BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

In re: Suboxone (Buprenorphine/Naloxone) Film Marketing, Sales Practices, and Products Liability Litigation	)))	**MDL Docket No. 3092**

DEFENDANTS' RESPONSE TO PLAINTIFFS' MOTION FOR TRANSFER AND COORDINATION OR CONSOLIDATION UNDER 28 U.S.C. § 1407 AND RESPONSE TO PLAINTIFFS' BRIEF IN SUPPORT

Pursuant to 28 U.S.C. § 1407 and Rule 6.1(c) and 6.2(e) of the Rules of Procedure of the United States Judicial Panel on Multidistrict Litigation, Defendants Indivior Inc., Indivior Solutions Inc., and Aquestive Therapeutics, Inc. (collectively, "Defendants[1]"), file their Response to Plaintiffs' Motion for Transfer and Coordination or Consolidation Under 28 U.S.C. § 1407 and Response to Plaintiffs' Brief in Support of that motion. Defendants agree that there are issues of fact common to the cases identified in the Schedule of Actions accompanying Plaintiffs' Brief. Defendants also agree that transfer of these and any subsequently filed "tag-along" cases involving similar factual allegations or claims to the Honorable J. Philip Calabrese, United States District Court for the Northern District of Ohio, for consolidated pretrial proceedings is appropriate. Plaintiffs in their motion and supporting brief level multiple allegations which are factually inaccurate, wholly irrelevant, or both. While Defendants will not exhaustively address each of those in this Response, certain of these are addressed below.

[1] Other named defendants have not yet appeared in the underlying cases identified in the Schedule of Actions accompanying Plaintiffs' Brief in Support of Motion for Transfer and Coordination Under 28 U.S.C. § 1407.

BACKGROUND

1. Opioid Use Disorder ("OUD") has impacted millions of individuals in the United States. Indivior Inc. was founded to help tackle the opioid crisis, one of the largest and most public health emergencies of our time, by bringing science-based, life-transforming treatment to patients. Indivior Inc. developed Suboxone® Sublingual Tablets, which received FDA approval in 2002 for treatment of opioid dependence. Indivior Inc. next developed Suboxone® Sublingual Film, another formulation of the Suboxone® tablet, which became available for patients in 2010. Suboxone® Sublingual Film is the product at issue in the present litigation.

2. Suboxone® Sublingual Film contains the active ingredients buprenorphine and naloxone. Buprenorphine is a partial-opioid agonist that Plaintiffs agree "helps patients suffering from opioid use disorder not to abuse opioids." Pls.' Br. 2. Suboxone® film is ingested by dissolving it under the tongue or inside the cheek. Like most prescription drugs, Suboxone® film has risks associated with its use. For Suboxone® film, those risks may include life-threatening events like respiratory depression.

3. Buprenorphine products, including buprenorphine/naloxone combination products such as Suboxone® tablets and film, have been recognized as effective treatments for OUD. "Numerous clinical studies and randomized clinical trials have demonstrated buprenorphine's efficacy in retaining patients in treatment and reducing illicit opioid use compared with treatment without medication and medically supervised withdrawal."[2] Studies have shown that

[2] *See* "Medications for Opioid Use Disorder" § 3D, Treatment and Improvement Protocol 63; Substance Abuse and Mental Health Services Administration (Updated 2021), available at TIP 63: Medications for Opioid Use Disorder (samhsa.gov) (last accessed December 6, 2023).

buprenorphine/naloxone products can safely and effectively be used in primary care settings.[3] Buprenorphine/naloxone products have proven critically important in helping patients with OUD.

4. On January 12, 2022, the FDA issued a Drug Safety Communication regarding oral buprenorphine-containing medicines and anecdotal reports of dental problems. In that communication, the FDA stated that it was requiring a warning about dental problems to be added to the prescribing information for all oral buprenorphine-containing medicines dissolved in the mouth. The FDA emphasized that "[d]espite these risks, buprenorphine is an important treatment option for opioid use disorder (OUD) and pain, and the benefits of these medicines clearly outweigh the risks." The correspondence advised patients to continue taking their buprenorphine medicine as prescribed, urged patients and treaters to monitor their dental health and suggested measures to minimize the possibility of dental problems. The FDA specifically reiterated in a message directed to practitioners treating OUD that "Health care professionals should be aware the benefits of buprenorphine medications clearly outweigh the risks and are an important tool to treat OUD."[4]

5. Less than two weeks later, on January 24, 2022, multiple professional academies, colleges and societies focused on treatment for addiction co-signed a letter to the FDA urging it to retract its buprenorphine letter.[5] These organizations stated in this letter that the FDA's

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[3] "Sublingual and Transmucosal Buprenorphine for Opioid Use Disorder: Review and Update," Winter 2016, Vol. 15, Issue 1; Substance Abuse and Mental Health Services Administration Advisory, available at Advisory, Sublingual and Transmucosal Buprenorphine for Opioid Use Disorder: Review and Update (samhsa.gov) (last accessed December 6, 2023).

[4] *See* FDA Drug Safety Communication (Jan. 12, 2022) (available at Buprenorphine: Drug Safety Communication - FDA warns about dental problems with buprenorphine medicines dissolved in the mouth to treat opioid use disorder and pain | FDA (last accessed December 6, 2023).

[5] January 24, 2022 Correspondence to Janet Woodcock, MD, Acting Commissioner, U.S. Food and Drug Administration, "A Call for the FDA to Retract its Safety Communication Regarding Buprenorphine," signed by American Academy of Addiction Psychiatry; American College of Academic Addiction Medicine; American College of Medical Toxicology; American Osteopathic

conclusions were not "based on solid research evidence" and reflected a "flawed analysis regarding causation." The letter warned that the FDA communication could "have predictable harmful effects" by discouraging the use of buprenorphine, and concluded with the statement "This is not a time to lose momentum in expanding life-saving care for Americans with opioid use disorder."

6. On June 17, 2022, Indivior Inc. added "Dental Adverse Events" to the "Warnings and Precautions" section of the Suboxone® film product label, stating in part that "Cases of dental caries, some severe (*i.e.*, tooth fracture, tooth loss), have been reported following the use of transmucosal buprenorphine-containing products." Suboxone® film remains available to patients in the United States as an important treatment option for opioid dependence.

7. On September 25, 2023, the first case in this litigation was filed in the United States District Court for the Northern District of Ohio.[6]

THE SUBOXONE® FILM PRODUCT LIABILITY LITIGATION

8. Plaintiffs in these cases assert product liability causes of action, claiming dental injury as a result of their alleged use of Suboxone® film. Plaintiffs generally allege that adverse event reports of "dental events in patients taking Suboxone" should have resulted in a label change prior to June 2022. Pls.' Br. 6. In their Complaints, Plaintiffs assert that "Defendants failed to provide timely and adequate warnings to physicians" regarding dental problems. *See, e.g.*, Pls' Ex. A-1 (J. Jackson Compl.), ¶ 150. Plaintiffs further claim that Defendants breached their duty not to design an unreasonably dangerous product by "designing Suboxone film in such a way that

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Academy of Addiction Medicine; American Society of Addiction Medicine; Association for Multidisciplinary Education and Research in Substance Use and Addiction; California Society of Addiction Medicine; College of Psychiatric and Neurologic Pharmacists; Massachusetts Medical Society; Massachusetts Society of Addiction Medicine; and Oregon Society of Addiction Medicine. Available at 22.01.24-a-call-for-the-fda-to-retract-its-1.12.2022-safety-communication-regarding-buprenorphine.pdf (asam.org) (last accessed November 28, 2023)

[6] *See* Plaintiffs' Ex. A-6 (D. Sorensen Complaint); and A-7 (H. Graham Complaint).

posed an unreasonable risk of dental injuries and placing and keeping Suboxone film on the market despite Suboxone film's defective condition." *See, e.g.*, Pls' Ex. A-1 (J. Jackson Compl.), ¶¶ 178-179.

9. Defendants deny the allegations set out in Plaintiffs' motion and brief relating to their underlying litigation claims. Among other things, Defendants dispute Plaintiffs' allegations that any of the referenced adverse event reports "put Defendants on notice" that Suboxone® "was inflicting dental injuries," and generally dispute Plaintiffs' characterization of the significance of the referenced adverse event reports. Defendants similarly dispute that between 2007 and 2021 they were required to change the product label via "Changes Being Effected" regulations or otherwise. *See* Pls.' Mot. ¶ 5-6.

10. In addition, Defendants dispute Plaintiffs' claims and allegations levied in the underlying Complaints. While Defendants will not describe every factual and legal dispute here, Defendants submit that the product information accompanying Suboxone® film adequately conveyed risk and other information regarding the use of that product at all times. Defendants dispute a causal relationship between Suboxone® film and the claimed dental injuries. Further, Defendants state that at no time did Suboxone® film suffer from any defect in design or formulation, and vigorously dispute Plaintiffs' reckless allegation that it (or by implication, its generic equivalents) should have been removed from the market at any time. *See, e.g.*, Pls' Ex. A-9 (K. King First Amended Compl.) ¶ 170.

COORDINATION OF THE SUBOXONE® FILM LITIGATION

Coordination or Consolidation of the Suboxone® Product Liability Litigation Under 28 U.S.C. § 1407 is Appropriate.

11. Defendants agree with Plaintiffs' observation that the cases at issue "will involve similar questions of fact, and will involve common discovery and pretrial motion practice." Pl.s' Mot. at ¶ 10. The shared factual issues in these cases are (1) whether Suboxone® film can cause the claimed dental injuries (general causation); (2) whether Defendants knew or should have known at any time of an alleged increased risk of dental problems due to Suboxone® film use but failed to provide adequate warning of that risk; and (3) and the viability of Plaintiffs' claim Suboxone® film was defectively designed.[7] Defendants further agree that "centralization will eliminate duplicative discovery, prevent inconsistent rulings, and conserve judicial resources." *Id*. at ¶ 11. The parties have discussed alternatives to centralization via other means and have reached a consensus that 28 U.S.C. § 1407 affords the best procedure for ensuring consistency and maximizing efficiency. Defendants thus submit that the circumstances of this litigation support the conclusion that transfer of the subject actions for coordinated and consolidated pretrial proceedings "will be for the convenience of parties and witnesses and will promote the just and efficient conduct of such actions." *See* 28 U.S.C. § 1407 (a).

12. Defendants also agree with statements in Section II of Plaintiffs' Brief supporting that the United States District Court for the Northern District of Ohio is the most suitable venue for this MDL and that Judge Calabrese is the most suitable jurist to preside. Judge Calabrese's

[7] However, Plaintiffs' claims will also present individual case-specific queries concerning liability, causation, and each plaintiff's alleged injuries and damages. These case-specific issues which will vary from case to case will require separate trials for each individual plaintiff.

background and experience reflects that he is qualified to adjudicate the issues that would arise in this MDL.

The MDL Descriptive Title Should Accurately Reflect that this Litigation Involves Only Product Liability Claims.

13. Rule 3.2(a)(i) of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation provides this Panel with authority to designate a descriptive title for a multidistrict litigation. *See id*. ("Each pleading [before the Panel] shall bear … the descriptive title designated by the Panel.") Defendants submit that such title should accurately reflect that this litigation involves product liability claims. As stated in Plaintiffs' Brief, "Suboxone film Plaintiffs allege several product-liability claims against Defendants who designed, manufactured and sold Suboxone film as a prescription drug that treats opioid use disorder." Pls.' Br. 2. Plaintiffs correctly note that all of their complaints "allege four identical claims: (1) strict products liability for failure to provide adequate warnings and instructions; (2) negligent failure to provide adequate warnings and instructions; (3) strict products liability for defective design; and (4) negligent design defect." Pls.' Br. 7. The causes of action asserted in these cases are thus limited to product liability claims.

14. Although Plaintiffs' claims are exclusively based in theories of product liability (failure to warn and design defect), in the caption accompanying their motion and other filings they propose a "descriptive title" for the proposed MDL that broadly encompasses issues outside the scope of these product liability claims. The descriptive title appearing on Plaintiffs' pleadings is "In re: Suboxone Film Marketing, Sales Practices, and Products Liability Litigation." The only role Plaintiffs ascribe to "marketing" and "sales practices" in the pleadings before this Panel and in the underlying complaints concern those activities as they relate to their product liability claims.

15. Plaintiffs do not assert any claims or theories of liability relating to "marketing" or "sales practices" separate from their product liability claims. Nor do they allege any non-product liability claims that are predicated on "marketing" or "sales practices." The only aspect of "marketing" Plaintiffs take issue with is subsumed within their product liability allegations of inadequate warnings. Plaintiffs' proposed descriptive title, therefore, does not accurately reflect the nature of the litigation at issue. Defendants request that the Panel exercise its authority under Judicial Panel on Multidistrict Litigation Rule 3.2(a)(i) and designate as the descriptive title for this litigation as follows: "In re: Suboxone (Buprenorphine/Naloxone) Film Products Liability Litigation."

Plaintiffs' Motion and Brief Include Allegations Not Relevant to Any Issue Before this Panel and Not Relevant to Any Issue in the Underlying Litigation.

16. Judicial Panel on Multidistrict Litigation Rule 6.1(b)(i) instructs that motions "shall briefly describe the action or relief sought" and that supporting briefs should "concisely state[] the background of the litigation and movant's factual and legal contentions." Allegations made in Plaintiffs' Motion ¶ 4 and Supporting Brief "Background" Subsection B far exceed these parameters. *See, e.g.,* Pls.' Mot. ¶ 4; Pls.' Br. at Background Subsection B. Plaintiffs' accusations regarding the supposed motivation to develop Suboxone® film and an alleged "schem[e] to increase prescriptions" – in addition to being inaccurate – bear no relevance to the issues before this Panel or to their underlying litigation claims. Similarly, sensational accusations that Defendants "pressured physicians" to use Suboxone® film "under the pretext of alleged 'safety' concerns" have nothing to do with whether consolidation is warranted under 28 U.S.C. § 1407 and has nothing to do with the causes of action asserted in Plaintiffs' complaints. Plaintiffs' gratuitous references to allegations in unrelated criminal and civil proceedings and the resolutions of those proceedings have no bearing on the Panel's decision on the determination it is asked to make here

and is not in any manner relevant to whether the Suboxone® film warnings adequately conveyed risk information or to the viability of Plaintiffs' design defect claim. Defendants dispute Plaintiffs' characterization of these allegations, but decline to engage them here, as they have nothing to do with the questions before this Panel or its decision regarding consolidation.

CONCLUSION

Defendants Indivior Inc., Indivior Solutions Inc., and Aquestive Therapeutics, Inc. respectfully join Plaintiffs' request that the Panel transfer the Suboxone® film actions listed in the Schedule of Actions attached as Exhibit A to Plaintiffs' Brief, along with any subsequently filed "tag-along" actions, to the Northern District of Ohio for coordinated or consolidated pretrial proceedings under 28 U.S.C. § 1407 before the Honorable J. Philip Calabrese. Defendants further request that the descriptive title to this MDL be designated by this Panel as "*In re: Suboxone (Buprenorphine/Naloxone) Products Liability Litigation.*"

Dated: December 6, 2023

Respectfully submitted,

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BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

In re: Suboxone (Buprenorphine/Naloxone) Film Marketing, Sales Practices, and Products Liability Litigation	)))	**MDL Docket No. 3092**

PROOF OF SERVICE

Under Rule 4.1(a) of the Rules of Procedure for the United States Judicial Panel on Multidistrict Litigation, I certify that a copy of the foregoing *Defendants' Response to Plaintiffs' Motion for Transfer and Coordination or Consolidation Under 28 U.S.C. § 1407 and Response to Plaintiffs' Brief in Support* was served by electronic mail on December 6, 2023, to the following:

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