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SETTLEMENT AGREEMENT

This Settlement Agreement (the "Agreement") is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General ("OIG") of the Department of Health and Human Services ("HHS"), the Defense Health Agency ("DHA"), acting on behalf of the TRICARE Program; and the United States Department of Veterans Affairs ("VA") (collectively, the "United States"); and Biohaven Pharmaceutical Holding Company Ltd. and its subsidiaries ("Biohaven"); and Patricia Frattasio ("Relator") (hereafter collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

- A. Biohaven is a corporation that was headquartered in New Haven, CT. Biohaven developed, distributed, marketed, and sold the drug sold under the trade name Nurtec ODT. In October 2022, Biohaven became a wholly-owned subsidiary of Pfizer Inc.
- B. On August 5, 2021, Patricia Frattasio filed a *qui tam* action in the United States District Court for the Western District of New York (the "Court"), captioned *United States et al.* ex rel. Frattasio v. Biohaven Pharmaceuticals Holding Company Ltd., Case No. 6:21-CV-06539, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the "Civil Action"). The United States is intervening in the Civil Action for purposes of settlement.
- C. The United States contends that Biohaven submitted or caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll ("Medicare"), the Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 ("Medicaid"); the TRICARE Program, 10 U.S.C. §§ 1071-1110b ("TRICARE"); and the Department of Veterans Affairs, Veterans Health Administration, 38 U.S.C. Chapter 17.
 - D. Biohaven has entered or will be entering into separate settlement agreements,

described in Paragraph 1.b., below (hereinafter referred to as the "Medicaid State Settlement Agreements"), with certain states and the District of Columbia in settlement of the Covered Conduct (defined herein). States with which Biohaven executes a Medicaid State Settlement Agreement in the form to which Biohaven and the National Association of Medicaid Fraud Control Units ("NAMFCU") Negotiating Team have agreed, or in a form otherwise agreed to by Biohaven and an individual State, shall be defined as "Medicaid Participating States."

E. The United States contends that it and the Medicaid Participating States have certain civil claims, as specified in Paragraph 3, below, against Biohaven for engaging in the following conduct during the period March 1, 2020 through September 30, 2022 (hereinafter referred to as the "Covered Conduct"):

The United States contends that Biohaven provided improper remuneration to health care providers to induce them to prescribe Nurtec ODT for federal health care program beneficiaries, in violation of the Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b(b). Biohaven paid health care providers ("providers") honoraria to present to other providers about Nurtec ODT at speaker programs, which were held virtually, in providers' offices, or at offsite venues, such as high-end restaurants. The United States contends that Biohaven selected certain providers to be part of the Nurtec ODT speaker bureau and/or provided paid speaking opportunities to providers with the intent that the speaker honoraria would induce these providers to prescribe Nurtec ODT. Biohaven paid some providers tens of thousands of dollars, and in some cases more than a hundred thousand dollars, for speaker programs. Speaker programs were also attended by individuals with no educational need to attend, such as the speaker's spouse or family members, friends, and colleagues from the speaker's own practice. The United States further contends that certain providers who attended multiple programs on the same topic, and received expensive meals and drinks paid for by Biohaven, received no educational benefit from attending these programs; rather, Biohaven intended the purchase of meals and drinks to induce these providers to prescribe Nurtec ODT.

As a result of this conduct, the United States contends that certain of Biohaven's speaker programs resulted in Biohaven providing remunerations to providers with the intent of causing providers to prescribe Nurtec ODT, which caused false claims to be submitted to Medicare, Medicaid, TRICARE, and VA.

F. Biohaven denies the United States' allegations in Paragraph E.

- G. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Agreement and to Relator's reasonable expenses, attorneys' fees and costs.
- H. This Agreement is neither an admission of liability by Biohaven nor a concession by the United States that its claims are not well founded.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

- 1. <u>Biohaven</u> shall cause to be paid to the United States and the Medicaid Participating States, collectively, the sum of \$59,746,277.54, less any deductions for States not participating in the Medicaid Participating States' agreements, plus interest at a rate of 4% per annum from August 30, 2024, and continuing until and including the date of payment (the "Settlement Amount") under the terms and conditions set forth in this Agreement. Of the Settlement Amount, \$29,873,138.77 is restitution. The Settlement Amount shall be paid to the United States and the Medicaid Participating States as follows:
 - a. Biohaven shall cause to be paid to the United States the sum of \$50,209,951.27, plus accrued interest as set forth above ("Federal Settlement Amount"). Of the Federal Settlement Amount, \$25,104,975.64 is restitution. The Federal Settlement Amount shall be paid no later than 14 days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the Civil Division of the United States Department of Justice.
 - b. Biohaven shall cause to be paid the Medicaid Participating States the sum of
 \$9,536,326.27, less any deductions for States not participating in the Medicaid
 Participating States' agreements, plus accrued interest as set forth above, to be disbursed

in accordance with written instructions from the NAMFCU Negotiating Team and under the terms and conditions of the agreements that Biohaven will enter into with the Medicaid Participating States.

- 2. Conditioned upon the United States receiving the Federal Settlement Amount and as soon as feasible after receipt, the United States shall pay \$8,410,166.84 to Relator by electronic funds transfer ("Relator's Share"). No other relator payments shall be made by the United States with respect to the matters covered by this Agreement.
- 3. Biohaven, Relator and Relator's counsel have entered into a separate agreement with respect to the payment by Biohaven of Relator's attorneys' fees, costs, and expenses pursuant to 31 U.S.C. § 3730(d)(1) and applicable state provisions.
- 4. Subject to the exceptions in Paragraph 6 (concerning reserved claims) below, and upon the United States' receipt of the Federal Settlement Amount under Paragraph 1.b., the United States releases Biohaven, together with its current and former parent corporations, affiliates, direct and indirect subsidiaries, brother or sister corporations, divisions, corporate owners, and the predecessors, successors, transferees, heirs, and assigns of any of them, from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.
- 5. Subject to the exceptions in Paragraph 6 below, and upon the United States' receipt of the Federal Settlement Amount under Paragraph 1.b., Relator, for herself and for her heirs, successors, attorneys, agents, and assigns, releases Biohaven, together with its current and former parent corporations, affiliates, direct and indirect subsidiaries, brother or sister corporations, divisions, corporate owners, and the predecessors, successors, transferees, heirs,

and assigns of any of them; and all of their current and former officers, directors, employees, attorneys, any other agents, and the predecessors, successors, transferees, heirs, and assigns of any of them, from any claims that Relator has asserted, could have asserted, or may assert in the future related to the Civil Action, including, from any civil monetary claim the Relator has on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733.

- 6. Notwithstanding the releases given in Paragraphs 4 and 5 of this Agreement, or any other term of this Agreement, the following claims and rights of the United States are specifically reserved (the "Reserved Claims") and are not released:
 - a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
 - b. Any criminal liability;
 - c. Except as explicitly stated in this Agreement, any administrative liability or enforcement right, including mandatory or permissive exclusion from Federal health care programs;
 - d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
 - e. Any liability based upon obligations created by this Agreement;
 - f. Any liability of individuals.
- 7. Relator and her heirs, personal representatives, legal representatives, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon Relator's receipt of the Relator's Share, Relator and her heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising

from the filing of the Civil Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action.

- 8. Relator, for herself, and for her heirs, personal representatives, legal representatives, successors, attorneys, agents, and assigns, releases Biohaven, together with its current and former parent corporations, affiliates, direct and indirect subsidiaries, brother or sister corporations, divisions, corporate owners, and the predecessors, successors, transferees, heirs, and assigns of any of them; and all of their current and former officers, directors, employees, attorneys, any other agents, and the predecessors, successors, transferees, heirs, and assigns of any of them, from any liability to Relator arising from the filing of the Civil Action, or under 31 U.S.C. § 3730(d) for expenses or attorneys' fees and costs.
- 9. Biohaven waives and shall not assert any defenses Biohaven may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.
- 10. Biohaven fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Biohaven has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct or the United States' investigation or prosecution thereof.
- 11. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare

Administrative Contractor, fiscal intermediary, carrier), TRICARE, Federal Employees Health Benefits Program ("FEHBP"), VA, or any state payer, related to the Covered Conduct; and Biohaven agrees not to resubmit to any Medicare contractor, TRICARE, FEHBP, VA, or any state payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

- 12. Biohaven agrees to the following:
- a. <u>Unallowable Costs Defined</u>: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Biohaven, its present or former officers, directors, employees, shareholders, and agents in connection with:
 - (1) the matters covered by this Agreement;
 - (2) the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;
 - (3) Biohaven's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);
 - (4) the negotiation and performance of this Agreement;
 - (5) the payment Biohaven makes to the United States pursuant to this

 Agreement and any payments that Biohaven may make to Relator,
 including costs and attorneys fees;

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and FEHBP (hereinafter referred to as Unallowable Costs).

- b. <u>Future Treatment of Unallowable Costs</u>: Unallowable Costs shall be separately determined and accounted for by Biohaven, and Biohaven shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Biohaven or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, VA, or FEHBP Programs.
- c. Treatment of Unallowable Costs Previously Submitted for Payment:

 Biohaven further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Biohaven or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Biohaven agrees that the United States, at a minimum, shall be entitled to recoup from Biohaven any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Biohaven or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on Biohaven or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

- d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Biohaven's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.
- 13. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraphs 4, 5, 8 and 14 (waiver for beneficiaries paragraph).
- 14. Biohaven agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.
- 15. Upon receipt of the payment described in Paragraph 1, above, the United States and Relator shall promptly sign and file in the Civil Action a Joint Notice of Dismissal of the Civil Action pursuant to Rule 41(a)(1) and subject to the terms of this Agreement. The dismissal shall be (1) with prejudice as to the United States' and Relators' claims as to the Covered Conduct; and (2) without prejudice as to the United States and with prejudice as to Relators as to all other claims set forth in the Civil Action.

- 16. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.
- 17. Each party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.
- 18. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Western District of New York. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.
- 19. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.
- 20. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.
- 21. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.
- 22. This Agreement is binding on Biohaven's successors, transferees, heirs, and assigns.
 - 23. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.
- 24. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.
- 25. This Agreement is effective on the date of signature of the last signatory to the Agreement ("Effective Date of this Agreement"). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

DATED: <u>1/16/2025</u>	BY:	Cassica Sarkis VESSICA M. SARKIS Trial Attorney Commercial Litigation Branch Civil Division United States Department of Justice
DATED:	BY:	DAVID M. CORIELL Assistant United States Attorney Western District of New York
DATED:	BY:	SUSAN E. GILLIN Assistant Inspector General for Legal Affairs Office of Counsel to the Inspector General Office of Inspector General United States Department of Health and Human Services
DATED:	BY:	SALVATORE M. MAIDA General Counsel Defense Health Agency United States Department of Defense

DATED:	BY:	JESSICA M. SARKIS Trial Attorney Commercial Litigation Branch Civil Division United States Department of Justice
DATED: 1/16/2025	BY:	DAVID M. CORIELL Assistant United States Attorney Western District of New York
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DATED:	BY:	JESSICA M. SARKIS Trial Attorney Commercial Litigation Branch Civil Division United States Department of Justice
DATED:	BY:	DAVID M. CORIELL Assistant United States Attorney Western District of New York
DATED: <u>1/15/25</u>	BY:	SUSAN GILLIN GILLIN Date: 2025.01.15 16:55:29 -05'00' SUSAN E. GILLIN Assistant Inspector General for Legal Affairs Office of Counsel to the Inspector General Office of Inspector General United States Department of Health and Human Services
DATED:	BY:	SALVATORE M. MAIDA General Counsel Defense Health Agency United States Department of Defense

DATED:	BY:	
		JESSICA M. SARKIS
		Trial Attorney
		Commercial Litigation Branch
		Civil Division
		United States Department of Justice
DATED:	BY:	DAVID M. CORIELL
		Assistant United States Attorney
		Western District of New York
		Western District of New York
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DATED:	BY:	
		SUSAN E. GILLIN
		Assistant Inspector General for Legal Affairs
		Office of Counsel to the Inspector General
		Office of Inspector General
		United States Department of Health and Human Services
		MAIDA.SALVATOR Digitally signed by
		F M IR 1019342049 2049
DATED:	BY:	Date: 2025.01.14 16:27:46 -05'00'
		SALVATORE M. MAIDA
		General Counsel
		Defense Health Agency
		United States Department of Defense

BIOHAVEN

DATED: 1/16/2025 | 4:56 PM EST | Ludru O'Connor | ANDREW O'CONNOR | Counsel for Biohaven

RELATOR

DATED:	1/16/2025	BY:	Patricia Frattasio Relator	
DATED:	1/16/2025	BY:	John J. Gross JOHN J. GROSS Counsel for Relate	or