UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE SUBOXONE (BUPRENORPHINE/ NALOXONE) FILM PRODUCTS LIABILITY LITIGATION	)	Case No. 1:24-md-03092-JPC
	)	MDL 3092
	)	Judge J. Philip Calabrese
This Document Applies to All Cases	)	

PLC'S NOTICE OF VIDEOTAPED FED. R. CIV. P. 30(B)(6) DEPOSITION OF THE CORPORATE REPRESENTATIVES FOR THE INDIVIOR DEFENDANTS (*CONCERNING ADVERSE EVENT HANDLING*)[1]

PLEASE TAKE NOTICE that under Fed. R. Civ. P. 30(b)(6), Plaintiffs, by and through the Plaintiffs' Leadership Committee, will take the deposition upon oral examination of the Indivior Defendants with respect to the topics set forth in Schedule A below as follows:

Date: September 17, 2025

Time: 9:00 a.m.

Location: McGuire Woods
800 East Canal Street
Richmond, Virginia 23219

The deposition will take place before a notary public or other person authorized by law to administer oaths and take depositions. The deposition will be recorded stenographically and by video recording. Plaintiffs reserve the right to use at the trial of this action the videotape recording of the deposition of the deponent under Fed. R. Civ. P. 32(a). Plaintiffs reserve the right to seek relief from the Court in the event

[1] The PLC originally noticed this deposition as ECF No. 210. The Court ruled on the disputed issues at the case-management conference on May 30, 2025. (ECF No. 244.)

Defendants do not properly prepare the designated person(s) to testify on behalf of Defendants with respect to each of the identified topics. Defendants are hereby requested and required under the federal rules to designate and produce at the deposition one or more officers, directors, managing agents, or other persons who consent to testify on their behalf on the following matters and documents from the launch of Suboxone Film to the present:

SCHEDULE A: DEPOSITION SUBJECT MATTERS

1. The overall process by which Defendants (or someone acting on their behalf) handle adverse events from any source related to Suboxone Film. "Handle" means the details of how Defendants (or someone acting on their behalf) receive, record, code, investigate, evaluate, report, resolve, trend, close, and maintain files of Suboxone Film adverse events from any source. This request is limited to adverse events related to dental injuries. This request specifically includes:

    a. Each step taken in the process and by whom (in terms of department, units, functions, third parties);

    b. An overview of the applicable policies and procedures for each step (including training of those tasked with handling adverse events; and

    c. Any substantive changes to the complete process, steps, and/or policies and procedures over time.

    d. Defendants' implementation of the regulatory framework governing classification of adverse events including, but not limited to, those set forth in the Code of Federal Regulations and FDA Guidance to Industry.

    To the extent Defendants chose to rely upon any third party (individual or vendor) to handle any step in the adverse event handling process, the witness should be prepared to discuss the same responsive information for each such third party generally.

2. Information about all internal or external audits, inspections, evaluations, and/or analyses of Defendants' adverse event-handling processes, policies, and/or procedures (including third parties acting on Defendants' behalf), when each such occurred, where they took place, and Defendants' response(s) and any corrective and/or remedial action taken in response to each, if applicable, including those of third parties acting on Defendants' behalf.

3. Information regarding FDA site inspections that related to dental or oral adverse events and/or adverse event handling policies, procedures, and processes that apply to the handling of Suboxone Film adverse events. The topics shall include the following: (a) whether FDA issued any written report to Defendants, including any informal communication, Establishment Inspection Report (EIR), Form 483 Report or other written observation(s); (b) the EIRs, 483 Reports, written observations or other informal communication outlining any corrective action FDA required or suggested; (c) any if informal or voluntary acts Defendants agreed with FDA to make following a site inspection; (d) the person or person responsible for preparing any materials provided to FDA prior to the site inspection(s); (e) the person or persons who interacted with FDA during any site inspection; (f) the role each person or persons played in conjunction with each FDA site inspection; and (g) the steps Defendants took to implement any corrective and/or remedial action it agreed to make with FDA. To be clear, this subject matter is intended to and covers any FDA inspections of Defendants' Suboxone Film adverse event handling systems generally and any inspections targeted to Suboxone Film dental or oral adverse events, if applicable.

4. The identity of all key individuals tasked with handling adverse events related to Suboxone Film and his or her department/unit/function. This includes third parties conducting adverse event handling on Defendants' behalf.

5. To the extent any witness comes to the deposition with previously unproduced documents, the witness should be prepared to discuss the contents of those documents.

6. To the extent any witness has reviewed any documents to prepare for the deposition, the witness should be prepared to discuss the contents of those documents.

7. To the extent the adverse event handling process for Suboxone Film differs in any way from other Buprenorphine/Naloxone products manufactured by Defendants, the witness should be prepared to discuss those differences and the rationale for a different adverse event handling process from Suboxone Film.

8. To the extent the adverse event handling process for adverse events related to dental injuries differs in any way from adverse events of other injuries, the witness should be prepared to discuss those differences and the rationale for a different adverse event handling process from Suboxone Film.

SCHEDULE B: DOCUMENTS TO BE PRODUCED[2]

1. All documents which the deponent(s) has utilized or may need to refresh his or her recollection as to any of the subject matters referenced in Schedule A.

2. All documents the deponent(s) consults or relies upon in preparation for the deposition.

3. All documents the deponent(s) creates (or are created on his/her behalf) to address any of the subject matters referenced in Schedule A.

4. The most current CV and/or resume for each of the person(s) being deposed pursuant to this notice.

5. All SOPs and work instructions applicable to each step in the adverse event handling process pertaining to Suboxone Film, including, but not limited to, training, intake, coding, investigating, evaluating, reporting, resolving, trending, closing and maintain files. This includes revisions over time to the extent such exist.

6. Any decision trees, flow charts, or similar documents reflecting the process by which Defendants (or anyone acting on their behalf) investigate adverse events related to Suboxone Film and determine the appropriate action(s), including whether an adverse event needs to be reported to FDA. This includes revisions over time to the extent such exist.

7. Organizational charts for any department, unit, or function tasked with any step in the adverse event-handling process, including those of third parties conducting any such steps on Defendants' behalf. This includes revisions over time to the extent such exist.

8. Written agreement(s) between Defendants and any third party conducting any step in the adverse event handling process on Defendants' behalf.

9. SOPs and work instructions reflecting the training of any individual (including third parties acting on Defendants' behalf) conducting any step in the adverse event handling process on Defendants' behalf. This request specifically includes any presentations or slides reflecting such training, including training on how to code adverse events related to Suboxone Film and training on how to identify and report adverse drug reactions internally and/or to FDA. This includes revisions over time to the extent such exist.

[2] Per the parties' agreement, production of the requested documents will be completed no later than July 31, 2025. (ECF No. 272, PageID #7048.)

10. Documents reflecting any FDA inspection and communications about these inspections related to Suboxone Film adverse event handling systems and any inspections targeted to Suboxone Film dental or oral adverse events, if applicable. For any site inspection that investigated in whole or in part Defendants' classification or handling of dental or oral adverse events, any document supplied to FDA in advance of and/or at the time of that site inspection and any EIR, Form 483, written observations or other informal communication with FDA regarding the inspection.

11. All audits, inspections, evaluations and/or analyses of Defendants' (including those acting on Defendants' behalf) complaint-handling processes, policies and/or procedures, and documents reflecting corrective actions taken in response thereto.

Dated: June 24, 2025

Respectfully submitted,

/s/ *Ashlie Case Sletvold*
Ashlie Case Sletvold
PEIFFER WOLF CARR KANE CONWAY & WISE, LLP
6370 SOM Center Road, Suite 108
Cleveland, Ohio 44139
(216) 589-9280
asletvold@peifferwolf.com

/s/ *Erin Copeland*
Erin Copeland
FIBICH, LEEBRON, COPELAND & BRIGGS
1150 Bissonnet Street
Houston, Texas 77005
(713) 424-4682
ecopeland@fibichlaw.com

/s/ *Timothy J. Becker*
Timothy J. Becker
JOHNSON // BECKER, PLLC
444 Cedar Street, Suite 1800
St. Paul, Minnesota 55101
(612) 436-1800
tbecker@johnsonbecker.com

Plaintiffs' Co-Lead Counsel

/s/ *Trent B. Miracle*
Trent B. Miracle
FLINT COOPER LLC
222 East Park Street, #500
Edwardsville, Illinois 62025
(618) 288-4777
tmiracle@flintcooper.com

/s/ *Alyson Steele Beridon*
Alyson Steele Beridon
HERZFELD, SUETHOLZ, GASTEL, LENISKI, & WALL, PLLC
600 Vine Street, Suite 2720
Cincinnati, Ohio 45202
(513) 381-2224
alyson@hsglawgroup.com

Plaintiffs' Liaison Counsel