

SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement ("Agreement") is entered into by and between the United States of America ("United States"), acting through the United States Attorney's Office for the Northern District of California, Civil Division ("USAO") (collectively the "United States"), and Golden Gate Pharmacy Holdings, Inc.; Golden Gate Pharmacy Services, Inc.; Ross Valley Compounding Pharmacy, Inc.; Paul W. Lofholm, and Rebecca E. Lofholm (collectively the "Lofholm Parties"), through their authorized representatives. All parties to the Agreement are collectively referred to as "the Parties."

II. RECITALS

The Parties agree to the following recitals:

1. The Drug Enforcement Administration ("DEA") is the component agency of the United States Department of Justice primarily responsible for administering the Controlled Substances Act, 21 U.S.C. § 801 *et seq.* ("the Act"), and is vested with the responsibility for investigating violations of the Act.

2. Golden Gate Pharmacy Services, Inc. and Ross Valley Compounding Pharmacy ("Ross Valley Pharmacy") are wholly-owned subsidiaries of Golden Gate Pharmacy Holdings, Inc. Golden Gate Pharmacy Services, Inc., d/b/a Golden Gate Pharmacy ("Golden Gate Pharmacy") is registered as a retail pharmacy with the DEA, under registration number BG4451251, with current authorization to handle Schedules II, III, IIIN, IV, and V controlled substances, and are subject to periodic audits and inspections.

3. Ross Valley Compounding Pharmacy, Inc. ("Ross Valley Pharmacy") is registered as a retail pharmacy with the DEA, under registration number FR5051216¹, with current authorization to handle Schedules II, III, IIIN, IV, and V controlled substances, and is subject to periodic audits and inspections. Ross Valley Pharmacy currently identifies as a compounding-only pharmacy, following the sale of its retail pharmacy operation in June 2013.

4. Golden Gate Pharmacy and Ross Valley Pharmacy are each required to operate in accordance with the statutory provisions of the Act and its implementing regulations.

5. The Attorney General, through the United States Attorney's Office, has primary authority to bring civil actions to enforce the Act. *See* 21 U.S.C. § 871 and 28 C.F.R. § 0.55(c).

6. The Act creates a closed system of distribution for those authorized to handle controlled substances and listed chemicals. The Act is designed to prevent diversion of controlled substances by, among other things, requiring DEA registrants to maintain and keep certain records.

7. The Act provides that it is unlawful for a person to "refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under this subchapter or subchapter II of this chapter" of the Act. 21 U.S.C. § 842(a)(5). By creating this closed system of distribution and the attendant recordkeeping requirements and imposing penalties for recordkeeping violations, the Act seeks to prevent harm to the general public and threats to the public safety created by

¹ At the time of the Scheduled Investigation, Ross Valley's DEA registration number was BG3090848.

diversion of controlled substances from the Act's permitted distribution scheme to prohibited uses of the controlled substances.

8. A registrant may not distribute to locations other than DEA-registered locations. 21 C.F.R. § 1301.12(a). A registrant may not engage in unauthorized manufacture of controlled substances to supply practitioners with stock for office-based dispensing. 21 C.F.R. § 1301.13(e). A registrant may not include Schedule III controlled substances on Schedule II inventory. 21 C.F.R. § 1304.04(h)(1). A registrant must account for all controlled substances on hand when the inventory is taken. 21 C.F.R. § 1304.11(a). A registrant must take inventory of a controlled substance on the effective date classifying it as a controlled substance. 21 C.F.R. § 1304.11(d). A registrant must include the finished form of each controlled substance on the biennial inventory. 21 C.F.R. § 1304.11(e)(1)(iii)(B). A registrant must include the number of units or volume of each finished form of controlled substance in each container on the biennial inventory. 21 C.F.R. § 1304.11(e)(1)(iii)(C). A registrant must include the number of commercial containers of each finished form of controlled substances on the biennial inventory. 21 C.F.R. § 1304.11(e)(1)(iii)(D). A registrant must include accurate weights on bulk forms. 21 C.F.R. § 1304.11(e)(1)(iv)(B). A registrant must include reasons for expired controlled substances being maintained and whether substances could be used in manufacture in biennial inventory. 21 C.F.R. § 1304.11(e)(1)(iv)(C).

9. A registrant must keep records documenting the receipt, manufacture, or distribution of controlled substances. 21 C.F.R. § 1304.21(a). A registrant must keep records including the number of units or volume of finished form of any controlled substances; acquisition records including the number of units, date, name, address and registration number;

and distribution records including the number of units, date, name, address and registration number. 21 C.F.R. §§ 1304.22(a)(2)(ii), 1304.22(a)(2)(iv), 1304.22(a)(2)(vii).

10. A registrant must keep records of the date shipped and number of packages shipped on the DEA Form 222; must complete and execute accurate DEA Form 222s; must retain the Purchaser Copy of the executed DEA Form 222; must retain the Supplier Copy of the DEA Form 222; must retain the Purchaser Copy of the executed electronic DEA Form 222; and must not distribute a Schedule II controlled substance without the requisite DEA 222 Form at the time of distribution. 21 C.F.R. §§ 1305.13(b), 1305.15(a), 1305.17(a), 1305.17(b), 1305.27(a), 1305.03.

11. A registrant must not fill a prescription issued for the purpose of obtaining controlled substances for general office dispensing, must not fill prescriptions signed by an individual without prescribing authority and must not fill improperly executed prescriptions. 21 C.F.R. §§ 1306.04(a), 1306.05(f).

12. A registrant must take and record a biennial inventory and must keep accurate and complete records of power of attorney designations matching the name of the person who signed the application for re-registration. 21 C.F.R. §§ 1304.11(c), 1305.05(d).

13. On September 4, 2014, the DEA initiated a Scheduled Investigation of Golden Gate Pharmacy and Ross Valley Pharmacy (the "Scheduled Investigation"). In the Scheduled Inspection, DEA reviewed the records of Golden Gate Pharmacy and Ross Valley Pharmacy covering a two year period from September 4, 2012 through September 4, 2014. The Scheduled Investigation revealed alleged record-keeping violations of the Act, which are described in the following paragraphs as the conduct covered by this Agreement.

14. The United States alleges that, between September 4, 2012 through September 4, 2014, Golden Gate Pharmacy and Ross Valley Pharmacy failed to keep and maintain adequate records pertaining to controlled substances, as required by 21 C.F.R. § 1304, *et seq.*

15. The United States alleges at least 4,777 violations by Golden Gate Pharmacy of the Act's recordkeeping requirements for the period in question – September 4, 2012 through September 4, 2014. For example, the United States alleges that, in at least 3,271 instances between September 4, 2012 and September 4, 2014, Golden Gate Pharmacy failed to keep records documenting the manufacture of controlled substances, in violation of 21 C.F.R. § 1304.21(a). The United States further alleges that, in at least 369 instances between September 4, 2012 through September 4, 2014, Golden Gate Pharmacy engaged in the unauthorized manufacture of controlled substances to supply practitioners with stock for office-based dispensing, in violation of 21 C.F.R. § 1301.13(e). By way of further example, the United States alleges that in at least 355 instances between September 4, 2012 through September 4, 2014, Golden Gate Pharmacy failed to keep distribution records including the number of units, date, and name, address and registration number of the recipient, in violation of 21 C.F.R. § 1304.22(a)(2)(vii). The United States also alleges that in at least 347 instances between September 4, 2012 through September 4, 2014, Golden Gate Pharmacy failed to keep records including the number of units or volume of finished form, in violation of 21 C.F.R. § 1304.22(a)(2)(ii). In addition, the United States alleges that a Golden Gate Pharmacy janitorial employee pilfered approximately 8,000 Oxycodone tablets during 2014-2015.

16. The United States alleges at least 384 violations by Ross Valley Pharmacy of the Act's recordkeeping requirements for the period in question – September 4, 2012 through

September 4, 2014. For example, the United States alleges that, in at least 151 instances between September 4, 2012 through September 4, 2014, Ross Valley Pharmacy filled improperly executed prescriptions in violation of 21 C.F.R. § 1306.05(f). The United States further alleges that, in at least 108 instances, Ross Valley Pharmacy failed to include reasons for expired controlled substances being maintained and whether substances could be used in manufacture in its biennial inventory, in violation of 21 C.F.R. § 1304.11(e)(1)(iv)(C). By way of further example, the United States alleges that Ross Valley Pharmacy, in at least 53 instances, failed to keep records documenting the manufacture of controlled substances, in violation of 21 C.F.R. § 1304.21(a).

17. For the purposes of this Agreement, "Covered Conduct" shall mean the violations alleged in paragraphs 13 through 16 above.

18. At all times relevant to the Covered Conduct, the Act authorizes the imposition of a civil penalty of as much as \$10,000 or as much as \$25,000 for each violation of 21 U.S.C. § 842(a), depending on the category of violation, and a civil penalty of as much as \$25,000 for each violation of 21 U.S.C. § 842(b)(1).

19. This Agreement is neither an admission by any of the Lofholm Parties of liability for any allegations made by the United States nor a concession by the United States that its claims are not well founded.

20. In consideration of the mutual promises, covenants, and obligations set forth in this Agreement, the Parties reach a full and final settlement pursuant to the Terms and Conditions below.

TERMS AND CONDITIONS

In reliance on the recitals and representations contained herein, and in consideration of the mutual promises, covenants, and obligations set forth below, and intending to be legally bound hereby, the Parties agree as follows:

21. The Lofholm Parties shall pay to the United States Seven Hundred Seventeen Thousand Two Hundred Fifty Dollars (\$717,250.00) (hereafter, the "Settlement Amount"), by electronic funds transfer, pursuant to written instructions to be provided by the Office of the United States Attorney for the Northern District of California upon execution of this Agreement, according to the schedule in Paragraph 22.

22. The Settlement Amount described in Paragraph 21 above shall be made by the Lofholm parties as follows:

- a. the Lofholm Parties shall pay Three Hundred Thousand Dollars (\$300,000.00) according to the terms of Paragraph 21 on or before May 31, 2017;
and
- b. the Lofholm Parties shall pay Four Hundred Seventeen Thousand Two Hundred Fifty Dollars (\$417,250) according to the terms of Paragraph 21 on or before June 30, 2017.

23. In consideration of the payment of the Settlement Amount described in Paragraphs 21 and 22 above in full, the United States agrees to settle and relinquish all claims for civil penalties it may have against the Lofholm Parties, including Golden Gate Pharmacy Holdings, Inc., Golden Gate Pharmacy, Ross Valley Pharmacy and any officers, directors,

agents, and employees of either Golden Gate or Ross Valley Pharmacies for possible violations of the Act, and the regulations promulgated thereunder, based on the Covered Conduct.

24. Nothing in this Agreement shall prevent, preclude, limit, or prejudice the United States' right to enforce compliance with any other requirements under the Act and regulations promulgated thereunder by commencing a civil or administrative action against one or more of the Lofholm Parties or any officers, directors, agents or employees of either Golden Gate or Ross Valley Pharmacies for violations of the Act that occurred or may occur subsequent to the period of the Covered Conduct described in this Agreement. In the event of such violations under the Act or the regulations promulgated thereunder, DEA will not be precluded from alleging and proving this Agreement and the evidence of the violations that led to this Agreement in any future actions taken against the Lofholm Parties, Golden Gate Pharmacy's DEA registrations, or Ross Valley Pharmacy's DEA registrations under 21 U.S.C. §§ 823 and 824.

25. The Lofholm Parties fully and finally release the United States, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which have been asserted, could have been asserted, or may be asserted in the future against the United States, its agencies, employees, servants, and agents, related to the investigation, prosecution and settlement of this matter.

26. Notwithstanding any term of this Agreement, specifically reserved and excluded from its scope and intent as to any entity or person are the following:

- a. Any potential criminal liability;
- b. Any criminal, civil, or administrative claims arising under Title 26 of the United States Code (Internal Revenue Code);

c. Any liability to the United States for any conduct other than the Covered Conduct; and

d. Any claims based on such obligations as are created by this Agreement.

27. The Lofholm Parties and each of them waives and shall not assert any defenses any of the Lofholm Parties 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. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

28. This Agreement is not intended by the Parties, and shall not be interpreted to constitute, a release of any person or entity not identified or referred to herein.

29. This Agreement shall be governed by the laws of the United States. Exclusive jurisdiction and venue for any dispute arising under this Agreement shall be the United States District Court for the Northern District of California.

30. This Agreement constitutes the entire agreement between the Parties, and cannot be amended, except in writing and signed by all the Parties to this Agreement.

31. Each of the signatories below represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever. For purposes of construction, 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.

32. All parties to this Agreement understand that it will be a matter of public record and consent to the United States' disclosure of this Agreement and information about this Agreement to the public.

33. Each person who signs this Agreement in a representative capacity warrants that he or she is fully authorized to do so.

34. This Agreement is binding on the Lofholm Parties' successors, transferees, heirs, and assigns.

35. The parties agree that the Lofholm Parties are jointly and severally liable for any failure by any one of them to satisfy the terms and conditions of this settlement agreement, including but not limited to the payment of the Settlement Amount described in Paragraph 21 or the schedule of payments described in Paragraph 22.

36. The Parties agree that in the event the Lofholm Parties do not make the payments described in Paragraphs 21 and 22 in full, the United States shall have the option of (a) filing suit to enforce this Agreement, or (b) rescinding this Agreement and seeking any and all available remedies against the Lofholm Parties arising from the Scheduled Investigation, including but not limited to the imposition of civil fines and penalties in the full amounts provided by the Controlled Substances Act and the pertinent regulations. Should the United States choose to rescind the agreement and pursue remedies under subsection (b) of this Paragraph, the Lofholm Parties agree not to plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that are

filed by the United States by July 31, 2017, except to the extent such defenses were available on the Effective Date of this Agreement.

37. The Parties further agree that in the event the Lofholm Parties fail to make either payment described in Paragraph 22 as provided, the Lofholm Parties shall be liable for interest calculated from the Effective Date of this Agreement, at a rate of 1.0% per annum.


38. If the Lofholm Parties' obligations under this Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Agreement and bring any civil and/or administrative claim, action, or proceeding against the Lofholm Parties for the claims that would otherwise be covered by the releases in this Agreement. The Lofholm Parties agree that (i) any such claims, actions, or proceedings brought by the United States are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) and the Lofholm Parties shall not argue or otherwise contend that the United States' claims, actions, or proceedings are subject to an automatic stay; (ii) the Lofholm Parties 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 claims, actions, or proceeding that are brought by the United States within 30 calendar days of written notification to the Lofholm Parties that the releases have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on the Effective Date of this Agreement; and (iii) the United States has valid claims against the Lofholm Parties for the full amount under relevant statutory and regulatory authority for each of the violations identified in the Scheduled Investigation.

39. This Agreement shall be effective on the date of signing by the last signatory to this Agreement ("Effective Date"). It may be executed in counterparts, each of which shall constitute an original and all of which shall constitute one and the same agreement. Facsimiles of signatures shall have the same effect as originals.

On behalf of the United States:

BRIAN J. STRETCH
United States Attorney
Northern District of California


DATED: April 3, 2017


JONATHAN U. LEE
Assistant U.S. Attorney
Attorneys for the United States

On behalf of the Lofholm Parties:

GOLDEN GATE PHARMACY HOLDINGS,
INC.

DATED: 3-31-2017


REBECCA E. LOFHOLM
President


GOLDEN GATE PHARMACY SERVICES,
INC.

DATED: 3-31-2017


REBECCA E. LOFHOLM
President

ROSS VALLEY COMPOUNDING
PHARMACY, INC.

DATED: 3-31-2017


REBECCA E. LOFHOLM
President

DATED: 3-31-2017



REBECCA E. LOFHOLM

DATED: 3-31-2017


PAUL W. LOFHOLM

CALIFORNIA PHARMACY LAWYERS

DATED: April 2, 2017


IVAN PETRZELKA, ESQ.
Attorneys for the Lofholm Parties