

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”) 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 Takeda Pharmaceuticals, U.S.A., Inc. (“Takeda”); [REDACTED]. Collectively, all of the above will be referred to as “the Parties.”

RECITALS

A. Takeda is a Delaware corporation with its principal place of business in Cambridge, Massachusetts. Pursuant to a 2007 co-development and co-marketing agreement with Lundbeck U.S., an affiliate of Danish pharmaceutical company H. Lundbeck A/S, (collectively, “Lundbeck”), Takeda marketed and sold a pharmaceutical product to treat Major Depressive Disorder (“MDD”) in the United States, vortioxetine, under the trade name Trintellix. The U.S. Food and Drug Administration originally approved vortioxetine under the trade name Brintellix. Trintellix, as used herein, refers to both Brintellix and Trintellix.

B. [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

C. The United States contends that Takeda caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395l11 (“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. Takeda 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 in settlement of the Covered Conduct (defined herein). States with which Takeda executes a Medicaid State Settlement Agreement in the form to which Takeda and the National Association of Medicaid Fraud Control Units (“NAMFCU”) Negotiating Team have agreed, or in a form otherwise agreed to by Takeda 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 against Takeda arising from the following conduct from January 20, 2014, through October 27, 2020—hereinafter referred to as the “Covered Conduct”:

The United States contends that Takeda provided improper remuneration to health care providers to induce them to prescribe Trintellix for Medicare, Medicaid, TRICARE, and VA beneficiaries, in violation of the Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b(b).

As part of its marketing efforts, Takeda conducted events known as “Trintellix Speaker Programs” at which a healthcare provider (“provider”) involved in the treatment of MDD was engaged to present to other providers involved in the treatment of MDD.

The United States contends that Takeda paid providers honoraria to present to other providers about Trintellix at speaker programs, which were held virtually, in providers' offices, or at offsite venues, such as high-end restaurants across the country. The United States contends that Takeda selected certain providers to be part of the Trintellix speaker bureau and/or provided paid speaking opportunities to providers with the intent that the speaker honoraria would induce these providers to prescribe Trintellix or reward the selected providers for past prescriptions.

Certain speaker programs exceeded Takeda's compliance spending limits for meals of \$125 per person for food and beverage. Some sales representatives invited the same providers to speaker program events on the same drug and featuring substantially the same content, often within six months. In other instances, providers who were paid to be Trintellix speakers attended speaker programs on the same topic, often within less than six months after speaking. The United States contends that these providers who attended multiple programs on the same topic, and received meals and drinks paid for by Takeda in excess of Takeda's internal \$125 limit, received no educational benefit from attending duplicate programs; rather, Takeda intended the purchase of meals and drinks to induce these providers to prescribe Trintellix.

As a result of this conduct, the United States contends that certain of Takeda's speaker programs resulted in providers prescribing Trintellix, which caused false claims to be submitted to Medicare, Medicaid, TRICARE, and the VA.

F. Takeda denies the United States' allegations in Paragraph E. This Settlement Agreement is neither an admission of facts or liability by Takeda nor a concession by the United States that its claims are not well founded.

G. [REDACTED]

H. Takeda received credit under the Department of Justice's guidelines for taking disclosure, cooperation, and remediation into account in False Claims Act cases, Justice Manual §4-4.112. Among other actions, Takeda voluntarily collected and produced key materials from a third-party entity that were central to the Government's investigation, obviating the need for the United States to use compulsory process to collect those materials; voluntarily terminated the Trintellix speaker program; and implemented appropriate remedial measures, including enhancing compliance policies and processes. Takeda also assisted the United States in determining the alleged damages caused to the United States.

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. Takeda shall pay to the United States and the Medicaid Participating States, collectively, \$13,670,921, less any deductions for States not participating in the Medicaid Participating States' agreements, plus interest at a rate of 4.125% per annum from December 19, 2025 on the Federal Settlement Amount (as defined below), and from March 26, 2026 on the State Settlement Amount (as defined below), 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, \$7,594,956.11 is restitution. The Settlement Amount shall be paid to the United States and the Medicaid Participating States as follows:

a. Takeda shall pay the United States the sum of \$12,848,947.19, plus accrued interest as set forth above ("Federal Settlement Amount"). Of the Federal Settlement Amount, \$7,138,303.99 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 Office of the United States Attorney for the Eastern District of California.

b. Takeda shall pay the Medicaid Participating States the sum of \$821,973.81, less any deductions for States not participating in the Medicaid Participating States' agreements, plus accrued interest as set forth above (the "State Settlement Amount"), to be disbursed in accordance with written instructions from the NAMFCU Negotiating Team and under the terms and conditions of the agreements that Takeda will enter into with the Medicaid Participating States.

2. [REDACTED]

[REDACTED]

3. Subject to the exceptions in Paragraph 5 (concerning reserved claims) below, and upon the United States' receipt of the Federal Settlement Amount, the United States releases Takeda, 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 (collectively, the "Takeda Entities"), 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 Administrative False Claims Act (formerly known as 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.

4. [REDACTED]

[REDACTED]

[REDACTED]

5. Notwithstanding the releases given in Paragraphs 3 and 4 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; and
- f. Any liability of individuals.

6. [REDACTED]

[REDACTED]

[REDACTED]

8. Takeda waives and shall not assert any defenses Takeda 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. Takeda 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 Takeda 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. [REDACTED]

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., Part D Plan, Medicare Administrative Contractor, fiscal intermediary, carrier), TRICARE, VA, or any state payer, related to the Covered Conduct; and Takeda agrees not to resubmit to any Medicare contractor, TRICARE, 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. Takeda 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 Takeda, 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) Takeda'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)

[REDACTED]

[REDACTED]

[REDACTED]

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: Unallowable Costs shall be separately determined and accounted for by Takeda, and Takeda 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 Takeda or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Takeda 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 Takeda 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. Takeda agrees that the United States, at a minimum, shall be entitled to recoup from Takeda 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 Takeda or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on Takeda 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 Takeda's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

13. Takeda agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Takeda shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Takeda further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

14. 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 15 (waiver for beneficiaries paragraph), below.

15. Takeda 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.

16. Takeda [REDACTED] hereby expressly waive all rights they may have by virtue of Section 1542 of the California Civil Code, which provides:

A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY.

17. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

18. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

19. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement; [REDACTED]

[REDACTED]

[REDACTED]

20. Each Party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

21. 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 Eastern District of California. 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.

22. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

23. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

24. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

25. This Agreement is binding on Takeda's successors, transferees, heirs, and assigns.

26. [REDACTED]

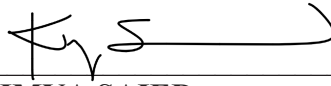
27. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

28. 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.


**[SIGNATURE PAGES FOLLOW]**

**THE UNITED STATES OF AMERICA**

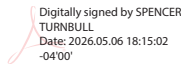
DATED: 5/7/26

BY:   
**KIMYA SAIED**  
Trial Attorney  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

DATED: 5/7/26

BY:   
**DAVID THIESS**  
Assistant United States Attorney  
Eastern District of California  
United States Attorney's Office

DATED: \_\_\_\_\_

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**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: 5/4/2026

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**For** **SALVATORE M. MAIDA**  
General Counsel  
Defense Health Agency  
United States Department of War

**TAKEDA - DEFENDANT**

DATED: May 14, 2026

BY: J. Christopher Allen, Jr.  
**J. CHRISTOPHER ALLEN, JR.**  
Head, Litigation & Global Investigations  
Takeda

DATED: May 14, 2020

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