

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE SUBOXONE)	Case No. 1:24-md-3092
(BUPRENORPHINE/NALOXONE))	
FILM PRODUCTS LIABILITY)	MDL No. 3092
LITIGATION)	
)	Judge J. Philip Calabrese
This Document Applies to All Cases)	
)	

MINUTES AND ORDER

On October 4, 2024 and continuing into October 5, 2024, the Court held an in-person status conference.

The following attended in-person on behalf of Plaintiffs: Tim Becker, Ashlie Case Sletvold, Erin Copeland, Trent Miracle, and Alyson Steele Beridon.

The following attended in-person on behalf of Defendants Indivior, Inc., Indivior Solutions, Inc., and Aquestive Therapeutics, Inc.: Randall Christian, Mary R. Pawelek, Denise A. Dickerson, Paige L. Cheung, and Patrick DeLaune.

The following attended remotely: Sara Schramm, Michelle Rodriguez, Laura Smith, Sara Watkins, Michelle Rossi, Stan Gipe, Davis Cooper, Joe Masterman, Joyce Chambers Reichard, Jessica Wieczorkiewicz, Alexandria M. Messner, Kristina J. Anderson, Sara Papantonio, Kathryn Avila, Edward Mosella, Jon Ver Halen, Lee Floyd, Rachel Archambeau, Lissa Racer, Jennifer Duffy, Paul Levin, Jeremy Levin, Alex Parker, Glenn Kohles, Jr., Asim Badaruzzaman, Meghan Connolly, Gerardo Guerra, Christiaan van Lierop, James Kimball, Hans Lin, Luis Escobar, Molly Long,

Lindsey Berg, Ryan McIntosh, Roy Bendavid, Lisa Gorshe, Edwin Guyandi, Victor Alves, David Chasen, Sina Toussi, and Reza Keshavarz.

On the record, the Court and counsel addressed the items on the agenda as follows:

1. Amendment of CMO No. 3 Following Dismissal of Indivior PLC, Reckitt Benckiser LLC, and Reckitt Benckiser Healthcare (UK) Ltd.

The Court and counsel discussed updates to the language of CMO No. 3 (ECF No. 48) in light of the dismissal of three defendants on September 10, 2024. The parties will jointly submit a proposed amendment to CMO No. 3 before the next status conference.

2. Rule 12(b)(6) Motion

The Court reported that it is working through the pending motion to dismiss filed by the remaining defendants (ECF No. 126) but was not prepared to discuss it further at this time.

3. Custodial and Non-Custodial Production Protocol for Defendants' Productions and Deadline for Negotiation of Search Terms

Before the status conference, counsel submitted proposed protocols for custodial and non-custodial document production to provide a basis for discussion. (See ECF No. 151.)

In discussions with counsel over a protocol for custodial and non-custodial productions from Defendants, the Court expressed its view that it would be reasonable and proportionate to the needs of the case to include up to 40 custodians for Indivior and potentially 20 for Aquestive. Defendants reported that they identified 24 Indivior custodians, which Plaintiffs were free to accept.

Counsel discussed logistics and timing for review and production. After hearing from counsel about the temporal scope of production, the Court believed that productions reaching back to different dates is likely appropriate. For those engaged in research and development, for example, review should begin with documents as early as October 1, 2006, to account for work pre-dating the technology development agreement. At this time, the Court does not set a cut-off date for production, running production to the present based on the PLC's theory that the label remains defective. As to non-custodial productions, the Court permitted the PLC to identify its priorities for production and review of categories of documents (*i.e.*, regulatory, research and development, etc.).

Then, the Court outlined a process for certifications of substantial completion for productions of the files of each custodian and each category of non-custodial documents. When it has more information to do so, the Court will set dates for the start and substantial completion of custodial and non-custodial productions.

Defendants represented that they will need agreement or a ruling on search terms before beginning review of electronically stored information. Plaintiffs represented that they had submitted proposed search terms to Defendants, who agreed to return comments to Plaintiffs' counsel by October 14, 2024. As part of the agenda for the next status conference, the parties shall submit agreed search terms or disputes about them so that the Court can resolve the matter to allow review and production to begin forthwith.

The Court agreed that discussion of the protocol for custodial and non-custodial productions does not address case-specific discovery, which will be the subject of future orders.

4. Status of Providing Information on Claimants on Schedule A

Plaintiffs disclosed 65 additional individuals (*see* ECF No. 150) who were inadvertently omitted from Schedule A. Defendants reserved their rights with regard to these individuals. Also, Plaintiffs provided an update on efforts to substantiate product identification and proof of injury for claimants listed on Schedule A. As of October 4, 2024, the PLC expects 1,418 individuals to fall off of Schedule A. That number will grow as this work continues.

5. Status of Providing Expert Discovery from Prior Litigation

The Court reported following up with counsel of record in the prior antitrust litigation. Based on his representations about the expert discovery at issue there, the Court is satisfied that discovery of experts from that litigation is not relevant in this dispute. If discovery in the MDL shows otherwise, the Court will revisit the issue.

6. Status of Production of Adverse-Event Reports

Defendants stated that they intend to produce electronic data regarding adverse event reports before the next status conference. At that conference, which will be by Zoom, the Court will discuss any disputes regarding the format of production from the different sources involved. Counsel should be prepared to use the technology and format of the conference to show the different formats in dispute.

7. Census Protocol, Bellwether Process, and Dismissals from Schedule A

After discussion on the foregoing topics, the Court then facilitated an informal working session over two days among counsel regarding the bellwether process, with particular attention to a census of all current claimants. Based on this discussion and the various options that counsel presented, the Court determined that there will be a single census process, not one that collects additional information from a subset of claimants. Further, the census will operate independently of any tolling. Along with the census form, all claimants will complete authorizations for Defendants to request dental and pharmacy records. Defendants will upload any records received to a common database.

Counsel discussed different options for a platform to host a common database for census data. Counsel agreed jointly to select a platform by October 11, 2024 and submit a proposed case management order for the census protocol by October 18, 2024. The census protocol shall provide 270 days to complete census forms, 60 days for Defendants to provide notice of any deficiencies, 30 days for Plaintiffs to cure deficiencies, and 14 days to meet and confer regarding disputes. Any disputes not resolved after meeting and conferring may be placed on the agenda for the next conference with the Court. This census process shall apply to cases currently filed and claimants identified on Schedule A. Plaintiffs filing on or after October 7, 2024 will be subject to future orders.

With input from the Court, counsel finalized the census form attached as Exhibit 1. Counsel will confirm with whichever platform vendor is selected that this form is compatible with the platform.

The Court and counsel also discussed a procedure for dismissals of claimants listed on Schedule A. Claimants who cannot substantiate injury or product identification will be dismissed with prejudice. Claimants who do not timely complete the census form due to transience or similar reasons will be dismissed without prejudice. Dismissals from Schedule A and notice of upcoming dismissals will be a regular reporting item at future status conferences.

8. Next Status Conference

The Court sets a status conference for November 21, 2024, at 9:00 a.m. by Zoom. The parties shall exchange proposed agenda items for the conference by November 13, 2024 and submit the agenda to the Court by November 15, 2024.

SO ORDERED.

Dated: October 8, 2024



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

SUBOXONE FILM CENSUS FORM

I. CASE INFORMATION

- A. Filed Case: (Yes/No)
 - 1. Caption:
 - 2. Docket number:
- B. Name, email, and phone number of attorney with whom Defendants' Counsel should correspond regarding Census Form/records (with alternative selection box for pro se Claimants):
- C. If you do not have a lawyer and are suing on your own behalf, please check here __

II. PLAINTIFF INFORMATION

- A. Full name:
- B. Date of birth:
- C. Current Address:
- D. Social Security number:
- E. Gender: Male Female Non-Binary
- F. Loss-of-consortium claim (Yes/No) [If Yes, spouse's name]:
- G. Is the injured party deceased? (Yes/No) [If Yes, name and contact information of estate representative]:

III. PRODUCT USE AND DURATION

- A. When were you first prescribed Suboxone Film (month/year)?
- B. When did you first use Suboxone Film (month/year)?
- C. Have you ever taken:
 - 1. Brand-name Suboxone Film?
 - 2. Generic version of Suboxone Film?
 - 3. Both.
- D. How long did you take brand-name Suboxone Film? (list total number of months)
- E. Did you take Suboxone Film or a generic version of Suboxone Film after July 2022? (Y/N)

IV. INJURIES

- A. Have you experience any dental injuries that you claim were caused in whole or in part by Suboxone Film? (Yes/No).
If **yes**, continue below.
- B. Are you claiming that your only injury is a cavity or cavities? (Y/N)
- C. Have you experienced a tooth fracture, which has not been extracted, that you claim was caused by Suboxone Film? (Y/N). If yes, indicate # of tooth fractures).
- D. Have you lost or had any teeth extracted as a result of using Suboxone film: Y/N. If yes, indicate # of teeth lost/extracted.
- E. Have you experienced any other significant dental related injuries not identified in IV(B)-(D)?
- F. Has a dental professional or any other medical professional ever treated your injuries caused by Suboxone film? Y/N
- G. Have you had any of your lost/extracted teeth replaced? Y/N

V. DAMAGES

- A. Check the box beside each type of damages you seek:
 - Emotional distress
 - Psychiatric injury
 - Medical/dental expenses
 - Lost wages
 - Other [Provide Description]

VI. HEALTHCARE PROVIDERS

- A. Please provide the name and address of:
 - 1. Healthcare provider(s) who prescribed Suboxone Film;
 - 2. Dental professional(s) who treated you for claimed injuries; and
 - 3. Pharmacies or MAT Clinic where you picked up Suboxone Film.

VII. RECORDS ESTABLISHING PROOF OF USE AND PROOF OF INJURY AND AUTHORIZATIONS

Plaintiff will provide:

- A. Documents establishing product identification/proof of use of brand-name Suboxone Film;

- B. Dental records establishing proof of subsequent dental injury, if any;
and
- C. Executed authorizations for dental records and x-rays, medical records,
and pharmacy dispensing records (attached).

VIII. DECLARATION

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the information provided in this Census Form is true and correct to the best of my knowledge and recollection.