

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) (collectively, the “United States”) and Jazz Pharmaceuticals plc, Jazz Pharmaceuticals, Inc., and Jazz Pharmaceuticals Ireland, Ltd. (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. Jazz Pharmaceuticals plc is an Ireland public limited company with principal executive offices located in Dublin, Ireland; Jazz Pharmaceuticals, Inc., is a corporation organized and existing under the laws of the State of Delaware having a principal place of business in Palo Alto, California; and Jazz Pharmaceuticals Ireland, Ltd., is a corporation organized and existing under the laws of Ireland having a principal place of business in Dublin, Ireland (collectively, “Jazz”). During the relevant period of time, Jazz manufactured pharmaceutical products marketed in the United States, including Xyrem and Prialt. Xyrem is approved to treat both cataplexy and excessive daytime sleepiness in narcolepsy; its active ingredient is Gamma Hydroxybutyrate (GHB), a central nervous system depressant and controlled substance. From January 1, 2011 through May 31, 2014, Jazz increased Xyrem’s list price by approximately 150%. Prialt is a non-opioid, non-NSAID analgesic agent approved for the management of severe chronic pain in patients for whom intrathecal therapy is warranted, and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjunctive therapies, or intrathecal morphine (collectively, the “Subject Drugs”).

B. The United States contends that Jazz caused to be submitted claims for payment for the Subject Drugs to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. § 1395-1395lll (“Medicare”).

C. When a beneficiary obtains a prescription drug covered by Medicare Part B or Part D, the beneficiary may be required to make a payment, which may take the form of a “copayment,” “coinsurance,” or “deductible” (collectively “copays”). The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, prohibits pharmaceutical companies from paying remuneration to induce Medicare beneficiaries to purchase, or their physicians to prescribe, drugs that are reimbursed by Medicare.

D. Caring Voice Coalition (“CVC”), an entity claiming 501(c)(3) status for tax purposes, operated funds that paid the copays of certain patients, including Medicare patients.

E. The United States contends that it has certain civil claims, as specified in Paragraph 2 below, against Jazz for engaging in the conduct below during the period from January 1, 2011, through May 31, 2014 (hereinafter referred to as the “Covered Conduct”). Specifically, the United States alleges that:

Jazz made donations to CVC and used CVC as a conduit to pay the copay obligations of Medicare patients taking the Subject Drugs.

In 2011, Jazz asked CVC to create a fund that would pay the copays of certain Xyrem patients, including Medicare patients. CVC then agreed to establish a “Narcolepsy Fund,” and Jazz was the sole donor to the fund. Xyrem accounted for a small share of the overall narcolepsy drug market. Theoretically, the CVC Narcolepsy Fund could cover patients taking any narcolepsy medication, but, in practice, it almost exclusively assisted patients taking Xyrem. Jazz donated to CVC with this understanding. Moreover, CVC disadvantaged any patients

seeking assistance for two competing narcolepsy drugs by requiring them to obtain a denial letter from another assistance plan before being eligible for CVC assistance. Jazz knew or should have known that CVC favored patients taking Xyrem, and disadvantaged patients taking other medications. In conjunction with the establishment of CVC's Narcolepsy Fund, Jazz changed the eligibility criteria for its program that provided free Xyrem to patients who could not afford it and, as a result of this change, Medicare patients no longer qualified for the program. Instead, Jazz directed its distribution vendor to refer any Xyrem Medicare patients with unaffordable copays to CVC in order for Jazz to generate revenue from Medicare and to induce purchases of the drug, which resulted in claims to Medicare to cover the cost of the drug.

With respect to Prialt, Jazz asked CVC to create a fund ostensibly to assist patients with the co-pays of any severe chronic pain drugs, and CVC then created a "Severe Chronic Pain Fund." In practice, this fund almost exclusively assisted patients taking Prialt. Shortly after the creation of the fund, CVC told Jazz that, when severe chronic pain patients seeking assistance with drugs other than Prialt contacted CVC, CVC would refer them to another assistance program. Jazz further knew that the CVC Severe Chronic Pain Fund would not appear on the CVC website, which would result in fewer patients taking medications other than Prialt accessing the CVC fund.

As a result of the foregoing conduct, the United States contends that Jazz caused false claims to be submitted to Medicare.

F. In consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Jazz shall pay to the United States fifty-seven million dollars (\$57,000,000), plus interest at a rate of 2.75% from April 10, 2018, through the day before full payment (the “Settlement Amount”), no later than ten business 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 District of Massachusetts. Of the Settlement Amount, \$28,500,000 is restitution to the United States.

2. Subject to the exceptions in Paragraph 4 (concerning excluded claims) below, and conditioned upon Jazz’s full payment of the Settlement Amount, the United States releases Jazz, together with its predecessors, and its current and former divisions, parents, subsidiaries, successors and assigns, from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-33, the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-12, or the common law theories of payment by mistake, unjust enrichment, and fraud.

3. In consideration of the obligations of Jazz in this Agreement and the Corporate Integrity Agreement (“CIA”) entered into between OIG-HHS and Jazz, and conditioned upon Jazz’s full payment of the Settlement Amount, the OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Jazz under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in this Paragraph and in Paragraph 4 (concerning excluded claims), below. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to

exclude Jazz from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 4, below.

4. Notwithstanding the releases given in paragraphs 2 and 3 of this Agreement, or any other term of this Agreement, the following claims 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, including mandatory 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.

5. Jazz waives and shall not assert any defenses Jazz 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.

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

7. 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 Jazz 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.

8. Jazz 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. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Jazz, 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 any civil or criminal investigations of the matters covered by this Agreement;

- (3) Jazz's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and any civil or criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);
- (4) the negotiation and performance of this Agreement;
- (5) the payment Jazz makes to the United States pursuant to this Agreement; and
- (6) the negotiation of, and obligations undertaken pursuant to the CIA to: (i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (ii) prepare and submit reports to the OIG-HHS,

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). However, nothing in paragraph 8.a.(6) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to Jazz.

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

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

9. 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 10 (waiver for beneficiaries paragraph), below.

10. Jazz 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.

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

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

13. 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 District of Massachusetts. 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.

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

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

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

17. This Agreement is binding on Jazz's successors, transferees, heirs, and assigns.

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

19. 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.

THE UNITED STATES OF AMERICA

DATED: 4/4/19 BY: [REDACTED]
GREGG SHAPIRO
ABRAHAM GEORGE
Assistant United States Attorneys
United States Attorney's Office
District of Massachusetts

DATED: 4/3/19 BY: [REDACTED]
AUGUSTINE RIPA / 9
SARAH ARNI
Attorneys
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 04/02/2019 BY: [REDACTED]
LISA M. RE
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

**JAZZ PHARMACEUTICALS plc
JAZZ PHARMACEUTICALS, INC.
JAZZ PHARMACEUTICALS IRELAND LTD.**

DATED:

BY: _____

PATRICIA CARR
Authorized Signatory
Jazz Pharmaceuticals plc

DATED: 4/3/2019

BY: _____

MATTHEW YOUNG
Executive Vice President and Chief Financial Officer
Jazz Pharmaceuticals, Inc.

DATED:

BY: _____

HUGH KIELY
Director
Jazz Pharmaceuticals Ireland Ltd.

DATED:

BY: _____

MITCHELL J. LAZRIS
MICHELE W. SARTORI
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Counsel for Jazz Pharmaceuticals plc, Jazz
Pharmaceuticals, Inc., and Jazz Pharmaceuticals Ireland
Ltd.

**JAZZ PHARMACEUTICALS plc
JAZZ PHARMACEUTICALS, INC.
JAZZ PHARMACEUTICALS IRELAND LTD.**

DATED: 3 Apr 2019

BY:



PATRICIA CARR
Authorized Signatory
Jazz Pharmaceuticals plc

DATED:

BY:

MATTHEW YOUNG
Executive Vice President and Chief Financial Officer
Jazz Pharmaceuticals, Inc.

DATED: 4-3-19

BY:



HUGH KIELY
Director
Jazz Pharmaceuticals Ireland Ltd.

DATED:

BY:

MITCHELL J. LAZRIS
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Pharmaceuticals, Inc., and Jazz Pharmaceuticals Ireland
Ltd.

**JAZZ PHARMACEUTICALS plc
JAZZ PHARMACEUTICALS, INC.
JAZZ PHARMACEUTICALS IRELAND LTD.**

DATED: **BY:** _____
PATRICIA CARR
Authorized Signatory
Jazz Pharmaceuticals plc

DATED: **BY:** _____
MATTHEW YOUNG
Executive Vice President and Chief Financial Officer
Jazz Pharmaceuticals, Inc.

DATED: **BY:** _____
HUGH KIELY
Director
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DATED: 4/3/19 **BY:** _____
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