

SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement ("Settlement Agreement" or "Agreement") is entered into by and between the **United States of America**, acting through the United States Department of Justice ("DOJ"),¹ and on behalf of the Drug Enforcement Administration ("DEA") (collectively the "United States"), and **Costco Wholesale Corporation** ("Costco"). The United States and Costco are collectively referred to herein as "the Parties," and each is referred to as a "Party."

II. RECITALS

1. Costco is a corporation organized and existing under the laws of the State of Washington. Costco's corporate headquarters and principal place of business is located at 999 Lake Drive, Issaquah, Washington. Costco operates membership warehouses in the United States and in various foreign countries. As part of its retail operations, Costco operates retail pharmacies in 44 states, the District of Columbia and Puerto Rico, as well as "Central Fill" and mail order pharmacies (each a "Pharmacy," and collectively "Pharmacies"). This Agreement relates only to Costco's Pharmacies in the United States that are or were registered with the DEA to dispense, distribute or otherwise handle controlled substances, and not to any other business conducted by Costco or its affiliates.

2. Costco is required to operate its Pharmacies in accordance with the applicable statutory provisions of the Comprehensive Drug Abuse Prevention and Control Act, 21 U.S.C. § 801 *et seq.*, popularly known as the Controlled Substances Act ("CSA"), and the related regulatory provisions of the Code of Federal Regulations ("C.F.R."), 21 C.F.R. § 1300 *et seq.*

¹ The Department of Justice is represented by the following United States Attorney's Offices: Central District of California; Eastern District of California; Eastern District of Michigan; Eastern District of Washington; and Western District of Washington.

Each Costco Pharmacy is separately registered with DEA and maintains a unique DEA registration number to dispense controlled substances as required by the CSA.

3. DEA is the Department of Justice component agency with primary responsibility for administering the CSA, and the regulations promulgated thereunder, and is vested with the responsibility of investigating violations of the CSA.

4. The United States Attorney General, through the United States Attorney's Offices, has primary authority to bring civil actions to enforce the CSA. 21 U.S.C. § 871; 28 C.F.R. § 0.55(c).

5. Pursuant to the CSA, a pharmacy may only fill valid and effective prescriptions. 21 U.S.C. § 829. To be valid, a controlled substance prescription must be issued by an individual practitioner who is (a) authorized to prescribe controlled substances by the jurisdiction in which he/she is licensed; and (b) registered by DEA (or otherwise exempted from registration). 21 C.F.R. § 1306.03. To be effective, a controlled substance prescription must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. *Id.* § 1306.04(a). All controlled substance prescriptions must also include the information specified in 21 C.F.R. § 1306.05. Costco acknowledges that its Pharmacies have a corresponding responsibility to fill only valid and effective controlled substance prescriptions. *Id.* § 1306.04(a). Costco acknowledges that its pharmacists may only fill controlled substance prescriptions while acting in the usual course of their professional practice. *Id.* § 1306.06.

6. A pharmacy is required to comply with certain record keeping requirements as provided under the CSA and the related regulatory provisions of the C.F.R. Costco acknowledges that the CSA and the related regulations require pharmacies to maintain complete

and accurate records of each controlled substance manufactured, received, sold, delivered, dispensed or otherwise disposed of by the pharmacy. 21 U.S.C. § 827(a)(3); 21 C.F.R. §§ 1304.03, 1304.21, 1304.22.

7. On November 1, 2012, Costco, DOJ and DEA entered into a Settlement Agreement concerning certain prescriptions issued by a physician without a valid DEA registration number and filled at six Costco Pharmacies located in the Eastern District of Michigan (the “EDMI Settlement”). Costco undertook numerous improvements to its systems and controls.

8. As part of separate DEA controlled substance diversion investigations unrelated to one another or to the 2012 investigation in the Eastern District of Michigan, DEA’s Los Angeles Field Division (“LA-FD”) and the Seattle Field Division (“SEA-FD”) discovered that certain Costco Pharmacies in Southern California and Washington had: (1) filled prescriptions issued by individual practitioners who did not have a valid DEA registration number; and (2) filled prescriptions issued by individual practitioners with a valid DEA registration number but then recorded and reported an incorrect and/or invalid DEA registration number in the Pharmacy’s records. SEA-FD further discovered that certain Costco Pharmacies in Washington failed to maintain proper prescription and other records required under the CSA. In addition, SEA-FD and the Sacramento Field Division (“SAC-FD”) discovered various irregularities and recordkeeping issues at the Costco Central Fill facilities located in Everett, WA and West Sacramento, CA, including an inventory shortage at the West Sacramento location.

9. Costco cooperated with the LA-FD, SEA-FD and SAC-FD investigations, providing DEA access to relevant Costco facilities and responding to numerous requests from

DOJ and DEA for information, documents and records. Costco again undertook numerous improvements to its systems and controls.

10. The United States contends that it has claims for civil penalties pursuant to 21 U.S.C. §§ 842(a)(1) and (5), 842(c)(1)(A) and (B), against Costco for the following conduct occurring in Costco Pharmacies in the United States from January 1, 2012 through December 31, 2015 (the “Covered Time Period”):

(a) filling prescriptions issued by individual practitioners who did not have valid DEA registration numbers, in violation of 21 U.S.C. § 829 and 21 C.F.R. §§1306.03, 1306.04(a), and 1306.06;

(b) filling prescriptions issued by individual practitioners who had a valid DEA registration number, but recording and reporting the prescription under incorrect and invalid DEA registration numbers in the Pharmacies’ records, in violation of 21 U.S.C. § 827 and 21 C.F.R. § 1304.21;

(c) filling prescriptions issued by individual practitioners for controlled substances outside the scope of the practitioner’s DEA registration, in violation of 21 U.S.C. § 829 and 21 C.F.R. § 1306.04(a);

(d) filling prescriptions that did not contain all required information, in violation of 21 U.S.C. § 829 and 21 C.F.R. § 1306.04;

(e) failing to maintain accurate dispensing records, in violation of 21 U.S.C. § 827 and 21 C.F.R. §§ 1306.04(a) and 1306.05;

(f) failing to properly execute DEA-222 order forms, in violation of 21 U.S.C. §§ 827, 828 and 21 C.F.R. § 1305.06;

- (g) failing to keep and maintain records, in violation of 21 U.S.C. § 827 and 21 C.F.R. § 1304.22(c);
- (h) failing to maintain accurate records for each controlled substance that Costco received, sold, dispensed, or otherwise disposed of at its registered locations, in violation of 21 U.S.C. § 827(a)(3) and 21 C.F.R. §§ 1304.03, 1304.04, 1304.21;
- (i) failing to maintain Central Fill records in a readily retrievable manner, in violation of 21 U.S.C. § 827 and 21 C.F.R. § 1306.27;
- (j) failing to comply with recordkeeping requirements for prescriptions filled at Central Fill facilities, in violation of 21 U.S.C. § 827 and 21 C.F.R. § 1306.27(a); and
- (k) conduct inconsistent or noncompliant with the CSA and its implementing regulations by any Pharmacy, the extent that such conduct was or could have been discovered by the United States through the exercise of due diligence through investigations of and inspections at Costco, or by the review of the reports and records submitted by Costco to DEA.

The conduct described in this Paragraph 10 shall be referred to collectively as “the Covered Conduct.”

11. Costco acknowledges that, at various times during the Covered Time Period, certain Costco Pharmacies did dispense controlled substances in a manner not fully consistent with their compliance obligations under the CSA and its implementing regulations.

12. In order to avoid the delay, uncertainty, inconvenience and expense of protracted litigation of these claims, the United States and Costco hereby enter into this full and final settlement pursuant to the Terms and Conditions set forth below.

III. TERMS AND CONDITIONS

THEREFORE, in consideration of the mutual promises, covenants, and obligations set forth below, and for good and valuable consideration as stated herein, the United States and Costco agree as follows:

13. Settlement Payment. Costco agrees to pay to the United States the sum of \$11,750,000.00 (the "Settlement Amount"). Full payment will be made by electronic funds transfer within thirty (30) days of the Effective Date of this Settlement Agreement, pursuant to instructions to be provided by the United States Attorney's Office for the Western District of Washington.

14. Release of Costco by the United States. Subject to the exceptions in Paragraph 16 below, in consideration of the fulfillment of the obligations of Costco set forth in this Agreement, and conditioned upon Costco's payment in full of the Settlement Amount, the United States agrees to:

- A. Release Costco including Costco's present, former, and future parents, subsidiaries, affiliates, and registrants, (collectively, the "Released Parties") from all civil penalty claims under 21 U.S.C. § 842 that the United States may have against Costco under the CSA, and the related

provisions of the C.F.R., based on the Covered Conduct for the Covered Time Period; and

- B. Refrain from filing any action for civil penalties against the Released Parties under 21 U.S.C. § 842 by any United States Attorney's Office and/or DOJ based on the Covered Conduct for the Covered Time Period.

15. Release of Costco by DEA. Subject to the exceptions in Paragraph 16 below, in consideration of the obligations set forth in this Agreement, and conditioned upon Costco's payment in full of the Settlement Amount, DEA agrees to release and to refrain from instituting, directing, or maintaining any administrative claim or administrative action against Costco based upon the Covered Conduct for the Covered Time Period. However, notwithstanding the preceding sentence, in any civil, criminal, or administrative proceedings against Costco permitted in Paragraph 16 below, and as otherwise permitted by law, DEA reserves the right to seek to admit evidence of the Covered Conduct for proper evidentiary purposes in any future administrative proceeding against Costco for non-Covered Conduct and Costco reserves the right to oppose and dispute the admissibility of any such evidence. Furthermore, nothing in this Settlement Agreement shall prohibit or limit any other agency of the United States or any State thereof, from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct. DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that has initiated or initiates an investigation, action, or proceeding involving the Covered Conduct, but will not otherwise initiate or refer any civil action to any U.S. Attorney's Office or to any component of DOJ, based on the Covered Conduct.

16. Reservations and Exclusions from Release of Costco. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement, including the release of Costco, are the following:

- (a) Any civil, criminal or administrative claims arising under Title 26, U.S. Code (Internal Revenue Code);
- (b) Any criminal liability;
- (c) Any administrative claims or liability, including claims for revocation of DEA authorization to possess or distribute controlled substances for any conduct other than the Covered Conduct;
- (d) Any liability to the United States (or its agencies or departments) for any conduct other than the Covered Conduct; and,
- (e) Any claims based upon such obligations as are created by this Agreement.

17. Release of the United States. In consideration of the obligations set forth in this Agreement, Costco, on behalf of its officers, directors, parents, subsidiaries, affiliates, agents and employees, fully and finally releases the United States, its officers, agents, employees, agencies and departments from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Costco has asserted, could have asserted, or may assert in the future against the United States, its officers, agents, employees, agencies and departments, related to the Covered Conduct or the United States' investigation or prosecution thereof.

18. CSA Compliance. From the Effective Date of this Agreement for a period of three (3) years, Costco agrees:

- a) To allow DEA to conduct, during regular business hours, unannounced and unrestricted inspections of all DEA-registered Costco Pharmacy locations without Administrative Inspection Warrants, and to reasonably cooperate in such unannounced inspections.
- b) To continually maintain a regularly-audited internal compliance program designed to prevent and detect diversion of controlled substances at all DEA-registered Costco Pharmacy locations.
- c) To fully comply with all compliance obligations imposed upon DEA registrants by the CSA and its implementing regulations.
- d) Costco's Pharmacy Compliance Officer shall oversee and be responsible for implementing Costco's compliance obligations under this Agreement.

19. Unallowable Costs. Costco agrees that any and all costs it has, will, or may incur in connection with this matter, including payment of the Settlement Amount, attorney's fees, costs of investigation, negotiation, future compliance efforts, and remedial action, shall be unallowable costs for government contracting accounting and for purposes of any government reimbursement program.

20. No Agreement Regarding Tax Treatment. Nothing in this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of any proceeding under Title 26 of the Internal Revenue Code.

21. Benefit of Parties Only. This Agreement is intended to be for the benefit of the United States and Costco only, and by this instrument neither the United States nor Costco release any claim against any other person or entity.

22. Attorneys' Fees and Costs. The United States and Costco will bear their own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

23. Voluntary Agreement. Costco represents that this Agreement is knowingly, freely and voluntarily entered into, without any degree of duress or compulsion whatever, and that it has been advised with respect to this Agreement by counsel.

24. Governing Law, Jurisdiction and Venue. The Agreement is governed by the laws of the United States. The United States and Costco agree that the exclusive jurisdiction and venue for any dispute arising between or among them under this Agreement will be the United States District Court for the Western District of Washington

25. Binding Effect. This Agreement is binding on Costco's successors, transferees, subsidiaries, and assigns.

26. Consent to Disclosure. The United States and Costco consent to the disclosure of this Agreement, and information about this Agreement, to the public.

27. Entire Agreement. This Agreement constitutes the complete agreement between and among the United States and Costco regarding the Covered Conduct. This Agreement may not be amended except by written consent of the United States and Costco.

28. Jointly-Drafted Agreement. For purposes of construction, this Agreement shall be deemed to have been drafted by both the United States and Costco, and in any subsequent dispute shall not be construed against any party based on separate drafting by that party.

29. Capacity to Execute. Costco warrants and represents that its undersigned officer is authorized to execute and deliver this Agreement and has the authority to bind Costco to its


terms. The United States warrants and represents that its undersigned representatives are authorized to execute and deliver this Agreement and bind the United States to its terms.

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

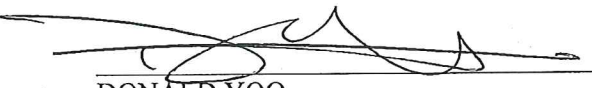
31. Effective Date. This Agreement shall become effective on the date of signature of the last signatory to this Agreement ("Effective Date").

THE UNITED STATES OF AMERICA

Dated: January 18, 2017


KERRY J. KEEFE
Assistant U.S. Attorney
Western District of Washington

Dated: January 3, 2017


DONALD YOO
Assistant U.S. Attorney
Central District of California

Dated: January __, 2017

M. ANDERSON BERRY
Assistant U.S. Attorney
Eastern District of California

Dated: January __, 2017

VANESSA R. WALDREF
Assistant U.S. Attorney
Eastern District of Washington

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Western District of Washington

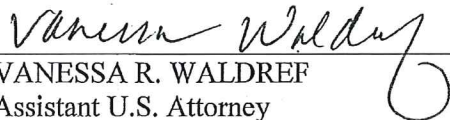
Dated: January __, 2017

DONALD YOO
Assistant U.S. Attorney
Central District of California

Dated: January __, 2017

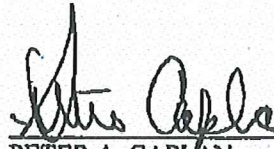
M. ANDERSON BERRY
Assistant U.S. Attorney
Eastern District of California

Dated: January 5, 2017



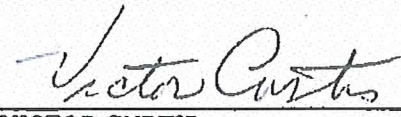
VANESSA R. WALDREF
Assistant U.S. Attorney
Eastern District of Washington

Dated: January 3, 2017


PETER A. CAPLAN
Assistant U.S. Attorney
Eastern District of Michigan

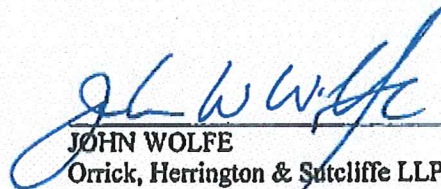
COSTCO WHOLESALE CORPORATION

Dated: January 17, 2017


VICTOR CURTIS
Sr. Vice President
Costco Wholesale Corporation

Approved as to form and content:

Dated: January 18, 2017


JOHN WOLFE
Orrick, Herrington & Sutcliffe LLP
Counsel for Costco Wholesale Corporation