

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

THE UNITED STATES OF AMERICA, *et al. ex rel.*
DR. PAUL BELLMAN,

Plaintiffs,

v.

GILEAD SCIENCES, INC.,

Defendant.

16 Civ. 6228 (PAE)

UNITED STATES OF AMERICA,

Plaintiff-Intervenor,

v.

GILEAD SCIENCES, INC.,

Defendant.

16 Civ. 6228 (PAE)

STIPULATION AND ORDER OF SETTLEMENT AND DISMISSAL

WHEREAS, this Stipulation and Order of Settlement and Dismissal (“Stipulation”) is entered into by and among plaintiff the United States of America (the “United States” or the “Government”), by its attorney, Jay Clayton, United States Attorney for the Southern District of New York, and on behalf of the Office of Inspector General for the Department of Health and Human Services (“OIG-HHS”) and the Defense Health Agency (“DHA”), acting on behalf of the TRICARE program (“TRICARE”); the relator Dr. Paul Bellman (“Relator”), by his authorized representatives; and defendant Gilead Sciences, Inc. (“Defendant,” and together with the Government and Relator, the “Parties”), by its authorized representatives;

WHEREAS, Gilead Sciences, Inc. is a corporation with headquarters in Foster City, California, which, among other things, develops, manufactures, and sells pharmaceuticals for the treatment of infectious diseases, including HIV/AIDS;

WHEREAS, on or about August 5, 2016, Relator filed a complaint against Defendant under the *qui tam* provisions of the False Claims Act (“FCA”), 31 U.S.C. § 3729 *et seq.*, which was subsequently amended on January 7, 2020, and further amended on April 26, 2021, alleging, *inter alia*, that Defendant violated the FCA and the Anti-Kickback Statute (“AKS”), 42 U.S.C. § 1320a-7b(b), by, *inter alia*, paying doctors remuneration to prescribe the drugs Stribild®, Genvoya®, Complera®, Odefsey®, Descovy®, and Biktarvy®, which are prescribed to treat HIV/AIDS (the “Relator Complaint”);

WHEREAS, the Government alleges that from January 1, 2011, through November 17, 2017 (the “Relevant Time Period”), Defendant offered and paid remuneration in the form of honoraria payments, meals, and travel expenses to healthcare practitioners who spoke at or attended Gilead speaker events to induce them to prescribe Stribild®, Genvoya®, Complera®, Odefsey®, Descovy®, and Biktarvy® (the “Gilead HIV Drugs”) in violation of the AKS and thereby caused, up to and through May 17, 2018, false claims for the Gilead HIV Drugs to be submitted to and paid by Medicare, Medicaid, TRICARE, and the AIDS Drug Assistance Program (“ADAP”) in violation of the FCA. The conduct and false claims described in this Paragraph are the “Covered Conduct” for purposes of this Stipulation;

WHEREAS, contemporaneous with the filing of this Stipulation, the Government is filing a Notice of Election to Intervene and Complaint-In-Intervention in the above-referenced *qui tam* action (“Government Complaint”), in which it is asserting claims against Defendant under the FCA and common law for the Covered Conduct;

WHEREAS, Gilead intends to enter into separate settlement agreements with various States (the “State Settlements”) to resolve claims under state laws for the Covered Conduct, and has agreed to pay a total of \$25,072,110.72 to the States pursuant to the State Settlements; and

WHEREAS, the Parties have, through this Stipulation, reached a mutually agreeable resolution addressing the claims asserted against Defendant in the Government Complaint and the Relator Complaint, for the Covered Conduct;

NOW, THEREFORE, upon the Parties’ agreement IT IS HEREBY ORDERED that:

TERMS AND CONDITIONS

1. The Parties agree that this Court has subject matter jurisdiction over this action and consent to this Court’s exercise of personal jurisdiction over each of them.
2. Defendant admits, acknowledges and accepts responsibility for the following conduct during the Relevant Time Period (the “Admitted Conduct”):

Marketing of Gilead’s Drugs through HIV Speaker Programs

- a. Gilead developed, marketed, and/or sold the following antiretroviral drugs primarily used to treat HIV: Stribild[®], Genvoya[®], Complera[®], Odefsey[®], Descovy[®], and Biktarvy[®]. Medicare typically paid well in excess of a thousand dollars for a one-month supply of these drugs.
- b. As part of its marketing efforts and to increase sales, Gilead conducted events known as “HIV Speaker Programs” at which a healthcare provider involved in the treatment of HIV (“HIV Speaker”) was engaged to present a slide deck and facilitate discussion about one of the drugs or a topic concerning HIV (an “HIV Disease State Topic”) to other healthcare providers involved in the treatment of HIV (“Attendees”).
- c. These HIV Speaker Programs were typically organized by sales representatives in Gilead’s HIV therapeutic area (“Sales Representatives”), at times in consultation with their direct supervisors (“Regional Directors”). HIV Speaker Programs were an important part of Gilead’s strategy for promoting its HIV drugs and increasing drug sales. A Gilead Regional Director’s HIV business plan from 2012 noted that a particular HIV Speaker was a “must win” account whose prescriptions “need to increase” and that the Regional Director should “[c]apitalize on program opportunities” for the doctor “as a speaker and attendee.”

- d. Gilead's Regional Directors had discretion to nominate individuals to become HIV Speakers in Gilead's HIV Speaker Bureau. Frequently, Regional Directors would nominate potential HIV Speakers at the recommendation of a Sales Representative. After an HIV Speaker was nominated, Gilead's Medical Affairs and Business Conduct groups were responsible for reviewing and approving the nomination, but nominations from Regional Directors were rarely rejected.
- e. Some Sales Representatives suggested, and some Regional Directors nominated, HIV Speakers based on the fact that they were either already high prescribers of Gilead HIV Drugs or had the potential to be.
- f. For each HIV Speaker Program, Gilead paid the HIV Speaker an honorarium of, on average, \$1,500 to present a slide deck and facilitate discussion about one of the drugs or an HIV Disease State Topic.
- g. Gilead's HIV Speaker Programs were often held in the evening at restaurants ("HIV Dinner Programs"). Gilead held over 17,300 HIV Speaker Programs, over 9,500 of which were HIV Dinner Programs.
- h. Gilead paid 548 healthcare providers who served as HIV Speakers a total of more than \$23.7 million in honoraria payments (\$13.7 million of which was for the HIV Dinner Programs). Gilead also paid for the HIV Speakers' and Attendees' meals and alcohol consumed at these events.
- i. Gilead paid many high-volume prescribers of HIV drugs tens or hundreds of thousands of dollars in honoraria to prepare and present as HIV Speakers. Gilead paid approximately 60 healthcare providers involved in the treatment of HIV over \$100,000 each in total honorarium payments, in addition to paying for their meals and any travel expenses, and the vast majority of these individuals prescribed a large volume of the Gilead HIV Drugs. For instance, one HIV Speaker, who received over \$300,000 in total honorarium payments, wrote prescriptions for Gilead HIV Drugs that resulted in over \$6 million in Medicare, Medicaid, and TRICARE payments.
- j. On many occasions, Gilead covered the travel costs of HIV Speakers who traveled long distances to speak at HIV Speaker Programs at desirable travel destinations, such as Hawaii, Miami, and New Orleans. This was sometimes in response to an HIV Speaker's request to be booked for an HIV Speaker Program in that city.

Speaker Programs at Luxury Restaurants

- k. Sales Representatives organized HIV Speaker Programs at high-end restaurants across the country. For instance, a significant percentage of the HIV Speaker Programs held in New York City were held at expensive restaurants, such as the James Beard House, Del Posto, Asiate, Palma, Vacluse, Ilili, and Limani. In particular, Gilead held 157 HIV Speaker Programs at the James Beard House, making it one of Gilead's most used venues for HIV Speaker Programs. A dinner

at the James Beard House typically included approximately six courses with alcoholic beverage pairings.

- l. While Gilead's internal policies limited the cost of food and beverage at HIV Dinner Programs to \$125 per person, Sales Representatives conducted numerous HIV Speaker Programs where the meals served exceeded the \$125 per person threshold. Furthermore, in certain instances, Sales Representatives circumvented the \$125 per person limit by including the cost of food and beverages in the reported "room fee," thereby concealing the true cost of the meal and making it appear like the per person cost was below \$125 when it was actually significantly higher.

Repeat Attendance at Speaker Programs

- m. At each HIV Speaker Program, the HIV Speaker was expected to present a slide deck, prepared by Gilead, regarding one of the Gilead HIV Drugs or an HIV Disease State Topic.
- n. Many healthcare providers who prescribed a high volume of Gilead HIV Drugs attended a large number of HIV Speaker Programs, frequently at high-end restaurants. Approximately 160 doctors and other healthcare providers who prescribed Gilead HIV Drugs attended or spoke at more than 50 HIV Speaker Programs.
- o. Sales Representatives repeatedly invited numerous doctors and other healthcare providers to attend the same HIV program over and over. Many repeatedly attended HIV Speaker Programs covering the exact same topic, often within a short period of time.
- p. Over 250 prescribers of the Gilead HIV Drugs attended HIV Dinner Programs on the same topic three times or more within a six-month period. And over 80 of them attended five or more HIV Dinner Programs on the same topic within a six-month period.
- q. For instance, a nurse practitioner in New York City attended 75 HIV Dinner Programs. This nurse practitioner attended 40 HIV Dinner Programs on the same topic three times or more within a six-month period. That nurse practitioner often brought their sibling—a pediatric nurse practitioner and non-prescriber of Gilead HIV drugs—to the programs. Similarly, a physician assistant in Miami attended 60 HIV Dinner Programs, with 32 repeat attendances, often attending with their spouse who was a pharmacist, on the same topic three times or more within a six-month period.
- r. Further, many healthcare providers who were paid to be HIV Speakers on a particular topic also attended HIV Dinner Programs on exactly the same topic, often within less than six months after speaking.

- s. In certain instances, the same group of doctors repeatedly attended the same HIV Speaker Programs together at various restaurants. For instance, a group of ten doctors in Manhattan spoke at or attended together approximately 384 HIV Dinner Programs (at which others were in attendance). Over 300 of these 384 HIV Dinner Programs were led by one of these 10 doctors. Each of the doctors repeatedly attended HIV Speaker Programs within 90 days of speaking on the same topic. In many instances, they attended a Dinner Program less than two weeks after speaking on the same topic.

Gilead's Compliance Program

- t. During the Relevant Time Period, Gilead's policies and procedures failed to prevent Sales Representatives and Regional Directors in its HIV therapeutic area from improperly providing honoraria payments, meals, and travel expenses to healthcare providers who spoke at or attended HIV Speaker Programs to induce them to prescribe the Gilead HIV Drugs.
- u. For example, before 2016, Gilead did not place any limits on repeat attendance at HIV Speaker Programs or on whether HIV Speakers could repeatedly attend programs on the same topics they spoke on.
- v. Gilead maintained or had access to data on its HIV Speaker Programs, including the venues used, the costs of the events, and the Attendees at its programs. However, Gilead failed to detect instances of HIV Speaker Program abuses by Sales Representatives and Regional Directors related to compliance with meal-spend limits, inappropriate venues, as well as excessive attendance by HIV Speakers and other healthcare providers at HIV Dinner Programs.

3. Defendant shall pay to the Government within fourteen (14) business days of the Effective Date (defined below in Paragraph 30) the sum of \$176,927,889.28, plus interest which shall be compounded annually at a rate of 4.25% accruing from March 11, 2025, to the date of the payment (the "Settlement Amount") in accordance with instructions to be provided by the Financial Litigation Unit of the United States Attorney's Office for the Southern District of New York. Of the Settlement Amount, \$88,463,944.64 constitutes restitution to the United States.

4. Defendant agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Stipulation. Upon reasonable notice, Defendant 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. Defendant 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.

5. Subject to the exceptions in Paragraph 10 (concerning reserved claims), Paragraph 11 (concerning default), and Paragraph 16 (concerning bankruptcy proceedings) below, and conditioned on Defendant's full compliance with the terms of this Stipulation, including full payment of the Settlement Amount to the United States pursuant to Paragraph 3 above, the United States releases Defendant, including its subsidiaries and corporate predecessors, successors, and assigns, from any civil or administrative monetary claim that the United States has for the Covered Conduct under the FCA, the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812, and the common law theories of fraud, payment by mistake, and unjust enrichment. For avoidance of doubt, this Stipulation does not release any current or former officer, director, employee, or agent of Defendant from liability of any kind.

6. Defendant fully and finally releases the United States, its agencies, officers, employees, servants, and agents from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Defendant has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, employees, servants, or agents related to the Covered Conduct or the United States' investigation, prosecution, and settlement thereof.

7. Conditioned on Defendant's full payment of the Settlement Amount to the United States pursuant to Paragraph 3 above, Relator, for himself and his heirs, successors, attorneys, agents, and assigns, releases Defendant, including its subsidiaries and corporate predecessors, successors and assigns, as well as all of its current and former officers, directors, employees, attorneys, and other agents, from any and all manner of claims, proceedings, liens, and causes of action of any kind or description that Relator has against Defendant; provided, however, that nothing in this Stipulation shall preclude Relator from seeking to recover his reasonable expenses and attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d).

8. In consideration of the execution of this Stipulation by Relator and the Relator's release as set forth in Paragraph 7 above, Defendant, including its subsidiaries, predecessors, and corporate successors and assigns, as well as all of its current and former officers, directors, employees, attorneys, and other agents, release Relator and his heirs, successors, attorneys, agents, and assigns, from any and all manner of claims, proceedings, liens, and causes of action of any kind or description that Defendant has against Relator.

9. In consideration of Defendant's obligations in this Stipulation, and conditioned upon Defendant's full payment of the Settlement Amount, and except as expressly reserved in this Paragraph and Paragraph 10 (concerning excluded claims), DHA agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking Defendant's exclusion from TRICARE under 32 C.F.R. § 199.9 for the Covered Conduct. DHA expressly reserves authority to exclude Defendant from TRICARE under 32 C.F.R. § 199.9(f)(l)(i)(A), (f)(l)(i)(B), and (f)(l)(iii) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes DHA or TRICARE from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 10 below.

10. Notwithstanding the releases given in Paragraph 5 and 9 above, or any other term of this Stipulation, the following claims of the Government are specifically reserved and are not released by this Stipulation:

- a. any liability arising under Title 26, United States Code (Internal Revenue Code);
- b. any criminal liability;
- c. except as explicitly stated in this Stipulation, any administrative liability or enforcement right, including but not limited to the mandatory or permissive exclusion from Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) or 42 U.S.C. § 1320a-7(b) (permissive exclusion);
- 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 Stipulation; and
- f. any liability of individuals.

11. Defendant shall be in default of this Stipulation if Defendant fails to make the required payment set forth in Paragraph 3 above on or before the due date for such payment, or if it fails to comply materially with any other term of this Stipulation that applies to it (“Default”). The Government will provide a written Notice of Default to Defendant of any Default in the manner set forth in Paragraph 29 below. Defendant shall then have an opportunity to cure the Default within seven (7) calendar days from the date of receipt of the Notice of Default by making the payment due and paying any additional interest accruing under the Stipulation up to the date of payment. If Defendant fails to cure the Default within seven (7) calendar days of receiving the

Notice of Default (“Uncured Default”), interest on the remaining unpaid balance shall thereafter accrue at the rate of 12% per annum, compounded daily from the date of Default, on the remaining unpaid total (principal and interest balance). In the event of an Uncured Default, Defendant shall agree to the entry of a consent judgment in favor of the United States against Defendant in the amount of the Settlement Amount as attached hereto as Exhibit A. Defendant also agrees that the United States, at its sole discretion, may (i) retain any payments previously made, rescind this Stipulation, and reinstate the claims asserted against Defendant in the Government Complaint, or bring any civil and/or administrative claim, action, or proceeding against Defendant for the claims that would otherwise be covered by the releases provided in Paragraphs 5, 8, and 9 above, with any recovery reduced by the amount of any payments previously made by Defendant to the United States under this Stipulation; (ii) take any action to enforce this Stipulation in a new action or by reinstating the Government Complaint; (iii) offset the remaining unpaid balance from any amounts due and owing to Defendant and/or affiliated companies by any department, agency, or agent of the United States at the time of Default or subsequently; and/or (iv) exercise any other right granted by law, or under the terms of this Stipulation, or recognizable at common law or in equity. The United States shall be entitled to any other rights granted by law or in equity by reason of Default, including referral of this matter for private collection. In the event the United States pursues a collection action, Defendant agrees immediately to pay the United States the greater of (i) a ten-percent (10%) surcharge of the amount collected, as allowed by 28 U.S.C. § 3011(a), or (ii) the United States’ reasonable attorneys’ fees and expenses incurred in such an action. In the event that the United States opts to rescind this Stipulation pursuant to this Paragraph, Defendant waives and agrees not to plead, argue, or otherwise raise any defenses of statute of limitations, laches, estoppel or similar theories, to any civil or administrative claims that (i) are filed by the

United States against Defendant within 120 days of written notification that this Stipulation has been rescinded, and (ii) relate to the Covered Conduct, except to the extent these defenses were available on August 5, 2016. Defendant agrees not to contest any offset, recoupment, and /or collection action undertaken by the United States pursuant to this Paragraph, either administratively or in any state or federal court, except on the grounds of actual payment to the United States. In the event of an Uncured Default, OIG-HHS may exclude Defendant from participating in all Federal health care programs until Defendant pays the Settlement Amount, with interest, as set forth above (“Exclusion for Default”). OIG-HHS will provide written notice of any such exclusion to Defendant. Defendant waives any further notice of the exclusion under 42 U.S.C. § 1320a-7(b)(7), and agrees not to contest such exclusion either administratively or in any state or federal court. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, Defendant wishes to apply for reinstatement, it must submit a written request for reinstatement to OIG-HHS in accordance with the provisions of 42 C.F.R. §§ 1001.3001-.3005. Defendant will not be reinstated unless and until OIG-HHS approves such request for reinstatement. The option for Exclusion for Default is in addition to, and not in lieu of, the options identified in this Stipulation or otherwise available.

12. Defendant, having truthfully admitted to the conduct set forth in Paragraph 2 hereof (the “Admitted Conduct”), agrees that it shall not, through its attorneys, agents, officers or employees, make any public statement, including but not limited to, any statement in a press release, social media forum, or website, that contradicts or is inconsistent with the Admitted Conduct or suggests that the Admitted Conduct is not wrongful (a “Contradictory Statement”). Any Contradictory Statement by Defendant, its attorneys, agents, officers, or employees, shall constitute a violation of this Stipulation, thereby authorizing the Government to pursue any of the

remedies set forth in Paragraph 11 of this Stipulation, or seek other appropriate relief from the Court. Before pursuing any remedy, the Government shall notify Defendant that it has determined that Defendant has made a Contradictory Statement. Upon receiving notice from the Government, Defendant may cure the violation by repudiating the Contradictory Statement in a press release or other public statement within four business days. If Defendant learns of a potential Contradictory Statement by its attorneys, agents, officers, or employees, Defendant must notify the Government of the statement within 24 hours. The decision as to whether any statement constitutes a Contradictory Statement or will be imputed to Defendant for the purpose of this Stipulation, or whether Defendant adequately repudiated a Contradictory Statement to cure a violation of this Stipulation, shall be within the sole discretion of the Government. Consistent with this provision, Defendant may raise defenses and/or assert affirmative claims or defenses in any proceeding brought by private and/or public parties, so long as doing so would not contradict or be inconsistent with the Admitted Conduct.

13. Relator and his heirs, successors, attorneys, agents, and assigns shall not object to this Stipulation; Relator agrees and confirms that the terms of this Stipulation are fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B).

14. Defendant agrees that it waives and shall not seek payment for any of the health care billings covered by this Stipulation 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. Defendant waives and shall not assert any defenses Defendant 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 Stipulation bars a remedy sought in such criminal prosecution or administrative action.

16. In exchange for valuable consideration provided in this Stipulation, Defendant acknowledges the following:

- a. Defendant has reviewed its financial situation and warrants that it is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I) and shall remain solvent following payment to the United States of the Settlement Amount.
- b. In evaluating whether to execute this Agreement, the Parties intend that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to Defendant, within the meaning of 11 U.S.C. § 547(c)(1), and the Parties conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange.
- c. The mutual promises, covenants, and obligations set forth herein are intended by the Parties to, and do in fact, constitute a reasonably equivalent exchange of value.
- d. The Parties do not intend to hinder, delay, or defraud any entity to which Defendant was or became indebted on or after the date of any transfer contemplated in this Stipulation, within the meaning of 11 U.S.C. § 548(a)(1).
- e. If Defendant's obligations under this Stipulation are avoided for any reason (including but not limited to through the exercise of a trustee's avoidance

powers under the Bankruptcy Code) or if, before the Settlement Amount is paid in full, Defendant or a third party commences a case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors seeking any order for relief of Defendant's debts, or to adjudicate Defendant as bankrupt or insolvent, or seeking appointment of a receiver, trustee, custodian, or other similar official for Defendant or for all or any substantial part of Defendant's assets:

- (1) the United States may rescind the releases in this Stipulation and bring any civil and/or administrative claim, action, or proceeding against Defendant for the claims that would otherwise be covered by the releases provided in Paragraphs 5, 8, and 9 above;
- (2) the United States has an undisputed, noncontingent, and liquidated allowed claim against Defendant in the amount of \$176,986,744, less any payments received pursuant to the Stipulation, provided, however, that such payments are not otherwise avoided and recovered from the United States by Defendant, a receiver, trustee, custodian, or other similar official for Defendant; and
- (3) if any payments are avoided and recovered by Defendant, a receiver, trustee, custodian, or similar official for Defendant, Relator shall, within thirty days of written notice from the United States to the undersigned Relator's counsel, return any portions of such payments already paid by the United States to Relator.

f. Defendant agrees that any civil and/or administrative claim, action, or proceeding brought by the United States under Paragraph 16(e) above is not subject to an “automatic stay” pursuant to 11 U.S.C. § 362(a) because it would be an exercise of the United States’ police and regulatory power. Defendant shall not argue or otherwise contend that the United States’ claim, action, or proceeding is subject to an automatic stay and, to the extent necessary, consents to relief from the automatic stay for cause under 11 U.S.C. § 362(d)(1). Defendant waives and shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claim, action, or proceeding brought by the United States within 120 days of written notification to Defendant that the releases have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on August 5, 2016.

17. 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), any TRICARE carrier, ADAP, or any state payer related to the Covered Conduct; and Defendant agrees not to resubmit to any Medicare contractor, any TRICARE carrier, ADAP, 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.

18. Defendant 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-6; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Defendant, including its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Stipulation;
- (2) the United States' audit(s) and civil investigation(s) of matters covered by this Stipulation;
- (3) Defendant's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with matters covered by this Stipulation (including attorneys' fees);
- (4) the negotiation and performance of this Stipulation;
- (5) the payment Defendant makes to the United States pursuant to this Stipulation and any payment Defendant may make to Relator, including expenses, 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: Unallowable Costs shall be separately determined and accounted for by Defendant, and Defendant 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 Defendant or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

- c. Treatment of Unallowable Costs Previously Submitted for Payment: Within 90 days of the Effective Date of this Stipulation, Defendant 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 Defendant 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. Defendant agrees that the United States, at a minimum, shall be entitled to recoup from Defendant 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, including the Department of Justice and/or the affected agencies, reserves its rights to disagree with any calculations submitted by Defendant or any of its subsidiaries or affiliates on the effect of inclusion of

Unallowable Costs (as defined in this Paragraph) on Defendant or any of its subsidiaries' or affiliates' cost reports, cost statements, or information reports.

- d. Nothing in this Stipulation shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Defendant's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

19. This Stipulation 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 as otherwise provided herein.

20. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Stipulation; provided, however, nothing in this Stipulation shall preclude Relator from seeking to recover his expenses or attorneys' fees and costs from Defendant, pursuant to 31 U.S.C. § 3730(d).

21. Any failure by the Government to insist upon the full or material performance of any of the provisions of this Stipulation shall not be deemed a waiver of any of the provisions hereof, and the Government, notwithstanding that failure, shall have the right thereafter to insist upon the full or material performance of any and all of the provisions of this Stipulation.

22. This Stipulation is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Stipulation is the United States District Court for the Southern District of New York.

23. For purposes of construing this Stipulation, this Stipulation shall be deemed to have been drafted by all Parties to this Stipulation and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

24. This Stipulation constitutes the complete agreement between the Parties with respect to the subject matter hereof. This Stipulation may not be amended except by written consent of the Parties. No prior agreements, oral representations or statements shall be considered part of this Stipulation.

25. The undersigned counsel and other signatories represent and warrant that they are fully authorized to execute this Stipulation on behalf of the persons and the entities indicated below.

26. This Stipulation is binding on Defendant's successors, transferees, heirs, and assigns.

27. This Stipulation is binding on Relator's successors, transferees, heirs, and assigns.

28. This Stipulation may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Stipulation. E-mails that attach signatures in PDF form or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Stipulation.

29. Any notice pursuant to this Stipulation shall be in writing and shall, unless expressly provided otherwise herein, be delivered by hand, express courier, or e-mail transmission followed by postage-prepaid mail, and shall be addressed as follows:

TO THE UNITED STATES:

Jacob M. Bergman
Allison M. Rovner
Rebecca S. Tinio
Lucas Issacharoff
Assistant United States Attorneys
United States Attorney's Office
Southern District of New York
86 Chambers Street, Third Floor
New York, New York 10007

Email: jacob.bergman@usdoj.gov
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rebecca.tinio@usdoj.gov
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TO DEFENDANT:

Jonathan M. Phillips
John D.W. Partridge
Mylan L. Denerstein
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30. The effective date of this Stipulation is the date upon which the Stipulation is approved by the Court (the “Effective Date”).

Agreed to by:

THE UNITED STATES OF AMERICA

Dated: New York, New York
_____, 2025

JAY CLAYTON
United States Attorney for the
Southern District of New York

By: _____
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Attorneys for the United States of America

RELATOR

Dated: _____,
_____, 2025

Dr. Paul Bellman
Relator

Dated: _____,
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Attorneys for Relator

DEFENDANT

Dated:

_____, 2025

GILEAD SCIENCES, INC.

By: _____

Deborah H. Telman
Executive Vice President, Corporate Affairs
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SO ORDERED:

HON. PAUL A. ENGELMAYER
UNITED STATES DISTRICT JUDGE

Dated: _____, 2025