

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

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

MINUTES AND ORDER

On March 11, 2025, the Court held a status conference in person.

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

The following attended in person on behalf of Defendants Indivior, Inc., Indivior Solutions, Inc., and Aquestive Therapeutics, Inc.: Randall Christian, Mary Pawelek, Paige Cheung, Patrick DeLaune, and Jason Lundry.

The following attended remotely: Tammy Yonker, Elizabeth Carroll, Roy BenDavid, Alyssa Reinhardt, Sarah Frank, Glen Kohles Jr. and Asim Badaruzzaman, Luis Escobar, Lisa Gorshe, Gabriela Lopez, Jessica Wieczorkiewicz, Robin Matney on behalf of Kristine Kraft, Bradley East, Deborah Schmitt, Stan Gipe, Kathryn Avila, Ashley Windsor, Shannon McFarland, Meghan P. Connolly, George Senteno, Clint James Casperson, Michelle Rodriguez, Laura Smith, Sara J. Watkins, Jemma C. Cota, Madeline Wise, Davis Cooper, Joyce Chambers Reichard, Matt Dorman, Victor Alves, Reza Keshavarz, and David Chasen.

On the record, the Court and counsel addressed the items on the agenda (ECF No. 201) as follows:

1. Discovery

1.a. Census Protocol

1.a.i. Update on Process to Date

Plaintiffs' counsel provided an update on the census process to date, including the revised Schedule A and consent to remove list submitted on March 7, 2025 (ECF No. 202-1; ECF No. 202-2), as well as the number of census forms completed. Counsel reported that 70 census forms are fully complete and that Defendants continue to follow up on deficiencies but none are ripe for the Court at this time. A large volume of census forms remains in process in advance of the August 1, 2025 deadline. (*See* Case Management Order No. 12, ECF No. 158, PageID #4041.)

1.a.ii. Removals from Schedule A

Based on discussion with counsel, the Court determined that it will enter an order to reflect the removals of claimants from Schedule A, by consent or otherwise, at the end of the process set forth in Case Management Order No. 12. Counsel shall advise the Court if any such interim orders are necessary or helpful.

1.a.iii. Provider Non-Compliance with Records Requests

Counsel reported few, if any, issues thus far with receiving records using the approved authorization.

1.b. Discovery from Defendants

1.b.i. Status of Negotiation on Search Terms

The Court and counsel participated in informal working sessions to address and resolve disputes over search terms for custodial productions from Indivior on March 10, 2025 and March 11, 2025. Based on discussions with counsel, the Court expects that the same search terms will be used for custodians with Indivior and Aquestive.

1.b.ii. Custodians

A. Caps

Plaintiffs argued for a cap on the number of Indivior custodians in the range of approximately 75, to allow flexibility in acquiring sufficient information to work up the case. Counsel for Plaintiffs and Defendants argued based on the number of custodians in other MDLs: Plaintiffs argued the trend is to permit between 65 and 75 custodians, while Defendants argued for a range of 15 to 58 custodians. Based on discussions with counsel, the Court remains of the view that 40 custodians from Indivior provides a reasonable starting point, adding more custodians by agreement or with an appropriate showing. Further, the Court articulated the view that selection of the appropriate number of custodians is not a mathematical exercise and must allow some opportunity for Plaintiffs to learn the case, within the limits of proportionality.

B. Identification of Custodians

Defendants represented that they identified custodians in September 2024 pursuant to Case Management Order No. 11 (ECF No. 136), including the

employment dates of those custodians. Since then, Defendants identified four additional custodians (three relating to Sublocade and an additional marketing employee), bringing the number of custodians identified to 28. Defendants take the position that these custodians cover the relevant information at issue in this litigation and that others add little or are duplicative. Of these 28 custodians, the PLC selected nine Indivior custodians for production of their files. They seek additional custodians from cross-functional teams, including marketing, commercial, pharmacovigilance, clinical, research and development, medical affairs, chemistry, manufacturing, controls, and regulatory affairs over a twenty-year timeframe from development of the product through present. By the next status conference, the Court directed Defendants to provide it with a list of the 28 custodians, including their job titles and dates of employment.

The parties have a dispute regarding one custodian not among the 28 identified thus far: Indivior's former chief executive officer. The Court directed the parties to confer by the end of the month. If no agreement is reached, the parties shall file a short joint notice to that effect by noon on March 31, 2025 then simultaneously file briefs, not to exceed five double-spaced pages, by noon on April 7, 2025. The Court will resolve any disputes on the issue at the next status conference.

Regarding Aquestive, defense counsel represented that they identified three custodians with relevant knowledge from before development of the product until recently. Based on the claims remaining against Aquestive, Defendant advocated for limited custodial productions to reflect the pre-approval claims remaining. In

response, the Court outlined the broader discovery obligations Aquestive has and would have even if not a party. Of the custodians identified, the PLC agreed to production from each. Counsel agreed that hit reports upon finalization of the search terms for electronically stored information might help advance discussions over additional custodians from Aquestive.

The parties reported an agreement to begin custodial productions by July 1, 2025.

To facilitate the process of identifying and selecting custodians, the PLC reported that it intends to serve notices for three Rule 30(b)(6) depositions addressing (1) corporate organization, (2) the June 2022 label change, and (3) Indivior's process for handling product complaints. Defendants objected that such notices are premature and the custodians already identified capture that information. In the Court's view, some of the information sought might be in the nature of a books-and-records deposition that will help Plaintiffs identify or select appropriate custodians but other topics (or parts of topics) are likely premature or better handled through depositions of custodians. The Court directed the PLC to serve notices by the end of March 2025 to inform further discussions between counsel and at the next status conference.

1.b.iii. Sublocade Regulatory File

The parties dispute whether the post-approval Sublocade regulatory file should be produced. Based on discussion with counsel, the Court deferred this issue until after production of the relevant custodial files.

1.b.iv. Adverse Event Reports

Counsel continue to discuss production of adverse event reports. The parties' discussions regarding search terms might lead to resolution of this issue.

1.c. Discovery Disputes

Except as discussed above, no other discovery disputes are ripe or require the Court's intervention at this time.

2. Newly Filed Cases

Defendants' counsel represented that they recently discovered that a large number of filed cases did not go through the protocol for service. The PLC will investigate and liaise with Plaintiffs' counsel as appropriate to remedy the issue and try to keep it from recurring.

Counsel reported that they reached agreement on the bundling of complaints. Such complaints will be the subject of a future census order. Upon review, the Court will enter this agreement as Case Management Order No. 14.

3. Bellwether Protocol

The Court discussed with counsel their competing proposals for building out the bellwether process. As a general matter, prior discussions with the Court have led to broad agreement on the overall process, and the disagreements that remain largely involve details of implementation or matters not previously discussed, including the process for replacing replacement Plaintiffs following a dismissal, the number and scope of authorizations and different stages of the bellwether process, determining substantial completion, and the deficiency process.

In the course of discussing these issues with counsel, for the reasons stated on the record, the Court determined, among other things, that, in the Record Collection Pool, there will be two rounds of replacement of Plaintiffs who dismiss their claims or otherwise drop out, authorizations will be limited to the healthcare providers listed in Case Management Order No. 12, and Defendants will have responsibility for providing regular updates or reports at future status conferences

For the Core Discovery Pool, the Court agreed with Defendants that an alternate pool of 50 additional Plaintiffs for completion of fact sheets and broader record collection (without depositions) will both aid the parties' knowledge of the cases in the MDL and allow work up of multiple cases in the Trial Pool.

Based on the discussions to date, the Court determined to enter the bellwether protocol with respect to the Record Collection Pool as Case Management Order No. 15 so that work can begin promptly. As the Court and the parties finalize the remaining phases of the bellwether process, the Court will amend Case Management Order No. 15.

NEXT STATUS CONFERENCE

The Court sets a status conference for April 17, 2025 at 10:00 a.m. Counsel will confer whether to hold this conference by Zoom or in person. Those who wish to listen by phone shall notify the Court's MDL Clerk, Andrew Rivera (Andrew_Rivera@ohnd.uscourts.gov), by April 15, 2025. Counsel shall confer on the agenda in advance and submit the agenda no later than 4:00 pm on April 14, 2025.

SO ORDERED.

Dated: March 14, 2025

A handwritten signature in black ink, appearing to read "J. Calabrese", written in a cursive style.

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