BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

In re: Suboxone Film Marketing, Sales Practices, and Products Liability Litigation	))))	**MDL Docket No. _____**

MOTION FOR TRANSFER AND COORDINATION OR CONSOLIDATION UNDER 28 U.S.C. § 1407

Per 28 U.S.C. § 1407 and Rule 6.2(a) of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, Plaintiffs Jeremy Schie, David Sorensen, Haleigh Graham, Teresita Badalamenti, Keith King, Santo Pietro, Steve Badalamenti, and Christian Miller respectfully move the Judicial Panel on Multidistrict Litigation for transfer and coordination or consolidation for pretrial purposes of all currently filed Suboxone film cases identified in the Schedule of Actions, attached as Exhibit 1 to the accompanying Brief in Support, and any Suboxone film cases subsequently filed involving similar facts or claims ("tag-along cases"), to the United States District Court for the Northern District of Ohio before the Honorable J. Philip Calabrese. Transfer or consolidation of these actions is appropriate for several reasons:

1. Suboxone film is a prescription drug that treats opioid use disorder by reducing withdrawal symptoms and the desire to use opioids without causing the cycle of highs and lows associated with opioid misuse. It does so by administering a synthetic opioid, buprenorphine, to partially activate opiate receptors in the brain.

2. Buprenorphine can be administered in several forms: subdermal or subcutaneous implant, intravenous or intramuscular injection, transdermal patch,

and oral forms including tablets and films dissolved in the mouth. In film form, the acidic makeup of Suboxone causes serious and permanent dental erosion and decay.

3. Suboxone was developed, designed, tested, labeled, packaged, manufactured, distributed, sold, and promoted, by Defendants. Suboxone tablets were approved by the United States Food and Drug Administration as an "Orphan Drug" in January 2002 to manage opioid dependence. The tablet's orphan-drug exclusivity expired on October 8, 2009.

4. Seeking to avoid generic competition with its Suboxone tablet product, Defendants developed the Suboxone sublingual film, which the FDA approved on August 30, 2010. Thereafter, Defendants began scheming to increase prescriptions for the film and decrease those for the tablets. Their scheming resulted in alleged antitrust violations and criminal convictions of senior executives.

5. As early as 2007, adverse event reports submitted to the FDA put Defendants on notice that the acidic formulation of Suboxone tablets and film was inflicting dental injuries. As early as 2012, published literature identified a possible link between sublingual administration of Suboxone tablets and severe dental decay.[1]

6. Between 2007 and 2021, Defendants were aware of at least 136 adverse events related to oral health associated with Suboxone use.[2] Despite the information about injuries to dental health Defendants received through AERs after Suboxone film was approved by FDA in 2010, and the body of literature indicating the same,

[1] Suzuki J and Park EM, *Buprenorphine/naloxone and dental caries: a case report.* Am J Addict. 2012 Sep–Oct;21(5):494–5.

[2] *See* Ex. 1-A to the Brief in Support (Sorenson Compl.) at ¶ 85.

Defendants failed to use the Changes Being Effected ("CBE") regulations, 21 C.F.R. § 314.07(c)(3), as they are required to do where there is new information about a causal relationship between an approved drug and a risk of harm. *See Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. ----, 139 S. Ct. 1668, 1673 (2019).

7. On January 12, 2022, the FDA issued a Safety Communication to manufacturers advising 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."[3] By that time, Defendants were aware of at least 136 adverse dental events related to Suboxone use, and reports have continued to grow.[4] Until June 2022, Defendants refused to update the Suboxone film prescribing information to include a warning regarding the risk of dental erosion and decay. Defendants implemented the change to the prescribing information only after the FDA required it and have yet to amend the patient medication guide to alert patients to the risks to their oral health posed by this product.

8. Defendants' failure to adequately warn of the potential dangers associated with Suboxone film prevented the medical community and general public from making informed decisions about prescribing and/or using the drug. As a result,

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[3] *See* FDA Drug Safety Communication (Jan. 12, 2022) (available at https://www.fda.gov/media/155352/download?attachment) (last accessed Nov. 13, 2023).

[4] *See* Ex. 1-A to the Brief in Support (Sorenson Compl.) at ¶ 87.

it is believed that thousands of individuals suffered adverse events due to their use of Suboxone film. Many of these injured individuals have filed or will file lawsuits against Defendants.

9. To date, there are 15 cases pending across five district courts in the country alleging that Suboxone film caused severe and/or permanent dental damage.

10. The pending Suboxone film actions and any tag-along actions against Defendants will involve similar questions of fact, and will involve common discovery and pretrial motion practice. Accordingly, there is the potential for inconsistent pretrial rulings if the cases are not transferred for consolidated proceedings under 28 U.S.C. § 1407.

11. Movants seek to create an MDL with respect to Plaintiffs that have suffered dental damage following their use of Suboxone film by centralizing all actions in the Northern District of Ohio with any subsequent tag-along actions. As explained in more detail in the supporting brief, centralization will eliminate duplicative discovery, prevent inconsistent rulings, and conserve judicial resources.

12. Transfer and coordination to the United States District Court for the Northern District of Ohio before the Honorable J. Philip Calabrese will serve the convenience of the courts, witnesses, parties, and counsel. The brief accompanying this motion elucidates why the Northern District of Ohio and Judge Calabrese are excellent choices to lead this litigation.