

SETTLEMENT AGREEMENT

This Settlement Agreement (“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-HHS”) of the Department of Health and Human Services (“HHS”), the Department of Defense, Defense Logistics Agency (“DLA”) (collectively, the “United States”), Bayer Corporation, Bayer HealthCare Pharmaceuticals Inc., Bayer HealthCare LLC, and Bayer AG (collectively “Bayer”), and Laurie Simpson (“Relator”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. The Bayer entities at issue are the following: Bayer HealthCare LLC, a Delaware limited liability company, is an indirect subsidiary of Bayer AG. Bayer HealthCare Pharmaceuticals Inc., is a Delaware corporation, all of whose issued and outstanding shares of common stock are owned by Schering Berlin Inc., and is an indirect subsidiary of Bayer AG. Bayer Corporation, an Indiana corporation, is wholly-owned by Bayer US Holding LP and an indirect subsidiary of Bayer AG. Bayer AG, a publicly held German stock company, has no parent company.

B. On August 5, 2005, Relator filed a *qui tam* action in the United States District Court for the District of New Jersey captioned *United States ex rel. Laurie Simpson v. Bayer Pharmaceutical Corp., Bayer Corporation, and Bayer A.G.*, case number 05-cv-3895, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the “New Jersey Action”). Relator filed nine amended complaints in the New Jersey Action, with the operative, Tenth Amended Complaint filed on April 14, 2015, which included *qui tam* claims brought on behalf of the United States and the States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New

Mexico, New York, Oklahoma, Rhode Island, Tennessee, Virginia, Wisconsin and the District of Columbia (collectively, "Plaintiff-States"). Separately, on October 5, 2006, Relator filed a second *qui tam* action in the United States District Court for the District of New Jersey pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) captioned *United States of America, State of California, State of Delaware, State of Florida, State of Hawaii, State of Illinois, Commonwealth of Massachusetts, State of Nevada, State of Tennessee, State of Texas, State of New York, and District of Columbia, ex rel. Laurie Simpson v. Bayer Corporation, Bayer A.G., Bayer Healthcare Pharmaceuticals Inc.*, case number 06-4796-PGS, which, in October 2008, was transferred to the United States District Court for the District of Minnesota, case number 08-cv-5758-MJD-ECW (the "Minnesota Action") (collectively with the New Jersey Action, the "Civil Actions"). Relator filed two amended complaints in the Minnesota Action, with the operative, Second Amended Complaint filed on November 23, 2010.

C. The United States declined to intervene in the New Jersey Action on February 10, 2010. The United States declined to intervene in the Minnesota Action on April 24, 2008.

D. Relator contends that the United States has certain civil claims against Bayer for submitting or causing to be submitted false claims for payment or approval 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"); and under DLA Troop Support Contract (January 11, 2001), Modification of No. SP0200-00-D-0506, and Blanket Purchase Agreement (February 14, 2001) SP0200-01-A-0013, Modification of SP0200-99-D-0506.

E. The claims pending in the Civil Actions as of the Effective Date of this Agreement shall be referred to as the "Covered Conduct."

F. This Settlement Agreement is neither an admission of liability by Bayer nor a concession by the United States that its claims are not well founded.

G. Bayer will have a separate arrangement with certain Plaintiff-States to resolve their respective claims as to the Covered Conduct. Those Plaintiff-States are referred to herein as “Medicaid Participating States.”

H. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relator’s reasonable expenses, attorneys’ fees and costs from defendants. Relator also claims entitlement under 31 U.S.C. § 3730(h)(2) to reasonable attorneys’ fees and costs for her retaliation claim against defendants.

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 Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Bayer shall pay forty million dollars (\$40,000,000.00) as the Settlement Amount plus interest on the Settlement Amount at a rate of 1.5 percent per annum from August, 22, 2022. The Settlement Amount shall constitute a debt immediately due and owing to the United States and the Medicaid Participating States and the debt shall be discharged by payments to the United States and the Medicaid Participating States as follows:

a. Of the Settlement Amount (\$40,000,000), Bayer shall pay to the United States the sum of thirty-eight million, eight hundred sixty thousand, five hundred fifty-five dollars (\$38,860,555) plus interest thereon at a rate of 1.5 percent per annum from August 22, 2022, to and including the Effective Date of this Agreement (the “Federal Settlement Amount”), of which twenty-one million, five thousand, seven hundred and five dollars (\$21,005,705) is restitution. Bayer shall pay the Federal Settlement Amount to the United States by electronic funds transfer pursuant to written instructions to be provided by the United States. Bayer shall

make the electronic funds transfer no later than 14 calendar days after the Effective Date of this Agreement.

b. Bayer shall pay the Medicaid Participating States the sum of one million, one hundred thirty-nine thousand, four hundred forty-five dollars (\$1,139,445) plus interest thereon at a rate of 1.5 percent per annum from August 22, 2022 (the “State Settlement Amount”). The State Settlement Amount shall be paid by electronic funds transfer in accordance with written instructions to be provided by the state negotiating team (“State Team”) pursuant to the separate arrangement agreed upon by Bayer and the State Team. Notwithstanding anything else in this Paragraph, the State Settlement Amount shall be reduced by the portion (to be determined between Bayer and the State Team) allocated to any Plaintiff-State that does not agree to dismiss with prejudice their claims for the Covered Conduct in the New Jersey action.

2. Bayer shall pay Relator the sum of six million dollars (\$6,000,000) to resolve Relator’s Retaliation Claim under 31 U.S.C. § 3730(h) (the “Retaliation Settlement Amount”). The Retaliation Settlement Amount will be paid within 14 calendar days after the Effective Date of this Agreement, pursuant to written instructions provided by Relator’s Counsel to Bayer’s Counsel.

3. Conditioned upon the United States receiving the Federal Settlement Amount from Bayer and as soon as feasible after receipt, the United States shall pay the sum of eleven million, seventy-five thousand, two hundred fifty-eight dollars and twenty cents (\$11,075,258.20), plus a pro rata share of the actual interest paid to the United States by Bayer pursuant to Paragraph 1(a) of this Agreement to Relator by electronic funds transfer (“Relator’s Share”).

4. Subject to the exceptions in Paragraph 6 (concerning reserved claims) below, and upon the United States’ receipt of the Federal Settlement Amount plus interest due under

Paragraph 1, the United States releases Bayer together with its current and former parent corporations; direct and indirect subsidiaries; brother or sister corporations; divisions; current or former corporate owners; and the corporate successors 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. In consideration of the obligations of Bayer as set forth in this Agreement, subject to the exceptions in Paragraph 6 below, and conditioned upon the United States' receipt of the Federal Settlement Amount plus interest due under Paragraph 1 and Relator's receipt of the Retaliation Settlement Amount set forth in Paragraph 2, Relator, for herself and for her heirs, successors, attorneys, agents, and assigns, releases Bayer, together with its current and former parent corporations; direct and indirect subsidiaries; brother or sister corporations; divisions; current or former corporate owners; the corporate successors and assigns of any of them; and attorneys and agents, from any claim that the Relator has on behalf of the United States or any State for the Covered Conduct, any claims for retaliation pursuant to any federal or state law, as well as any and all other liability, claims, demands, actions, or causes of action whatsoever, whether known or unknown, fixed or contingent, in law or in equity, in contract or in tort, under any federal or state statute or regulation, or in common law, that Relator otherwise would have standing to bring for herself or any other person or entity as of the date of this Agreement. However, any claims Relator has on behalf of any Plaintiff-States for the Covered Conduct will be subject to resolution through separate arrangements between the Plaintiff-States and Bayer as indicated in Paragraph 1(b), and between the Plaintiff-States and Relator; and provided, however, Relator (and her attorneys, agents and assigns) do not release Relator's claims for

reasonable expenses, attorneys' fees and costs incurred in connection with the Civil Actions pursuant to 31 U.S.C. §§ 3730(d) and 3730(h)(2), and applicable state law provisions.

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 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;
- g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- h. Any liability for failure to deliver goods or services due; and
- i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

7. Relator and her heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that the Settlement Amount and this Agreement are 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 payment described in Paragraph 3,

Relator and her heirs, successors, attorneys, agents, and assigns 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 Actions or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Actions.

8. Bayer waives and shall not assert any defenses Bayer 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.

9. Bayer 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 Bayer 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.

10. Bayer, together with its current and former parent corporations; direct and indirect subsidiaries; brother or sister corporations; divisions; current or former corporate owners; the corporate successors and assigns of any of them; and attorneys and agents, releases the Relator and her heirs, successors, attorneys, agents, and assigns from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Bayer has asserted, could have asserted, or may assert in the future against the Relator, related to the Civil Actions and the Relator's investigation and prosecution thereof, as well as any and all other liability, claims, demands, actions, or causes of action whatsoever, whether known or unknown, fixed or contingent, in law or in equity, in contract or in tort, under any federal or state statute or

regulation, or in common law, that Bayer otherwise would have standing to bring for themselves or any other person or entity as of the date of this Agreement.

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) or any state payer, related to the Covered Conduct; and Bayer agrees not to resubmit to any Medicare contractor 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. Bayer agrees to the following:

a. Unallowable Costs Defined: 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 Bayer, 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) Bayer'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; and
- (5) the payment Bayer makes to the United States or any State pursuant to this Agreement or the separate arrangement with certain Plaintiff-States and

any payments that Bayer 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 Federal Employees Health Benefits Program ("FEHBP") (hereinafter referred to as "Unallowable Costs").

b. Future Treatment of Unallowable Costs: Bayer 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 Bayer or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Bayer 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 Bayer 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. Bayer agrees that the United States, at a minimum, shall be entitled to recoup from Bayer 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 Bayer or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Bayer 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 Bayer'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 Paragraph 14 (waiver for beneficiaries Paragraph), below.

14. Bayer 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 payments described in Paragraphs 1 and 2 above, Relator and Bayer shall promptly sign and file in the Civil Actions Joint Stipulations of Dismissal pursuant to Rule 41(a)(1), dismissing with prejudice all remaining claims, but reserving Relator's claims against Bayer for reasonable expenses, attorneys' fees and costs pursuant to 31 U.S.C. §§ 3730(d) and 3730(h) and analogous provisions of state law.

16. Except for Relator's claims against Bayer for reasonable expenses, attorneys' fees and costs pursuant to 31 U.S.C. §§ 3730(d) and 3730(h)(2) and analogous provisions of

applicable state law, each Party shall bear its own legal and other costs incurred in connection with the Civil Actions, 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 jurisdictions and venues for any dispute relating to this Agreement are the United States District Court for the District of New Jersey for disputes relating to the New Jersey Action and the United States District Court for the District of Minnesota for disputes relating to the Minnesota action. If a dispute relates to both the New Jersey and Minnesota actions, the parties will jointly notify the courts in the District of New Jersey and the District of Minnesota of the dispute, and follow the Courts' instruction (if any) regarding the venue in which to proceed. 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 Bayer'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.

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THE UNITED STATES OF AMERICA

DATED: 9/2/2022 BY: 
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Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 9/2/2022 
ANN M. BILDTSSEN
First Assistant U.S. Attorney
U.S. Attorney's Office
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DATED: September 2, 2022



KRUTI D. DHARIA
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BAYER DEFENDANTS

DATED: SEPT 1, 2022

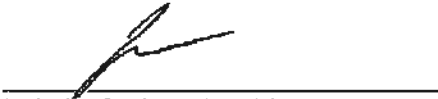
BY:



Bayer Defendants


DATED: 9/1/2022


BY:



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RELATOR

DATED: 9/1/22 BY: 
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DATED: 9.1.22 BY: 
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