

**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, 5<sup>th</sup> 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.



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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 4<sup>th</sup> 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](mailto:Quyen.Toland@doj.ca.gov)

12 *Attorneys for Plaintiff State of California*

13  
14  
15  
16  
17  
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23  
24  
25  
26  
27  
28

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, 7<sup>th</sup> Floor  
Denver, CO 80203  
Email: [Carla.Baumel@coag.gov](mailto: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](mailto:nicole.demers@ct.gov)

*Attorneys for Plaintiff State of Connecticut*

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*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., 5<sup>th</sup> 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, 10<sup>th</sup> 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](mailto: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, 2<sup>nd</sup> Floor  
P.O. Box 83720  
Boise, Idaho 83720-0010  
Telephone: (208) 334-2424  
[john.olson@ag.idaho.gov](mailto: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. 11<sup>th</sup> Fl.

Chicago, Illinois 60601

[Elizabeth.maxeiner@ilag.gov](mailto: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](mailto: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](mailto: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. 3<sup>rd</sup> St., 4<sup>th</sup> Floor.  
Baton Rouge, LA 70802  
Tel: 225.326.6400  
Fax: 225.326.6499

[AldermanC@ag.Louisiana.gov](mailto: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](mailto: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](mailto: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](mailto: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](mailto:Justin.mccully@nebraska.gov)  
[Colin.snider@nebraska.gov](mailto: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](mailto:nsydow@nmag.gov)

*Attorneys for Plaintiff State of New Mexico*

FOR THE STATE OF NEW YORK  
LETITIA 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](mailto: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., 26<sup>th</sup> Floor  
Columbus, OH 43215  
Telephone: (614) 466-4328  
Fax: (614) 995-0266  
Email: [Beth.Finnerty@OhioAGO.gov](mailto:Beth.Finnerty@OhioAGO.gov)

*Attorneys for Plaintiff State of Ohio*

Date: May 26, 2023

FOR PLAINTIFF STATE OF OKLAHOMA:

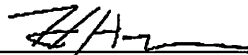
GENTNER DRUMMOND  
ATTORNEY GENERAL

/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](mailto: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

14<sup>th</sup> Floor Strawberry Square,

Harrisburg, PA 17120-1410

Telephone: (717) 787-4530

[twertz@attorneygeneral.gov](mailto: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](mailto: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, 5<sup>th</sup> 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 9<sup>th</sup> 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](mailto: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](mailto:cooleygj@doj.state.wi.us)