IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE SUBOXONE (BUPRENORPHINE HYDROCHLORIDE AND NALOXONE) ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: *Wisconsin, et. al. v. Indivior Inc. et. al.*	MDL No. 2445 Master File No. 2:13-MD-2445-MSG Case No. 2:16-cv-5073-MSG
STATE OF WISCONSIN et. al. Plaintiffs, v. Indivior Inc. f/k/a Reckitt Benckiser Pharmaceuticals, Inc., et. al. Defendants.	Civ. A. No. 16-cv-5073

[PROPOSED] STIPULATED FINAL JUDGMENT
AND DISMISSAL WITH PREJUDICE

Plaintiff States filed their Complaint in this matter pursuant to 15 U.S.C. §§ 1 and 2, 15 U.S.C. § 26 and their respective state laws. The Plaintiff States and Defendant Indivior Inc., by their respective attorneys, have reached an agreement to resolve this case through settlement, and without trial or final adjudication of any issue of fact or law, and stipulate to entry of this Stipulated Final Judgment and Dismissal with Prejudice ("Order") to resolve all matters in dispute in this Action.

FINDINGS

1. The Court has jurisdiction over the subject matter and the parties to this Action for the purpose of entering into and enforcing this Order. Jurisdiction is retained by this Court for the purpose of enabling the Plaintiff States or Indivior to enforce this Order.

2. Venue for this matter is proper in this Court under 15 U.S.C. § 22 and 28 U.S.C. § 139l(b) and (c).

3. The Complaint alleges that Indivior engaged in violations of the Sherman Act and violations of the laws of the Plaintiff States, by engaging in anticompetitive activities designed to impede competition from generic equivalents of the brand-name drug Suboxone. Indivior disputes these allegations.

4. This Order does not constitute any evidence against Indivior, or an admission of liability or wrongdoing by Indivior in this case or in other litigation. Rather, the terms of this Order reflect a negotiated compromise, entered into as a means to resolve contested issues without the burdens of litigation. This Order shall not be used in any way, as evidence or otherwise, in any other litigation or proceeding; provided that, nothing in this provision prevents the Plaintiff States or Indivior from using this Order in any proceeding regarding enforcement of this Order or as otherwise required by law.

5. Entry of this Order is in the public interest.

STIPULATIONS

1. Indivior and Plaintiff States, by and through their counsel, have agreed that entry of this Order fully and finally resolves the Released Claims, including all issues between the parties arising from the specific events giving rise to the allegations described in the Complaint, and

precludes further litigation between Plaintiff States and Indivior regarding the Released Claims, except for the purposes of enforcing this Order.

2. Indivior admits the facts necessary to establish personal and subject matter jurisdiction of this Court in this matter.

3. Indivior denies the charges in the Complaint and disputes that the Plaintiff States are entitled to obtain relief.

4. Indivior and Plaintiff States stipulate that they shall comply with the provisions of this Order pending its entry by the Court.

5. Indivior and Plaintiff States stipulate that they will bear their own costs in this matter and shall not make any claims against the other party for attorney's fees or costs.

6. Indivior and Plaintiff States waive all rights to appeal or otherwise challenge or contest the validity of this Order.

7. The obligations set out below relate solely to business operations within the Plaintiff States.

DEFINITIONS

1. "505(b)(2) Application" means an application filed with the United States Food and Drug Administration pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(b)(2).

2. "Action" means Civil Action Number 2:16-CV-5073 (MSG), consolidated into MDL No. 13-MD-2445 in the United States District Court for the Eastern District of Pennsylvania.

3. "ANDA" means Abbreviated New Drug Application filed with the United States Food and Drug Administration pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j).

4. "Authorized Generic" means a Drug Product that is manufactured pursuant to an NDA and Marketed in the United States under a name other than the proprietary name identified in the NDA.

5. "Citizen Petition" means a public request that the FDA issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action pursuant to 21 C.F.R. § 10.30.

6. "Commerce" has the same definition it has in 15 U.S.C. § 44.

7. "Complaint" means any complaint filed by the Plaintiff States in Civil Action Number 2:16-CV-5073 (MSG), consolidated into MDL No. 13-MD-2445 in the United States District Court for the Eastern District of Pennsylvania, including but not limited to the First Amended Complaint.

8. "Control" or "Controlled" means the holding of more than 50% of the common voting stock or ordinary shares in, or the right to appoint more than 50% of the directors of, or any other arrangement resulting in the right to direct the management of, the said corporation, company, partnership, joint venture, or entity.

9. "Direct Cost" means the variable costs incurred to produce or sell an Original Drug Product or Follow-on Drug Product, including the costs of ingredients and manufacturing, as well as the costs of marketing that product. The term Direct Cost does not include any allocation of overhead costs, administrative costs, research and development costs, or any other fixed costs.

10. "Drug Product" means a finished dosage form (e.g., tablet, capsule, solution, or patch) as defined in 21 C.F.R. § 314.3(b), approved under a single NDA, ANDA, or 505(b)(2) Application, and available by prescription, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients. Notwithstanding the foregoing, the

term Drug Product, as used in this Order, shall not include products that are predominantly purchased over-the-counter ("OTC") in the United States.

11. "Effective Date" means the day that this Order is entered by the Court.

12. "Effective Price" means the net price paid by a payor for a Drug Product, taking into account all discounts, refunds, reimbursements, and rebates.

13. "FDA" means the U.S. Food and Drug Administration.

14. "Follow-on Drug Product" means a Drug Product a) for which Indivior has submitted an NDA, controls an approved NDA, or has the right to distribute in the United States; b) that contains an active ingredient that is (i) the same as an active ingredient in a previously approved Original Drug Product, or (ii) an isomer, salt form variant, or metabolite of an active ingredient in a previously approved Original Drug Product; and c) that treats the same condition or targets the same patient population as the previously approved Original Drug Product. Notwithstanding the foregoing, for purposes of this Order, the term Follow-on Drug Product shall not include an Authorized Generic version of the Original Drug Product.

15. "Indivior" means Defendant Indivior Inc.

16. "Liaison States" means the States of Wisconsin and the State of Utah. All documentation provided to liaison states should be addressed to:

State of Wisconsin- Office of the Attorney General
Attn: Public Protection Unit (Antitrust)
17 W. Main St.
Madison, WI
Gwendolyn.Cooley@wisconsin.gov

And

State of Utah- Office of the Attorney General
Attn: Antitrust and Data Privacy Section
160 E 300 S, 5th Floor
PO BOX 140830

Salt Lake City, UT 84114-0830
dsonnenreich@agutah.gov
mwmartin@agutah.gov

17. "Market," "Marketed," or "Marketing" means the promotion, offering for sale, sale, or distribution of a Drug Product.

18. "Monetary Payment" means the amount that Indivior will pay the States via the method specified in Section III, "MONETARY PAYMENT".

19. "NDA" means a New Drug Application filed with the United States Food and Drug Administration pursuant to Section 505(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(b), including all changes or supplements thereto that do not result in the submission of a new NDA.

20. "Opioids Litigation" means any claims or potential claims related to the subject matter of *In Re: National Prescription Opiate Litigation*, Case No. 1:17-md-2804, MDL 2804 (Northern District of Ohio), in that or any other venue.

21. "Original Drug Product" means a Drug Product that is Marketed in the United States and for which Indivior controls the NDA or has the right to distribute in the United States.

22. "Released Claims" means any and all civil or administrative causes of action or claims whatsoever, in law or equity, that the Plaintiff States had as of the date of the Order, that were or could have been raised in this Action under any statute or common law, related to the facts alleged in the Complaint or alleged anticompetitive conduct related to Suboxone Film, including but not limited to claims for injunctive relief, damages, disgorgement, civil penalties, legal fees, and costs; provided, however that "Released Claims" do not include: (i) claims alleging a violation of this Order; (ii) Opioid Litigation claims; (iii) environmental claims; (iv) claims of political subdivisions to the extent that the Plaintiff States lack legal authority to release such claims; and

(v) claims related to any potential tax liability. Nothing in this Order, however, shall be construed to waive or otherwise limit Indivior's arguments or defenses regarding claims released by the Plaintiff States in other agreements, including but not limited to claims excluded from the definition of Released Claims.

23. "Person" means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business, and any subsidiaries, divisions, groups, or affiliates thereof.

24. "Plaintiff States" means the District, Commonwealth, or State of Wisconsin, Alabama, Alaska, Arkansas, California, Colorado, the District of Columbia, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Hampshire, New Mexico, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington, and West Virginia, who are Plaintiff States in Civ. A. No. 16-CV-5703 (Eastern District of Pennsylvania). Plaintiff States does not mean the Federal government or individual consumers.

25. "Released Entities" means Indivior Inc., Indivior PLC, Indivior Solutions, and any joint venture, subsidiary, division, group, predecessor, successor, or affiliate that could be liable for any acts of the foregoing named entities, along with all directors, officers, employees, and agents of the same.

26. "Status Quo Period" means a period beginning the day Indivior begins Marketing a Follow-on Drug Product in the United States and ends on the earlier of (i) six (6) months after a Third Party begins Marketing a Drug Product approved under an ANDA or 505(b)(2) Application for which the Original Drug Product is the reference listed drug, or (ii) three (3) years after the day

Indivior or a licensee of Indivior begins Marketing the Follow-on Drug Product in the United States.

27. "Third Party" means any Person other than Plaintiff States or Indivior.

I. PROHIBITED ACTIVITY: CITIZEN PETITION PROCESS

If Indivior files a Citizen Petition, Indivior shall simultaneously disclose such filing to both the FDA and the Liaison States:

A. All studies and data on which the Citizen Petition relies; and

B. All studies and data within the knowledge or possession of Indivior that address the validity or strength of one or more of the material contentions in the Citizen Petition

II. PROHIBITED ACTIVITY: PRODUCT SWITCHING CONDUCT

A. Indivior shall provide a notification to the Liaison States thirty (30) calendar days after Indivior files an NDA for a Follow-on Drug Product in the United States. This notification shall include, *inter alia,* the following information: (i) a reference to this Order, (ii) the NDA number for the Follow-on Drug Product, and (iii) the associated Original Drug Product and NDA number under which it was approved.

B. Indivior shall provide a second notification to the Liaison States six (6) months before the date specified for FDA approval of the Follow-on Drug Product under the Prescription Drug User Fee Act. This notification shall reference this Order and the previous notification submitted as required in the above Section II.A for the Follow-on Drug Product. Indivior shall submit the following documents and information with the notification:

1. Documents sufficient to show the company's pricing plans for the Original Drug Product and Follow-on Drug Product;

2. Documents sufficient to show the forecasted sales for the Original Drug Product and Follow-on Drug Product;

3. Transcripts of any of the Indivior's investor calls during the prior twelve months that discuss the Follow-on Drug Product;

4. A statement of all claimed benefits of the Follow-on Drug Product compared to the Original Drug Product; and

5. A statement of whether Indivior intends to materially alter the terms on which it sells the Original Drug Product, and, if so, identification of these terms, and all reasons for materially altering them.

C. If, on the date when Indivior or its licensee begins Marketing a Follow-on Drug Product in the United States, a Third Party has submitted an ANDA or 505(b)(2) Application for which the Original Drug Product is the reference listed drug, then during the Status Quo Period, Indivior shall be prohibited from:

1. Destroying inventory or withdrawing from the market any strength or formulation of the associated Original Drug Product; provided, however, Indivior may destroy Drug Product that has passed its Saleable Expiration Date.

2. Failing to fill orders for the Original Drug Product on the same terms and conditions (except for those terms and conditions relating to Effective Price, which are addressed below in Section II.C.3) within the same time frame and with the same convenience as are orders for the Follow-on Drug Product. For the avoidance of doubt, this clause does not prohibit Indivior from offering different terms or conditions for a given Original Drug

Product or Follow-on Drug Product to different customers, so long as each customer is offered the same terms and conditions for the Original Drug Product as for the Follow-on Drug Product.

3. Offering an Effective Price for the associated Original Drug Product to any Customer that is higher than the Effective Price Indivior offers to that Customer for the Follow-on Drug Product;

Provided, however, this prohibition does not apply (a) if the Effective Price of the Original Drug Product is not increased by more than the corresponding increase in the prescription drug price component of the Consumer Price Index at any time during the eighteen (18) months prior to introduction of the Follow-on Drug Product or during the Status Quo Period; or (b) if the difference in Effective Price is attributable solely to a difference in the Direct Costs of the products.

4. Deleting the National Drug Code for the associated Original Drug Product from the National Drug Data File;

Provided, however, that Indivior shall have no obligations under Section II.C with respect to an Original Drug Product: (a) for which the associated Follow-on Drug is no longer Marketed in the United States, or (b) that the FDA has determined should no longer be Marketed in the United States because of safety concerns. Indivior may recall and destroy products consistent with 21 C.F.R. Part 7, Subpart C; may take reasonable steps to protect safety in the event of manufacturing defects; and may take any action that is requested by FDA;

Provided further, for clarity, this Section II.C does not apply to Sublocade because any relevant Status Quo Period with respect to that Drug Product has ended.

III. MONETARY PAYMENT

Indivior will pay to the Plaintiff States a Monetary Payment in the amount of $102,500,000 (One Hundred Two Million, Five Hundred Thousand Dollars) before the latter of (i) thirty (30) days after the Effective Date or (ii) ten (10) days after receiving complete wire instructions and any related verifications from the Plaintiff States. Such payment shall be made via electronic deposit to the State of Maine, who will distribute such funds to the Plaintiff States. Such Monetary Payment is provided for the purpose of settlement only, and constitutes neither a penalty nor a fine. The payment may be used for any one or more of the following purposes, by the Attorneys General as they, in their sole discretion, see fit:

A. payment of attorneys' fees and expenses;

B. antitrust or consumer protection law enforcement;

C. for deposit into a state antitrust or consumer protection account (e.g., revolving account, trust account), for use in accordance with the state laws governing that account;

D. for deposit into a fund exclusively dedicated to assisting state attorneys general enforce the antitrust laws by defraying the costs of a) experts, economists, and consultants in multistate antitrust investigations and litigation, b) training or continuing education in antitrust for attorneys in state attorney general offices, or c) information management systems used in multistate antitrust investigations and litigation; or

E. for any other purpose as the attorneys general deem appropriate, consistent with the various states' laws.

Plaintiff States agree to notify Indivior of the amount of any Monetary Payment paid to class members in MDL No. 13-MD-2445 in the United States District Court for the Eastern District of Pennsylvania, if any.

IV. NOTIFICATION REQUIREMENT

Indivior shall notify the Liaison States within 30 calendar days of starting to Market, either directly or through a licensee, Drug Products in the United States by:

A. Receiving FDA approval to Market a Drug Product in the United States;

B. Acquiring Control of a Person that has FDA approval to Market a Drug Product in the United States; or

C. Acquiring or licensing a Drug Product that, at the time of such acquisition, has FDA approval to be Marketed in the United States.

V. REPORTING REQUIREMENTS

Indivior shall submit to the Liaison States all reports required under Section V of the Stipulated Order for Permanent Injunction and Equitable Monetary Relief (ECF No. 5) entered in *Federal Trade Commission v. Indivior Inc.*, 1:20-cv-00036-JPJ-PMS (W.D. Va.).

VI. CHANGE OF CORPORATE CONTROL

A. Indivior shall notify Liaison States at least 30 calendar days prior to:

1. Any proposed dissolution of Indivior;
2. Any proposed acquisition, merger, or consolidation of Indivior; or
3. Any other change in Indivior, including, but not limited to, assignment and the creation, sale or dissolution of subsidiaries, if such change might affect the compliance obligations arising out of this Order.

B. No information or documents obtained by the means provided in Section VI shall be divulged by the Plaintiff States to any person other than an authorized representative of the Plaintiff States, except in the course of a legal proceeding regarding enforcement of this Order, or as otherwise required by law.

C. If any Plaintiff State receives a request to divulge information provided by Indivior under Section VI.A to any person other than an authorized representative of the Plaintiff States (whether pursuant to a Freedom of Information Act, a Sunshine law, a subpoena, or otherwise), the Plaintiff State shall notify Indivior of this request as soon as practicable, consistent with the shorter of 21 days' notice or the notice provided by state law, before any such disclosure is made.

VII. ACCESS TO INFORMATION

A. For the purpose of determining or securing compliance with this Order and subject to any legally recognized privilege or any applicable privacy laws and regulations, Indivior shall, upon reasonable notice and in response to a written request by any of the Plaintiff States:

1. Provide the requesting Plaintiff State with documents and other electronically-stored information in Indivior's possession, custody, or control, that are relevant to compliance under the Order; and
2. Permit the requesting Plaintiff State to interview officers, directors, or employees of Indivior, who may have counsel (representing the Indivior, the individual, or both) present, regarding matters that are relevant to compliance under the Order.

B. No information or documents obtained by the means provided in this Section VII shall be divulged by the Plaintiff States to any person other than an authorized representative of

the Plaintiff States, except in the course of a legal proceeding regarding enforcement of the Order, or as otherwise required by law.

C. If any Plaintiff State receives a request to divulge information provided by Indivior under Section VII.A to any person other than an authorized representative of the Plaintiff States (whether pursuant to a Freedom of Information Act, a Sunshine law, a subpoena, or otherwise), the Plaintiff State shall notify Indivior of this request as soon as practicable, consistent with the shorter of 21 days' notice or the notice provided by state law, before any such disclosure is made.

VIII. RETENTION OF JURISDICTION

This Court shall retain jurisdiction of this matter for purposes of enforcing this Order. Should a Plaintiff State or Indivior have a reasonable basis to believe that a party has engaged in a practice that violates a provision of this Order subsequent to the Effective Date, then such Plaintiff State or Indivior shall notify the party in writing of the specific objection, identify with particularity the provision of this Order that the practice appears to violate, and give the party thirty (30) days to respond to the notification before seeking relief from this Court.

IX. EXPIRATION OF THE ORDER

Unless otherwise specified in this Order, Sections I, II, IV, V, VI, and VII of this Order shall expire upon expiration of the Stipulated Order for Permanent Injunction and Equitable Monetary Relief (ECF No. 5) entered in *Federal Trade Commission v. Indivior Inc.,* 1:20-cv-00036-JPJ-PMS (W.D. Va.).

X. DISMISSAL AND RELEASE OF CLAIMS

This Action and Complaint are hereby dismissed with prejudice and each party shall bear its own costs.

In exchange for the Monetary Payment and agreement to abide by the terms contained in this Order, the Plaintiff States hereby fully and forever release and discharge the Released Entities from the Released Claims.

This Order and legal process to enforce the terms of this Order shall provide the sole and exclusive remedy for any and all Released Claims, and the Plaintiff States shall be forever barred from initiating, asserting, maintaining, or prosecuting any and all Released Claims against Indivior. Plaintiff States expressly waive, solely with respect to the Released Claims, any and all rights and benefits conferred by Section 1542 of the California Civil Code or similar state laws. Plaintiff States may hereafter discover facts other than or different from those which it knows or believes to be true with respect to the Released Claims, but Plaintiff States hereby expressly release any known or unknown, foreseen or unforeseen, suspected or unsuspected, contingent or non-contingent Released Claims, whether or not concealed or hidden, without regard to the subsequent discovery or existence of such different or additional facts.

XI. ADDITIONAL PROVISIONS

A. All required notices to the Liaison States under this Order may be made by electronic mail to the addresses set forth in the definition of Liaison States. All required notices to Indivior under this Order shall be made by both regular and electronic mail to the following addresses:

Indivior, Inc.
Attn: Chief Legal Officer
10710 Midlothian Tpke
Suite 125
North Chesterfield, VA 23235
Legal@indivior.com

Both the Plaintiff States and Indivior may change the addresses for notice by providing written notice of the updated addresses to the other party.

B. This Order may be modified or amended only by a written stipulation of the Parties as approved by the Court.

C. Indivior shall not knowingly cause a third party to engage in practices prohibited by this Order on its behalf.

D. Any failure by any party to this Order to insist upon the strict performance by any other party of any of the provisions of this Order shall not be deemed a waiver of any of the provisions of this Order, and such party, notwithstanding such failure, shall have the right thereafter to insist upon the specific performance of any and all of the provisions of this Order.

E. This Order represents the full and complete terms of the settlement entered into by the Parties hereto. In any action undertaken by the Parties, no prior versions of this Order and no prior versions of any of its terms that were not entered by the Court in this Order, may be introduced for any purpose whatsoever.

F. This Order may be executed in counterparts, and an electronic signature shall be deemed to be, and shall have the same force and effect as, an original signature.

[PROPOSED] ORDER

And now on this [____] day of June 2023, pursuant to and upon consideration of the Stipulated Final Judgment and Dismissal with Prejudice is APPROVED and SO ORDERED.

It is further ORDERED that having resolved all claims against the last remaining Defendant and pursuant to the provisions of Rule 41.1(b) of the Local Rules of Civil Procedure, the above action is DISMISSED with prejudice, without costs.

BY THE COURT:

_____

Judge Mitchell S. Goldberg

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May 26, 2023

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May 31, 2023

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CERTIFICATE OF SERVICE

I hereby certify that on June 1, 2023, I electronically filed the [Proposed] Stipulated Final Judgment and Dismissal with Prejudice using the Court's CM/ECF system, which will automatically send email notification of such filing to all attorneys of record. Unredacted copies were sent to the Court via U.S. Mail and were served on all parties via electronic mail.

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