination, which will require further factual development and analysis of the prior submissions to FDA. Therefore, the Court cannot say on a motion to dismiss that the changes-being-effected regime was not available to add additional safety information to the label.

Nor does *Yates* dictate a contrary conclusion. There, when it came to a failure to warn, the birth-control patch at issue warned of a risk of stroke—the specific injury at issue. Accordingly, on summary judgment, the case presented "no genuine issue of material fact for a jury on the issue of whether defendants failed to adequately warn [the plaintiff], through her prescribing medical provider, of the risk of stroke associated with [the drug]." *Yates*, 808 F.3d at 291. In addition, the plaintiff's treating physician testified "that she was well aware of the risk of stroke at the time she counseled [the plaintiff]," and the plaintiff "admitted to being counseled about the risk of stroke associated with [the drug]." *Id.* at 290–91. In contrast, the amended complaint alleges that Mr. Bennett and his "treating physicians were given no warning and had no knowledge of the serious risk of dental erosion and decay Suboxone film posed." (*Bennett* ECF No. 12, ¶ 15, PageID #112–13.) Nor does the label FDA originally approved warn of the risk of dental injures. (MDL ECF No. 121-2, PageID #2282.)

Further, *Albrecht*'s requirement for clear evidence makes prevailing as a matter of law difficult for Defendants in this case, at least at this stage of the proceedings. There, the Supreme Court clarified that such evidence must show "that the drug manufacturer 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." 587 U.S. at 303. At the pleading stage here, Defendants cannot make such a showing.

III. Loose Ends

Two final matters remain for the Court to address.

III.A. Group Pleading

Defendants argue for dismissal to the extent the amended complaint fails to differentiate among the various entities and the particular responsibility of each to manufacture, distribute, or sell Suboxone film. (MDL ECF No. 126, PageID #2791.) Here, the amended complaint tends to make its allegations generally, without regard to which specific Defendant engaged in particular alleged conduct. Ordinarily, such allegations fail to provide notice of the specific conduct for which a plaintiff seeks to hold a defendant liable. As set forth above, however, the pleadings contain sufficient information to identify the legal theories on which Plaintiff asserts liability against each remaining Defendant.

As for the failure-to-warn claim, federal law holds a drug's sponsor responsible for the label. *See* 21 U.S.C. § 355(o)(4)(I); *Wyeth*, 555 U.S. at 568. And Plaintiff clarified that he only brings this claim against the holder of the new drug application, Indivior Inc. (MDL ECF No. 135, PageID #3245.) Therefore, to the extent that

Plaintiff's amended complaint could be read as raising any failure-to-warn claim against Aquestive Therapeutics or Indivior Solutions, such a claim does not withstand Defendants' motion to dismiss.

III.B. Constitutionality

Plaintiff argues that the Court should consider the constitutionality of preemption doctrine, particularly based on the Supreme Court's recent decision in *Loper Bright v. Raimondo*, 144 S. Ct. 2244 (2024). (MDL ECF No. 135, PageID #3247–57.) That case says little, if anything, about preemption doctrine. Instead, *Loper Bright* involves questions of deference to agency interpretations of ambiguous statutes, and preemption involves determining the intent of Congress, not an agency. Although the Sixth Circuit in *Yates* based preemption of post-approval design defect claims on a regulation, 808 F.3d at 298–99, that regulation proceeds from the congressional enactment giving FDA and only FDA authority for approval of new drugs. 21 U.S.C. § 355(a). Therefore, preemption of State-law claims requiring the marketing of a product following agency approval flows from the congressional intent expressed in the statute. In any event, Supreme Court and Sixth Circuit precedent compel application of preemption doctrine unless and until one or both courts say otherwise.

CONCLUSION

For the foregoing reasons, the Court **GRANTS IN PART** and **DENIES IN PART** Defendants' motion to dismiss. Plaintiff may proceed on his claims for pre-approval design defect against Indivior Inc., Indivior Solutions, and Aquestive Therapeutics and for failure to warn against Indivior Inc.

SO ORDERED.

Dated: December 31, 2024

J. Philip Calabrese
United States District Judge
Northern District of Ohio