SETTLEMENT AGREEMENT AND RELEASE

I. PARTIES

1. This Settlement Agreement ("Agreement") is entered into between the United States of America, through the United States Attorney's Office for the Western District of Washington (the "United States") and on behalf of the Drug Enforcement Administration ("DEA"), and Seattle Cancer Care Alliance ("SCCA"). SCCA and the United States are referred to collectively as the "Parties."

II. RECITALS

- 2. SCCA is an outpatient cancer treatment center in Seattle, Washington. To facilitate the treatment of cancer patients, SCCA operates a DEA-registered pharmacy on its premises, which dispenses, among other things, opioids for the relief of pain that can be caused by certain cancers. Opioids possess a high potential for abuse and/or physical and psychological dependency and, thus, are generally classified as Schedule II drugs under the Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801, et seq., and are subject to strict regulation.
- 3. The United States contends that from approximately May 2011 to December 2013, an oncology nurse employed by SCCA successfully diverted more than ninety-six thousand (96,000) tablets of oxycodone from SCCA's pharmacy through a scheme devised to mislead SCCA, its pharmacists and physicians. The United States further contends that the nurse altered prescriptions to significantly increase the potency of the dosage and the number of tablets prescribed for those patients by SCCA physicians (without their knowledge), frequently altering a prescription for 40, 60 or 80 tablets to a prescription for 240, 260 or 280 tablets. Further, the United States contends the nurse evaded detection in this scheme by picking up the fraudulent prescriptions herself from SCCA's pharmacy (ostensibly as a courtesy to patients) and paying for many of the prescriptions in cash.
- 4. As a DEA-registered pharmacy, SCCA's pharmacy is subject to various requirements under the CSA and its implementing regulations. The United States contends that SCCA, through acts and omissions related to the events described in paragraph 3, violated these regulations, specifically 21 C.F.R. §§ 1306.06 and 1304.22(c), and is, therefore subject to civil penalties under 21 U.S.C. § 842 for these acts and omissions (hereinafter the "Covered Conduct").
- 5. The United States acknowledges that SCCA discovered, investigated, and timely reported the nature and scope of nurse's diversion scheme and fully cooperated in all respects with the investigation of the United States. The United States further acknowledges that SCCA took additional action in response to the discovery of the diversion, including notifying the patients whose names were used, terminating the nurse, reporting the matter to appropriate State Agencies and strengthening their policies and procedures to help eliminate the likelihood of a similar diversion.
- 6. For its part, SCCA and its medical staff, pharmacy and pharmacy staff specifically deny that any of them violated the CSA or engaged in any wrongful or unlawful conduct and each denies any liability to the United States.

7. This Agreement is neither an admission of liability by either party nor a concession by either party that its claims or defenses are not well-founded. To avoid delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, the Parties agree to a full and final civil settlement, pursuant to the Terms and Conditions below.

III. TERMS AND CONDITIONS

In accordance with the mutual covenants and agreements made herein, and with full authority to enter into this agreement and to be bound thereby, the Parties agree to each of the following terms as follows:

- 8. <u>SCCA.</u> SCCA agrees to the following terms and conditions:
- a. *Payment.* SCCA shall pay TWO HUNDRED AND FIFTY THOUSAND DOLLARS (\$250,000) to the United States within 60 days of the Effective Date of this Agreement; said payment to be made according to wire transfer instructions provided by the Financial Litigation Unit, United States Attorney's Office, 700 Stewart Street, Suite 5200, Seattle, Washington, 98103.
- b. Compliance. SCCA shall comply with all applicable federal laws and regulations concerning registration, buying, storing, selling and dispensing of Schedule II controlled substances, including 21 U.S.C. § 842. Compliance with federal laws shall be interpreted to include a requirement that, if an SCCA pharmacist is presented with a prescription for a controlled substance that does not appear appropriate for the patient based upon the patient's prior prescription history, the pharmacist will personally consult with the prescriber or take other reasonable steps to confirm the prescription's appropriateness and veracity.
- c. Records of Dispensing. Neither the United States nor the DEA represent that dispensing controlled substances to persons other than the ultimate user or a member of their household is a lawful or appropriate practice and nothing in this Agreement should be construed otherwise. That said, to the extent SCCA engages in the practice of permitting persons other than the ultimate user or a member of their household to pick up controlled substances from the SCCA pharmacy, SCCA shall keep a log ("Dispensing Log") reflecting: the name of the pharmacist filling the prescription; the name of the technician or cashier engaged in the transaction; the drug name, quantity, and dosage filled; the name of the patient/ultimate user for whom the prescription was written; the name and phone number of the party picking up the prescription; and date and time the prescription was picked up. The United States specifically agrees that the maintenance of the log and practices described in this Section will not be used as the basis to assert a claim under the Controlled Substances Act that SCCA violated the "ultimate user" rule of dispensing.
- d. Notice to Affected Patients. For each patient (or former patient) of SCCA whose name was on one or more of the prescriptions filled for the nurse who illegally diverted the drugs during the period of the covered conduct ("Affected Patients"), SCCA shall make notations in both the SCCA pharmacy and clinic records noting that the patient's name was improperly used by the nurse to obtain oxycodone. SCCA previously provided notice of the incident to the Affected Patients as discussed in paragraph 5 above. SCCA shall designate a point person who will respond to inquiries regarding each Affected Patient's prescription history and explain the

circumstances and error for a period of two years from the effective date of this Agreement. After that time, it is the expectation of the Parties' that inquiries may be addressed by any SCCA staff responding to them through consultation with the Affected Patients' clinic or pharmacy record.

- 9. The United States. The United States agrees to the following terms and conditions. In consideration of the full and timely payment of the sum agreed upon in paragraph 7(a) of this agreement and material compliance with any and all of the other above described terms and conditions, the United States fully and finally releases SCCA, its successors and assigns, past, present, and future members, officers, directors, employees, attorneys, agents, managers, representatives, medical staff, pharmacy staff and all persons acting by, through, under, or in concert with them, from all civil and administrative claims, complaints, causes of action, demands, and penalties of any nature whatsoever arising from the Covered Conduct.
- 10. <u>Costs and Fees.</u> Each party to this Agreement shall bear its own costs, expenses, and fees, including attorneys, accountants, and expert witness fees which have been incurred in connection with the investigation and settlement of this matter.
- 11. <u>Full Agreement.</u> This agreement constitutes the full and complete agreement between the parties, with respect to the matters covered herein, and no modification hereof shall be effective unless in writing and signed by the party against which it is sought to be enforced.
- 12. Governing Law. This Agreement shall be governed by the laws of the United States. If any disputes arise under this Agreement, exclusive jurisdiction and venue shall lie in the United States District Court for the Western District of Washington, and, to the extent that any state law may apply to the dispute, the Parties agree that the law of Washington State shall apply.
- 13. <u>Disclosure</u>. Either party to this Agreement may disclose the existence of this Agreement and information about this Agreement to the public without restriction.
- 14. <u>Counterparts.</u> This Settlement Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same agreement. Copies or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Settlement Agreement.
- 15. <u>Binding.</u> This Settlement Agreement is binding on SCCA and its successors, transferees, and assigns.
- 16. <u>Effective Date.</u> This Settlement Agreement shall be effective when the last signatory to this Settlement Agreement executes the Agreement.
- 17. <u>Drafting.</u> For purposes of construing this Settlement 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.
- 18. <u>Authority to Sign.</u> Each person who signs this Settlement Agreement in a representative capacity warrants that he or she is fully authorized to do so. The government signatories represent that they are signing this Settlement Agreement in their official capacities.

IN WITNESS WHEREOF, the United States and SCCA have duly executed this Settlement Agreement with the intent to be bound by the terms, conditions, and representations herein.

| FOR SEATTLE CANCER CARE ALLIANCE: | Date: <u>07/06/16</u> |
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| FOR THE DEPARTMENT OF JUSTICE: | Date: 7/7/16 |