

ATTORNEY GENERAL OF THE STATE OF NEW YORK
HEALTH CARE BUREAU
LAW ENFORCEMENT MISCONDUCT INVESTIGATIVE OFFICE

In the Matter of

Assurance No. 25-050

**Investigation by LETITIA JAMES,
Attorney General of the State of New York, of**

Indivior Inc.,

Respondent.

ASSURANCE OF DISCONTINUANCE

The Office of the Attorney General of the State of New York (“OAG”) commenced an investigation pursuant to N.Y. Exec. Law §§ 63(12) and 75 related to the Broome County Sheriff’s Office’s (“BCSO”) purchase of Opvee, a nasal spray medication containing nalmefene, an opioid antagonist, for use in its opioid overdose prevention program (“OOPP”). Opvee is manufactured and sold by Respondent Indivior Inc. (“Indivior”). This Assurance of Discontinuance (“Assurance”) contains the findings of OAG’s investigation related to BCSO’s purchase of Opvee from Indivior and the relief agreed to by OAG and Indivior, whether acting through its respective directors, officers, employees, representatives, agents, affiliates, or subsidiaries, etc. (collectively, the “Parties”).

APPLICABLE LAW

1. In New York, only persons authorized to prescribe, dispense, and administer prescription medications may do so. Unless otherwise authorized, non-medical personnel are not permitted to prescribe, dispense, and administer prescription medications, and doing so risks

running afoul of New York licensing statutes prohibiting the unauthorized practice of medicine. *See* N.Y. Educ. Law § 6512.

2. For the purposes of opioid overdose prevention, New York law permits health care professionals to prescribe and distribute opioid antagonists to non-medical persons, including law enforcement personnel, through a non-patient specific standing order, so that they can administer opioid antagonists without a health professional's direct involvement to any individual who is believed to be experiencing an opioid overdose. N.Y. Pub. Health Law § 3309. N.Y. Pub. Health Law § 3309(3)(a)(i) specifically restricts the opioid antagonist that may be used by non-medical persons "to naloxone and other medications approved by the [New York State Department of Health ("DOH")]" for such purpose."

3. While the U.S. Food and Drug Administration ("FDA") approved Opvee in 2023 for the "emergency treatment of known or suspected opioid overdose in adults and pediatric patients 12 years of age and older," Opvee has not been approved by N.Y. DOH for use by non-medical personnel under N.Y. Pub. Health Law § 3309. Naloxone is currently the only medication approved by N.Y. DOH as an opioid antagonist pursuant to N.Y. Pub. Health Law § 3309, its implementing regulations in 10 NYCRR § 80.138, and N.Y. DOH's Guide for New York State's Registered OOPPs.

OAG's FACTUAL FINDINGS

4. As of January 4, 2024, Indivior representatives corresponded with at least fifteen (15) New York counties about Opvee and conducted presentations about Opvee to individuals including county administrators, commissioners, sheriffs, public and mental health officers, and EMS chiefs.

5. In and around January 2024, BCSO and an employee of Indivior corresponded about the potential sale of Opvee to BCSO. At that time, while Opvee was available by prescription in New York, N.Y. DOH had not approved it for non-prescription use through a standing order for use in an OOPP.

6. BCSO contracts with PrimeCare Medical of New York, based in Harrisburg, PA, and its affiliates (collectively, “PrimeCare”) to provide all medical and mental health care services to Broome County’s incarcerated population.

7. In March and April of 2024, BCSO advised an employee of Indivior that N.Y. DOH had told BCSO that Opvee was not approved for use through a standing order in an OOPP. The Indivior employee stated in response that BCSO was not barred from writing its own non-patient-specific standing order for Opvee. On April 3, 2024, the Broome County Sheriff’s Correctional Division Physician Medical Director (“BCCD Medical Director”), an employee of PrimeCare, provided his medical license information to Indivior and certified that he would be responsible for an Opvee shipment to BCSO.

8. On or about the same day, the BCCD Medical Director signed an undated non-patient-specific standing order for use of Opvee by “trained staff” of BCSO and by PrimeCare’s Broome County-affiliated health care provider personnel.

9. On April 10, 2024, the BCSO Sheriff directed Indivior to open an account for BCSO to purchase Opvee, and on April 11, 2024, BCSO requested to purchase 300 units of Opvee for \$22,500 from Indivior. Indivior shipped 300 units of Opvee to BCSO the same day.

10. On April 22, 2024, BCSO publicly announced that its Opvee “pilot program” was active.

11. On May 20, 2024, a Broome County sheriff's deputy used Opvee on an unconscious person who was experiencing a known or suspected opioid overdose and who had already received a dose of Narcan that was not administered by BCSO.

12. On July 2, 2024, OAG sent BCSO a Cease-and-Desist notification, advising it to immediately cease and desist from obtaining, distributing, administering or utilizing nalmeferene in any way, as doing so may constitute a violation of N.Y. Pub. Health Law § 3309, its implementing regulations in 10 NYCRR § 80.138, and N.Y. DOH's Guide for New York State's Registered Opioid Overdose Prevention Programs.

13. On July 9, 2024, BCSO advised OAG that BCSO complied with the Cease-and-Desist notification.

14. Beginning on July 9, 2024, OAG requested information from Indivior related to its investigation into the BCSO's purchase of Opvee from Indivior. Indivior provided documents in response to OAG's requests and has cooperated with OAG's investigation.

CONCLUSIONS OF LAW

15. OAG finds that BCSO purchased Opvee from Indivior in violation of N.Y. Pub. Health Law § 3309(a)(i), N.Y. Educ. Law § 6512, and 10 NYCRR § 80.138.

16. Indivior admits the OAG's Findings of Fact, paragraphs (4)-(14) above. Indivior does not admit the Conclusions of Law, but agrees to this Assurance to reach resolution on this matter.

17. The OAG finds the relief and agreements contained in this Assurance appropriate and in the public interest.

THEREFORE, the OAG is willing to accept this Assurance pursuant to Executive Law §§ 63(15) and 75, in lieu of commencing a proceeding, action, or continued investigation based on the conduct described above in OAG's Findings of Fact, paragraphs (4)-(14).

IT IS HEREBY UNDERSTOOD AND AGREED, by and between the Parties:

PROSPECTIVE RELIEF

18. The headings used in this Assurance are for reference purposes only and shall not affect the interpretation of the provisions. The terms of this Assurance shall be interpreted based on their content and not the headings provided for convenience.

19. General Injunction:

- a. Indivior hereby acknowledges that, with respect to Opvee:
 - i. It understands and will comply with all applicable federal, state, and local laws and regulations, including but not limited to N.Y. Pub. Health Law § 3309, N.Y. Educ. Law § 6512, and 10 NYCRR § 80.138, and further shall not engage, attempt to engage, assist, or encourage any New York State public entity or agency with respect to conduct by that agency or entity that violates any applicable federal, state, and local laws, including but not limited to N.Y. Pub. Health Law § 3309, N.Y. Educ. Law § 6512, and 10 NYCRR § 80.138. Indivior expressly agrees and acknowledges that any violation of such laws, or any action on its part to engage, assist, or encourage any New York State public entity or agency to violate such laws, is a violation of this Assurance, and that the OAG thereafter may commence the civil action or proceeding contemplated in the Conclusion,

supra, in addition to any other appropriate investigation, action, or proceeding.

- ii. It shall comply with all applicable federal and New York laws and regulations concerning controlled substances, included but not limited to guidance issued by applicable regulators.

- b. With regard to Opvee, Indivior acknowledges its understanding of and continued compliance with any and all applicable federal, state, local laws, and administrative and policy guidances.

20. Nothing in the foregoing section shall affect, infringe upon, or modify Indivior's rights under applicable state and federal laws, including the First Amendment to the United States Constitution.

21. Programmatic Relief:

- a. Indivior will not provide nalmefene to any New York State public entity or agency for use under N.Y. Pub. Health Law § 3309 unless:
 - i. N.Y. Pub. Health Law § 3309 is amended to include nalmefene as an approved opioid antagonist under the statute or related regulations;
 - ii. NY DOH otherwise approves nalmefene as an opioid antagonist under N.Y. Pub. Health Law § 3309; or
 - iii. Nalmefene is otherwise authorized for use in New York State by a governmental authority with the power to provide such authorization.
- b. Indivior will enhance its existing training for its commercial personnel responsible for marketing, promoting, or selling Opvee in the applicable New York state laws. The enhancement of existing training will cover, *inter alia*,

approved statements about Opvee consistent with federal and state requirements, and reiterate that, while a licensed healthcare professional can prescribe Opvee, nalmeferene is not currently an approved opioid antagonist under N.Y. Pub. Health Law § 3309, is not approved by N.Y.DOH in an OOPP, and cannot be used in a standing order in a NYS OOPP program. Indivior will provide OAG with a copy of the enhanced training materials as well as certification of this requirement as part of the compliance certification in Paragraph 22(a).

- c. Within ten (10) days of signing this Assurance, Indivior will accept the return of the 294 unused units of nalmeferene it sold to BCSO and refund BCSO for the full purchase price of \$22,500 for 300 units.
- d. Indivior shall not make any written or oral statement about nalmeferene/Opvee that is unfair, false, misleading, deceptive or unconscionable.
- e. Indivior shall not represent that nalmeferene/Opvee has approvals, characteristics, uses, benefits, or qualities that it does not have.
- f. If, after the Effective Date, Indivior believes there is a material change to state or federal laws, regulations, or non-patient specific standing orders, then upon request of Indivior, the parties will meet and confer about proposed modifications of the Assurance in a manner that is consistent with the changed laws or regulations.
- g. Acceptance of this Assurance by the OAG is not an approval or endorsement by OAG of any of Indivior's policies, practices or procedures, and Indivior shall make no representation to the contrary.

22. Oversight:

- a. *Certification of Compliance:* Indivior shall provide OAG with a certification affirming its compliance with the requirements set forth in this Assurance, paragraph 21, to be submitted to OAG within 60 days following the Effective Date. This certification shall be in writing and be signed by an appropriate authorized individual on behalf of Indivior.
- b. In the event that OAG believes that Indivior has defaulted in the performance of any obligation set forth in this Assurance, OAG will provide written notice of such alleged default to the designated representative of Indivior. Indivior shall then have fourteen (14) days to attempt to cure any alleged default and to certify that that any alleged default has been cured, and seven (7) days to confer with OAG to certify that OAG agrees that any alleged default has been cured, which period may be extended by OAG ("Response and Cure Period"). OAG will not initiate any civil action or other proceeding to enforce or for alleged violations of this Assurance until after the expiration of the Response and Cure Period.
- c. Indivior expressly agrees and acknowledges that a default in the performance of any obligation under this paragraph is a violation of the Assurance, and that OAG thereafter may commence an action or proceeding contemplated, *supra*, in addition to any other appropriate investigation, action, or proceeding, and that evidence that the Assurance has been violated shall constitute prima facie proof of the statutory violations described in paragraphs 4 through 17, pursuant to N.Y. Exec. Law §§ 63(15) and 75.

MISCELLANEOUS

Subsequent Proceedings.

23. Indivior expressly agrees and acknowledges that this Assurance applies only to OAG's investigation related to BCSO's purchase of Opvee from Indivior and Indivior's marketing of Opvee in New York State.

24. Indivior expressly agrees and acknowledges that OAG may initiate an investigation, civil action, or proceeding to enforce this Assurance, for violations of the Assurance, or if the Assurance is voided pursuant to paragraph 32, and agrees and acknowledges that in such event:

- a. Any statute of limitations or other time-related defenses are tolled from and after the effective date of this Assurance;
- b. The OAG may use statements, documents or other materials produced or provided by Indivior prior to or after the effective date of this Assurance;
- c. Any civil action or proceeding must be adjudicated by the courts of the State of New York, and that Indivior irrevocably and unconditionally waives any objection based upon personal jurisdiction, inconvenient forum, or venue.
- d. Evidence of a violation of this Assurance shall constitute prima facie proof of a violation of the applicable laws pursuant to Executive Law § 63(15).

25. If a court of competent jurisdiction determines that Indivior has violated the Assurance, Indivior shall pay to OAG the reasonable cost, if any, of obtaining such determination and of enforcing this Assurance, including without limitation legal fees, expenses, and court costs.

Effects of Assurance:

26. This Assurance does not create any rights or remedies for any third party and is not intended for use by any third party in any other proceeding.

27. This Assurance is not intended: (1) as an admission of liability, fault, or wrongdoing whatsoever by Indivior in any other proceeding; or (2) as an admission by Indivior at any fact-finding hearing in any other proceeding. This does not apply to proceedings brought pursuant to paragraph 22(c).

28. All terms and conditions of this Assurance shall continue in full force and effect on any successor, assignee, or transferee of Indivior. Indivior shall include any such successor, assignment or transfer agreement a provision that binds the successor, assignee or transferee to the terms of the Assurance. No party may assign, delegate, or otherwise transfer any of its rights or obligations under this Assurance without the prior written consent of OAG.

29. Nothing contained herein shall be construed as to deprive any person of any private right under the law.

30. Any failure by OAG to insist upon the strict performance by Indivior of any of the provisions of this Assurance shall not be deemed a waiver of any of the provisions hereof, and OAG, notwithstanding that failure, shall have the right thereafter to insist upon the strict performance of any and all of the provisions of this Assurance to be performed by Indivior.

Communications:

31. All notices, reports, requests, and other communications pursuant to this Assurance must reference Assurance No. 25-050, and shall be in writing and shall, unless expressly provided otherwise herein, be given by hand delivery; express courier; or electronic

mail at an address designated in writing by the recipient, followed by postage prepaid mail, and shall be addressed as follows:

- a. If to Indivior, to: (1) Chief Legal Officer Jeff Burris (Jeff.Burris@Indivior.com) c/o Indivior Inc., 10710 Midlothian Turnpike, Suite 125, Richmond, VA 23235, or in his absence, to the person holding the title of Chief Legal Officer (Legal@Indivior.com); and (2) Counsel to Indivior Vanessa L. Chen (VChen@McGuireWoods.com).

If to OAG, to: Tina Peng (tina.peng@ag.ny.gov) and Susan Lambiase (susan.lambiase@ag.ny.gov), or in their absence, to Darsana Srinivasan (darsana@ag.ny.gov) or the person holding the title of Bureau Chief, Health Care Bureau.

Representations and Warranties:

32. The OAG has agreed to the terms of this Assurance based on, among other things, the representations made to OAG by Indivior and its counsel and OAG's own factual investigation as set forth in Findings, paragraphs (4)-(14) above. Indivior represents and warrants that neither it nor its counsel has made any material representations to OAG that are inaccurate or misleading. If any material representations by Indivior or its counsel are later found to be inaccurate or misleading, this Assurance is voidable by OAG in its sole discretion.

33. No representation, inducement, promise, understanding, condition, or warranty not set forth in this Assurance has been made to or relied upon by Indivior in agreeing to this Assurance.

34. Indivior represents and warrants, through the signatures below, that the terms and conditions of this Assurance are duly approved.

General Principles:

35. Unless a term limit for compliance is otherwise specified within this Assurance, Indivior's obligations under this Assurance are enduring. Nothing in this Agreement shall relieve Indivior of other obligations imposed by any applicable state or federal law or regulation or other applicable law.

36. Indivior agrees not to take any action or to make or permit to be made any public statement denying, directly or indirectly, any finding in the Assurance or creating the impression that the Assurance is without legal or factual basis. Nothing in this paragraph shall affect Indivior's right and ability to advance legal or factual positions in response to, in anticipation, or defense of, any inquiry, audit, litigation, regulatory proceedings, investigations, requests for information, inquiries, potential claims, or other matters, including, without limitation, any inquiry or action brought by an individual, entity, or governmental authority. Nothing contained herein shall be construed to limit the remedies available to OAG in the event that Indivior violates the Assurance after its effective date.

37. This Assurance may not be amended except by an instrument in writing signed on behalf of the Parties to this Assurance.

38. In the event that any one or more of the provisions contained in this Assurance shall for any reason be held by a court of competent jurisdiction to be invalid, illegal, or unenforceable in any respect, in the sole discretion of OAG, such invalidity, illegality, or unenforceability shall not affect any other provision of this Assurance.

39. Indivior acknowledges that it has entered this Assurance freely and voluntarily and upon due deliberation with the advice of counsel.


40. This Assurance shall be governed by the laws of the State of New York without regard to any conflict of laws principles.


41. The Assurance and all its terms shall be construed as if mutually drafted with no presumption of any type against any party that may be found to have been the drafter.

42. This Assurance may be executed in multiple counterparts by the parties hereto. All counterparts so executed shall constitute one agreement binding upon all parties, notwithstanding that all parties are not signatories to the original or the same counterpart. Each counterpart shall be deemed an original to this Assurance, all of which shall constitute one agreement to be valid as of the effective date of this Assurance. For purposes of this Assurance, copies of signatures shall be treated the same as originals. Documents executed, scanned and transmitted electronically and electronic signatures shall be deemed original signatures for purposes of this Assurance and all matters related thereto, with such scanned and electronic signatures having the same legal effect as original signatures.


43. The effective date of this Assurance shall be September 29, 2025.

LETITIA JAMES
Attorney General of the State of New York
28 Liberty Street
New York, NY 10005

By: 
Darsana Srinivasan
Bureau Chief, Health Care Bureau

By: 
Tyler Nims
Bureau Chief, LEMIO

Indivior Inc.

By: 
Jeff Burris
Secretary

STATE OF)
COUNTY OF) ss.:
)

On the 3 day of September in the year 2025 before me personally came Jeff Burris to me known, who, being by me duly sworn, did depose and say that he/she/they reside(s) in 423 Hunt Street, Marietta GA 30060 [if the place of residence is in a city, include the street and street number, if any, thereof]; that he/she/they is (are) the Secretary duly appointed of Indivior Inc., the corporation described in and which executed the above instrument; that he/she/they know(s) the seal of said corporation; that the seal affixed to said instrument is such corporate seal; that it was so affixed by authority of the board of directors of said corporation, and that he/she/they signed his/her/their names(s) thereto by like authority.

Sworn to before me this

3 day of September, 2025

NOTARY PUBLIC

