

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 Alexion Pharmaceuticals, Inc. (“Alexion”) (hereafter collectively referred to as the “Parties”), through their authorized representatives.

RECITALS

A. Alexion is a Delaware corporation with principal executive offices located in Boston, Massachusetts. Alexion manufactures and markets pharmaceutical products in the United States, including Soliris, which is an intravenously administered complement inhibitor. From January 1, 2010, through June 30, 2016, (the “Relevant Time Period”) Soliris was indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria (“PNH”) to reduce hemolysis and for the treatment of patients with atypical hemolytic uremic syndrome (“aHUS”) to inhibit complement-mediated thrombotic microangiopathy. In 2010, the list price for a 300 mg / 30 mL dose of Soliris was approximately \$5,300, and it increased to approximately \$6,300 in 2016. The indicated yearly dosing recommendation for Soliris varies between approximately 90 and 120 doses per year.

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

C. When a Medicare 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. Patient Services Inc. (“PSI”), an entity claiming 501(c)(3) status for tax purposes, operates funds that pay the copays of certain patients, including Medicare patients. During the Relevant Time Period, PSI operated a fund entitled Complement Mediated Diseases (“CMD”) that paid the copays of certain patients, including Medicare patients, prescribed Soliris.

E. The United States contends that it has certain civil claims, as specified in Paragraph 2 below, against Alexion for engaging in the conduct below during the Relevant Time Period (hereinafter referred to as the “Covered Conduct”). Specifically, the United States alleges:

Alexion made donations to PSI’s CMD fund and used it as a conduit to pay the copay obligations of patients taking Soliris and to induce those patients’ purchases of Soliris, including Medicare patients. Alexion knew that the price for Soliris could pose a barrier to patients’ purchases of it. In particular, Alexion approached PSI in January 2010 to request that PSI create a fund to provide financial assistance to Soliris patients, including by paying patients’ Soliris Medicare copays and other medical expenses for Soliris patients. Over the next several months, Alexion and PSI discussed the coverage parameters that Alexion desired for the fund, including Alexion’s desire that PSI “not support a patient with any of these [CMD] diagnoses for other reasons tha[n] Soliris therapy.” After the fund opened, Alexion—the sole donor to the fund—understood that PSI’s provision of financial assistance to a patient was contingent on the patient taking Soliris. Alexion noted internally that it needed to be diligent in letting PSI know if a patient had stopped taking Soliris so that PSI would not use Alexion’s donations on patients who were not starting or maintaining Soliris therapy. Meanwhile, Alexion had a general practice of not permitting Medicare patients to participate in its free drug program, which was open to other

financially needy patients, even if those Medicare patients could not afford their copays for Soliris. Instead, in order to generate revenue from Medicare and induce purchases of Soliris, Alexion referred Medicare patients prescribed Soliris to PSI, through PSI's referral portal software. The referral portal reported information back to Alexion confirming those Soliris patients who were approved for copay or other financial assistance from PSI and detailed PSI's payments to them. This above conduct resulted in claims to Medicare to cover the cost of Soliris.

As a result of the foregoing conduct, the United States contends that Alexion 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. Alexion shall pay to the United States thirteen million dollars (\$13,000,000), plus interest at a rate of 2.865% from December 12, 2018, through the day before full payment (the "Settlement Amount") no later than ten 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, \$7,020,000 is restitution to the United States.

2. Subject to the exceptions in Paragraph 4 (concerning excluded claims) below, and conditioned upon Alexion's full payment of the Settlement Amount, the United States releases Alexion, 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. OIG-HHS expressly reserves all rights to institute, direct, or to maintain any administrative action seeking exclusion against Alexion and/or its officers, directors, and employees from Medicare, Medicaid, and all other 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) or 42 U.S.C. § 1320a-7a (permissive exclusion).

4. Notwithstanding the releases given in paragraph 2 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 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.

5. Alexion waives and shall not assert any defenses Alexion 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. Alexion 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 Alexion 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 Alexion 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. Alexion 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 Alexion, 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) Alexion'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; and
- (5) the payment Alexion makes to the United States pursuant to this Agreement

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 Alexion, and Alexion 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 Alexion or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

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


GREGG SHAPIRO

Assistant United States Attorney
United States Attorney's Office
District of Massachusetts

DATED: 4/3/19

BY:


AUGUSTINE RIPA

SARAH ARNI

Attorneys

Commercial Litigation Branch

Civil Division

United States Department of Justice

DATED: 04/02/2019

BY:


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

ALEXION PHARMACEUTICALS, INC.

DATED: 4/1/19

BY:


ELLEN V. CHINIARA
Alexion Pharmaceuticals, Inc.
General Counsel

DATED: _____

BY: _____

JOSH S. LEVY
Ropes & Gray LLP
Counsel for Alexion Pharmaceuticals, Inc.

DATED: _____

BY: _____

JOHN RAH
DLA Piper LLP
Counsel for Alexion Pharmaceuticals, Inc.

ALEXION PHARMACEUTICALS, INC.

DATED: _____

BY: _____
ELLEN V. CHINIARA
Alexion Pharmaceuticals, Inc.
General Counsel

DATED: 4/1/19

BY: [REDACTED]
JOSH S. LEVY
Ropes & Gray LLP
Counsel for Alexion Pharmaceuticals, Inc.

DATED: 4/1/19

BY: [REDACTED]
JOHN RAH
DLA Piper LLP
Counsel for Alexion Pharmaceuticals, Inc.