

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

IN RE SUBOXONE (BUPRENORPHINE
HYDROCHLORIDE AND NALOXONE)
ANTITRUST LITIGATION

MDL No. 2445

THIS DOCUMENT RELATES TO:

Master File No. 2:13-MD-2445-MSG

Wisconsin, et. al. v. Indivior Inc. et. al.

Case No. 2:16-cv-5073-MSG

STATE OF WISCONSIN et. al.

Plaintiffs,

Civ. A. No. 16-cv-5073

v.

Indivior Inc. f/k/a Reckitt Benckiser
Pharmaceuticals, Inc., et. al.

Defendants.

**[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. § 1391(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

FOR INDIVIOR INC.



Jeff Burris
Director and Secretary
10710 Midlothian Tpke
Suite 125
North Chesterfield, VA 23235

FOR THE STATE OF WISCONSIN
JOSHUA L. KAUL
ATTORNEY GENERAL

By: 

Gwendolyn J. Lindsay Cooley
Assistant Attorney General
17 W. Main St
PO Box 7857
Madison, WI 53707-7857

Wisconsin v. Indivior, Case No. 16-CV-5073

May 26, 2023

STATE OF ALABAMA

STEVE MARSHALL, ATTORNEY GENERAL

By: 

Olivia W. Martin

Assistant Attorney General

Alabama Office of the Attorney General

501 Washington Ave., Montgomery, AL 36103

Wisconsin v. Indivior, Case No. 16-CV-5073
May 31, 2023

STATE OF ALASKA
TREG TAYLOR, ATTORNEY GENERAL

By: /s/ Ian Engelbeck
Ian R. Engelbeck
Assistant Attorney General
Alaska Department of Law
Special Litigation Section
1031 West 4th Ave., Suite 200
Anchorage, AK 99501

Attorney for Plaintiff State of Alaska

FOR PLAINTIFF STATE OF ARKANSAS:

TIM GRIFFIN
ATTORNEY GENERAL



AMANDA J. WENTZ
Ark. Bar No. 2021066
Assistant Attorney General
Office of the Arkansas Attorney General
323 Center Street, Suite 200
Little Rock, AR 72201
(501) 682-1178
Amanda.Wentz@ArkansasAG.gov

Attorney for Plaintiff State of Arkansas

1 ROB BONTA
2 Attorney General of California
3 PAULA BLIZZARD
4 Senior Assistant Attorney General

4 */s/ Quyen D. Toland*
5 QUYEN D. TOLAND
6 Deputy Attorney General
7 Office of the Attorney General
8 455 Golden Gate Ave., Suite 11000
9 San Francisco, CA 94102-7004
10 Tel.: (415) 510-3534
11 E-mail: Quyen.Toland@doj.ca.gov

12 *Attorneys for Plaintiff State of California*

13
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FOR PLAINTIFF STATE OF COLORADO:

PHILIP J. WEISER
ATTORNEY GENERAL

/s/ Carla J. Baumel

Carla J. Baumel
Assistant Attorney General
Consumer Protection Section
Colorado Department of Law
Ralph L. Carr Colorado Judicial Center
1300 Broadway, 7th Floor
Denver, CO 80203
Email: Carla.Baumel@coag.gov
Telephone: (720) 508-6235

Attorneys for Plaintiff State of Colorado

FOR PLAINTIFF STATE OF CONNECTICUT

WILLIAM TONG
ATTORNEY GENERAL

/s/ Nicole Demers

Nicole Demers

Deputy Associate Attorney General

Antitrust Section

Connecticut Office of the Attorney General

165 Capitol Ave.

Hartford, CT 06106

Tel.: (860) 808-5030

nicole.demers@ct.gov

Attorneys for Plaintiff State of Connecticut

Wisconsin v. Indivior, Case No. 16-CV-5073
May 31, 2023

STATE OF DELAWARE
KATHLEEN JENNINGS, ATTORNEY GENERAL

By: /s/ Michael A. Undorf
Michael A. Undorf
Deputy Attorney General
Delaware Department of Justice
820 N. French St., 5th Floor
Wilmington, DE 19801
(302) 683-8816
Michael.Undorf@delaware.gov

Attorney for Plaintiff State of Delaware

FOR THE PLAINTIFF STATE THE DISTRICT OF COLUMBIA:

BRIAN L. SCHWALB
ATTORNEY GENERAL

JENNIFER C. JONES
Deputy Attorney General
Public Advocacy Division

BETH MELLE
WILLIAM F. STEPHENS
Assistant Deputy Attorneys General
Public Advocacy Division

/s/Adam Gitlin

ADAM GITLIN [90004308]
Chief, Antitrust and Nonprofit Enforcement
Section
Public Advocacy Division
ELIZABETH G. ARTHUR [1531185]
Assistant Attorneys General
Public Advocacy Division
400 6th Street NW, 10th Floor
Washington, D.C. 20001
Tel.: 202-442-9864

*Attorneys for Plaintiff State the District of
Columbia*

Wisconsin v. Indivior, Case No. 16-CV-5073

May 31, 2023

STATE OF FLORIDA
ASHLEY MOODY, ATTORNEY GENERAL

By: /s/ Nicholas J. Weilhammer

Nicholas J. Weilhammer (FL Bar No. 479322)
Associate Deputy Attorney General for Enforcement

Lizabeth A. Brady (FL Bar No. 457991)

Director of Antitrust Enforcement

R. Scott Palmer (FL Bar No. 220353)

Special Counsel for Antitrust Enforcement

Rachel S. Brackett (FL Bar No. 109775)

Assistant Attorney General

Florida Office of the Attorney General

Antitrust Division

PL-01, The Capitol

Tallahassee, FL 32399

Telephone: (850) 414-3300

Fax: (850) 488-9134

Email: Nicholas.weilhammer@myfloridalegal.com

Attorneys for the Plaintiff State of Florida

FOR PLAINTIFF STATE OF GEORGIA

/s/ Charles Thimmesch

Christopher M. Carr 112505

Attorney General

Margaret K. Eckrote 238709

Deputy Attorney General

Jeffrey W. Stump 690425

Senior Assistant Attorney General

Charles Thimmesch 322197

Assistant Attorney General

Office of the Attorney General

40 Capitol Square, SW

Atlanta, Georgia 30334

(404) 458-3626

cthimmesch@law.ga.gov

Counsel for Georgia

Wisconsin v. Indivior, Case No. 16-CV-5073

May 31, 2023

STATE OF HAWAII
ANNE E. LOPEZ, ATTORNEY GENERAL

By: /s/ Rodney I. Kimura.
Rodney I. Kimura
Deputy Attorney General
Department of the Attorney General
State of Hawaii
425 Queen Street
Honolulu, HI. 96813

Attorneys for Plaintiff State of Hawaii

FOR PLAINTIFF STATE OF IDAHO:

RAÚL R. LABRADOR
ATTORNEY GENERAL

/s/ John K. Olson

John K. Olson, Acting Division Chief
Consumer Protection Division
Office of the Attorney General
954 W. Jefferson Street, 2nd Floor
P.O. Box 83720
Boise, Idaho 83720-0010
Telephone: (208) 334-2424
john.olson@ag.idaho.gov

Attorneys for Plaintiff State of Idaho

FOR PLAINTIFF STATE OF ILLINOIS

KWAME RAOUL
ATTORNEY GENERAL

By: /s/ Elizabeth L. Maxeiner

Elizabeth L. Maxeiner

Chief, Antitrust Bureau

Office of the Illinois Attorney General

100 W. Randolph St. 11th Fl.

Chicago, Illinois 60601

Elizabeth.maxeiner@ilag.gov

Attorneys for Plaintiff State of Illinois

FOR PLAINTIFF STATE OF IOWA:

BRENNA BIRD
ATTORNEY GENERAL

/s/ Noah Goerlitz

Noah Goerlitz
Assistant Attorney General
Office of the Iowa Attorney General
1305 E. Walnut St.
Des Moines, IA 50319
Telephone: (515) 725-1018
noah.goerlitz@ag.iowa.gov

Attorney for Plaintiff State of Iowa

FOR PLAINTIFF STATE OF KANSAS:

KRIS W. KOBACH
ATTORNEY GENERAL

/s/ Lynette R. Bakker

Lynette R. Bakker
First Assistant Attorney General
Antitrust & Business Organizations
Public Protection Division
Office of the Kansas Attorney General
120 S.W. 10th Avenue, 2nd Floor
Topeka, KS 66612-1597
Telephone: (785) 296-3751
Fax: (785-291-3699
Email: lynette.bakker@ag.ks.gov

Attorneys for Plaintiff State of Kansas

Office of the Attorney General of Kentucky

s/ Jonathan E. Farmer

Jonathan E. Farmer

Deputy Executive Director of Consumer Protection

Office of the Attorney General of Kentucky

1024 Capital Center Drive, Suite 200

Frankfort, KY 40601

Tel: 502-696-5448

Fax: 502-573-8317

Jonathan.Farmer@ky.gov

ATTORNEY FOR THE STATE OF KENTUCKY

Respectfully submitted,

JEFF LANDRY
ATTORNEY GENERAL
Attorney General of Louisiana

By: /s/ Christopher J. Alderman
Christopher J. Alderman (LA #38652)
Section Chief, Assistant Attorney General
Public Protection Division, Complex Litigation
Unit

1885 N. 3rd St., 4th Floor.
Baton Rouge, LA 70802
Tel: 225.326.6400
Fax: 225.326.6499

AldermanC@ag.Louisiana.gov

FOR PLAINTIFF STATE OF MAINE:

AARON M. FREY
ATTORNEY GENERAL

/s/ Christina M. Moylan

Christina M. Moylan, AAG
Chief, Consumer Protection Division
Office of the Attorney General
6 State House Station
Augusta, Maine 04333-0006
Telephone: (207) 626-8800
christina.moylan@maine.gov

Attorneys for Plaintiff State of Maine

Wisconsin v. Indivior, Case No. 16-CV-5073
May 31, 2023

STATE OF MARYLAND
ANTHONY G. BROWN, ATTORNEY GENERAL

By: /s/Schonette J. Walker
Schonette J. Walker
Assistant Attorney General
Chief, Antitrust Division

Gary Honick
Assistant Attorney General
Deputy Chief, Antitrust Division

Byron Warren
Assistant Attorney General
Office of the Maryland Attorney General
200 St. Paul Place
Baltimore, MD 21202

FOR PLAINTIFF COMMONWEALTH OF MASSACHUSETTS:

ANDREA JOY CAMPBELL
Attorney General

/s/ William T. Matlack
WILLIAM T. MATLACK (MA BBO No. 552109)
Assistant Attorney General, Chief, Antitrust Division
Office of the Attorney General One
Ashburton Place, 18th Floor Boston,
MA 02108
Tel: (617) 727-2200
Email: William.Matlack@mass.gov

FOR THE PLAINTIFF STATE OF MICHIGAN:

DANA NESSEL
ATTORNEY GENERAL

/s/ Carl J. Hammaker

Carl J. Hammaker (P81203)
Darrin F. Fowler (P53464)
Assistant Attorneys General
Michigan Dep't of Attorney General
Corporate Oversight Division
P.O. Box 30736
Lansing, MI 48909
Email: HammakerC@michigan.gov
Telephone: (517) 335-7632

Attorneys for Plaintiff State of Michigan

May 31, 2023

KEITH ELLISON
Attorney General
State of Minnesota

JESSICA WHITNEY
Deputy Attorney General

JAMES W. CANADAY
Deputy Attorney General

/s/ Justin Moor
JUSTIN MOOR
Assistant Attorney General
Atty. Reg. No. 0397596

445 Minnesota Street, Suite 1400
St. Paul, Minnesota 55101-2130
(651) 724-9627
justin.moor@ag.state.mn.us

ATTORNEYS FOR THE STATE OF MINNESOTA

FOR PLAINTIFF STATE OF MISSISSIPPI

LYNN FITCH, ATTORNEY GENERAL
STATE OF MISSISSIPPI

By: /s/ Hart Martin

Hart Martin (MSB # 106129)
Deputy Director and Special Assistant Attorney General
Consumer Protection Division
Mississippi Attorney General's Office
Post Office Box 220
Jackson, Mississippi 39205
Telephone: 601-359-4223
Fax: 601-359-4231
Hart.martin@ago.ms.gov

FOR THE STATE OF MISSOURI

ANDREW BAILEY
ATTORNEY GENERAL

By: 

Michael Schwalbert
Assistant Attorney General
Consumer Protection Section
Missouri Attorney General's Office
815 Olive Street | Suite 200
Saint Louis, Missouri 63101
michael.schwalbert@ago.mo.gov
Phone: 314-340-7888
Fax: 314-340-7981

FOR PLAINTIFF STATE OF NEBRASKA

MICHAEL T. HILGERS
ATTORNEY GENERAL

/s/ Justin C. McCully

Justin C. McCully
Colin P. Snider
Assistant Attorney General
Consumer Protection Bureau
Nebraska Attorney General's Office
2115 State Capitol
Lincoln, NE 68509-8920
Telephone: (402) 471-2682
Fax: (402) 471-4725
Justin.mccully@nebraska.gov
Colin.snider@nebraska.gov

Attorneys for Plaintiff State of Nebraska

FOR PLAINTIFF STATE OF NEW HAMPSHIRE:

JOHN T. FORMELLA
ATTORNEY GENERAL

/s/ Zachary Frish

Zachary A. Frish

Attorney

Consumer Protection & Antitrust Bureau

New Hampshire Department of Justice | Office of the Attorney General

33 Capitol Street

Concord, NH 03301

(603) 271-2150

zachary.a.frish@doj.nh.gov

Attorney for Plaintiff State of New Hampshire

FOR PLAINTIFF STATE OF NEW MEXICO:

RAÚL TORREZ
ATTORNEY GENERAL

/s/ Nicholas M. Sydow

Nicholas M. Sydow
Deputy Solicitor General
Office of the New Mexico Attorney General
408 Galisteo St.
Santa Fe, NM 87501
Telephone: (505) 490-4060
nsydow@nmag.gov

Attorneys for Plaintiff State of New Mexico

FOR THE STATE OF NEW YORK
LETTITIA JAMES
ATTORNEY GENERAL

/s/ Elinor R. Hoffmann

Elinor R. Hoffmann

Chief, Antitrust Bureau

Amy McFarlane

Deputy Chief, Antitrust Bureau

Saami Zain, Assistant Attorney General

28 Liberty Street

New York, NY 10005

FOR PLAINTIFF STATE OF NORTH CAROLINA

JOSHUA H. STEIN
ATTORNEY GENERAL

/s/ Jessica V. Sutton

Jessica V. Sutton
Special Deputy Attorney General
Kimberley D'Arruda
Director, Technology, Healthcare, and Antitrust Section
Consumer Protection Division
North Carolina Department of Justice
P.O. Box 629
Raleigh, NC 27602
Tel.: (919) 716-0998
jsutton2@ncdoj.gov

Attorneys for Plaintiff State of North Carolina

FOR PLAINTIFF STATE OF OHIO:

DAVE YOST
ATTORNEY GENERAL

/s/ Beth A. Finnerty

Beth A. Finnerty
Section Chief, Antitrust Section
Office of the Ohio Attorney General
30 E. Broad St., 26th Floor
Columbus, OH 43215
Telephone: (614) 466-4328
Fax: (614) 995-0266
Email: Beth.Finnerty@OhioAGO.gov

Attorneys for Plaintiff State of Ohio

Date: May 26, 2023

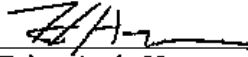
FOR PLAINTIFF STATE OF OKLAHOMA:

GENTNER DRUMMOND
ATTORNEY GENERAL

/s/ Caleb J. Smith

Caleb J. Smith, OBA No. 33613
Assistant Attorney General
Consumer Protection Unit
Office of the Oklahoma Attorney General
15 West 6th Street
Suite 1000
Tulsa, OK 74119
Tel. (918) 581-2230
Fax (918) 938-6348
Email: caleb.smith@oag.ok.gov

Attorney for Plaintiff State of Oklahoma



Brian A. de Haan
Senior Assistant Attorney General
Civil Enforcement Division
Oregon Department of Justice
100 SW Market Street
Portland, OR 97201
Tel. (971) 673-1880
brian.a.dehaan@doj.state.or.us

FOR PLAINTIFF COMMONWEALTH OF PENNSYLVANIA:

MICHELLE A. HENRY
ATTORNEY GENERAL

/s/ Tracy W. Wertz

Tracy W. Wertz

Chief Deputy Attorney General

Antitrust Section

Pennsylvania Office of Attorney General

14th Floor Strawberry Square,

Harrisburg, PA 17120-1410

Telephone: (717) 787-4530

twertz@attorneygeneral.gov

Attorneys for Plaintiff Commonwealth of Pennsylvania

FOR PLAINTIFF STATE OF RHODE ISLAND:

PETER F. NERONHA
ATTORNEY GENERAL

/s/ Adam D. Roach

Adam D. Roach
Special Assistant Attorney General
State of Rhode Island | Office of the Attorney General
150 South Main Street
Providence, RI 02903
Email: aroach@riag.ri.gov
Telephone: (401) 274-4400 x 2490

Attorneys for Plaintiff State of Rhode Island

Wisconsin v. Indivior, Case No. 16-CV-5073

May 31, 2023

STATE OF SOUTH CAROLINA
ALAN WILSON, ATTORNEY GENERAL

By: /s/ Clark Kirkland, Jr.

Clark Kirkland, Jr.

Assistant Attorney General

Office of the Attorney General

State of South Carolina

P.O. Box 11549

Columbia, SC 29211

FOR PLAINTIFF STATE OF TENNESSEE

JONATHAN SKRMETTI
ATTORNEY GENERAL

/s/ J. Tate Ball

J. Tate Ball

Assistant Attorney General

Consumer Protection Division

Office of the Tennessee Attorney General

P.O. Box 20207

Nashville, Tennessee 37202

Email: Tate.Ball@ag.tn.gov

Telephone: (615)741-8091

Attorneys for the Plaintiff State of Tennessee

Wisconsin v. Indivior, Case No. 16-CV-5073
May 31, 2023

STATE OF UTAH
SEAN D. REYES, ATTORNEY GENERAL

DAVID SONNENREICH
Deputy Attorney General
Antitrust and Data Privacy Section Director

By: /s/ Marie W.L. Martin
Marie W.L. Martin
Assistant Attorney General
Utah Office of the Attorney General
Antitrust and Data Privacy Section
160 E 300 S, 5th Floor
P.O. Box 140830
Salt Lake City, UT 84114-0830
(801)366-0260
mwmartin@agutah.gov

Attorneys for Plaintiff State of Utah

FOR PLAINTIFF STATE OF VERMONT

CHARITY R. CLARK
ATTORNEY GENERAL

By: /s/ Jill S. Abrams

Jill S. Abrams

Assistant Attorney General

Director, Consumer Protection and Antitrust Unit

109 State Street

Montpelier, VT 05609

Attorneys for Plaintiff State of Vermont

FOR PLAINTIFF COMMONWEALTH OF VIRGINIA

JASON S. MIYARES
ATTORNEY GENERAL

By: /s/ Tyler T. Henry
Tyler T. Henry
Assistant Attorney General/Unit Manager
Antitrust Unit
Office of the Virginia Attorney General
202 North 9th Street
Richmond, Virginia 23219
THenry@oag.state.va.us

Attorneys for Plaintiff Commonwealth of Virginia

FOR PLAINTIFF STATE OF WASHINGTON:

ROBERT W. FERGUSON
Attorney General

s/ *Lumi Nodit*

LUMINITA NODIT
Lumi.Nodit@atg.wa.gov
Assistant Attorney General, Antitrust Division
Washington State Office of the Attorney General
800 Fifth Ave., Suite 2000
Seattle, WA 98104
Tel: (206) 254-0568

Attorneys for Plaintiff State of Washington

FOR PLAINTIFF STATE OF WEST VIRGINIA:

PATRICK MORRISEY
ATTORNEY GENERAL

/s/ Douglas L. Davis

Douglas L. Davis, Senior Assistant Attorney General
Consumer Protection and Antitrust Division
Office of the Attorney General
1900 Kanawha Boulevard East
Building 6, Suite 401
Charleston, WV 25305
Telephone: (304) 558-8986
douglas.l.davis@wvago.gov

Attorneys for Plaintiff State of West Virginia

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.

/s Gwendolyn J. Lindsay Cooley
GWENDOLYN J. COOLEY
Assistant Attorney General
State Bar #1053856
Wisconsin Department of Justice
Post Office Box 7857
Madison, Wisconsin 53707-7857
(608) 261-5810
(608) 266-2250 (Fax)
cooleygj@doj.state.wi.us