UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, Plaintiff, v. ROCHESTER DRUG CO-OPERATIVE, INC., Defendant.	19 Civ. 3568 (___)

STIPULATION AND ORDER OF SETTLEMENT AND DISMISSAL

WHEREAS, on or about April 23, 2019, the United States of America (the "United States" or "Government"), by its attorney, Geoffrey S. Berman, United States Attorney for the Southern District of New York, commenced the above-captioned civil law enforcement action by filing a complaint (the "Complaint") in this Court against Rochester Drug Co-operative, Inc. ("RDC" or "Defendant," and together with the Government, the "Parties");

WHEREAS, this Stipulation and Order of Settlement and Dismissal (this "Stipulation") is entered into among the United States and RDC by their authorized representatives;

WHEREAS, RDC is a regional wholesale drug cooperative that distributes drugs, including controlled substances, and healthcare products to approximately 1,300 independently-owned pharmacies in several states;

WHEREAS, RDC is a DEA-registered distributor of Schedule II through V controlled substances under the Controlled Substances Act, 21 U.S.C. §§ 801 *et seq.* ("the CSA");

WHEREAS, RDC operates distribution centers in Rochester, New York and Fairfield, New Jersey;

WHEREAS, on or about July 6, 2015, RDC entered into a Consent Order with the United States to resolve a prior investigation into RDC's failure to comply with its reporting obligations under the CSA, including RDC's failure to electronically report to the DEA acquisition/distribution transactions of controlled substances through the DEA's Automation of Reports and Consolidated Orders System ("ARCOS") and RDC's failure to include controlled substances theft and loss data in its ARCOS reports;

WHEREAS, the regulations promulgated under the CSA require distributors of controlled substances to design and operate a system to detect "suspicious orders" for controlled substances, and to inform the DEA of such orders when discovered, *see* 21 C.F.R. § 1301.74(b);

WHEREAS, suspicious orders include "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency," *see id.*;

WHEREAS, on or about September 27, 2006 and December 27, 2007, the DEA sent letters to all DEA-registered distributors of controlled substances, including RDC, that discussed the requirements of 21 C.F.R. § 1301.74(b) and contained guidance for the identification and reporting of suspicious orders to the DEA (the "DEA Letters");

WHEREAS, the DEA's suspicious order reporting requirements for controlled substances are an integral part of its efforts to identify and prevent the illicit distribution of narcotics and other dangerous drugs;

WHEREAS, the CSA authorizes the imposition of a civil penalty of up to $10,000 for each violation of 21 C.F.R. § 1301.74(b), *see* 21 U.S.C. § 842(a)(5); 21 U.S.C. § 842(c);[1]

WHEREAS, the Complaint alleges that between May 2012 and November 2016 (the "Covered Period"), RDC repeatedly violated 21 C.F.R. § 1301.74(b) by knowingly failing to operate an adequate system to detect, investigate, and report to the DEA suspicious orders of controlled substances, including thousands of suspicious orders of oxycodone, fentanyl, hydrocodone, amphetamine, and buprenorphine products (the "Covered Conduct");

WHEREAS, in connection with settlement discussions, RDC has submitted information concerning its financial condition to the United States, including but not limited to information relating to RDC's assets, liabilities, lines of credit, revenues, profits, and financial projections ("Financial Information");

WHEREAS, the Parties have reached a mutually agreeable resolution of the claims against RDC in the Complaint;

WHEREAS, on or about the date it entered into this Stipulation, RDC also entered into a Deferred Prosecution Agreement (the "DPA") with the Criminal Division of the United States Attorney's Office for the Southern District of New York in connection with a three-count Information charging RDC with, among other things, knowingly failing to furnish suspicious order reports to the DEA in violation of 21 U.S.C. §§ 842(a)(5) and (c)(2);

NOW, THERFORE, upon the Parties' agreement IT IS HEREBY ORDERED:

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[1] The maximum penalty for a violation increased to $15,040 for penalties assessed after January 29, 2018, where the associated violation occurred after November 2, 2015. *See* 28 C.F.R. § 85.5.

TERMS AND CONDITIONS

1. The Court's subject matter jurisdiction is undisputed and RDC consents to the Court's exercise of personal jurisdiction over it.

2. RDC admits, acknowledges, and accepts responsibility for the following conduct during the Covered Period:

a. RDC knowingly failed to implement an adequate system to detect, investigate, and report suspicious orders of controlled substances to the DEA. RDC received and fulfilled over 1.5 million orders for controlled substances from its pharmacy customers, including hundreds of thousands of orders for highly-abused drugs, such as oxycodone, fentanyl, and hydrocodone. However, during this period, RDC reported only a total of 4 suspicious orders to the DEA, notwithstanding senior management's awareness of the company's reporting obligations under the CSA. RDC failed to report to the DEA at least two thousand orders of controlled substances made by its pharmacy customers that should have been reported as suspicious pursuant to the criteria set forth in 21 C.F.R. § 1301.74(b) and the guidance contained in the DEA Letters.

b. Several of RDC's largest pharmacy customers exhibited ordering patterns that should have resulted in further investigation to determine whether the pharmacies, and/or certain physicians who prescribed drugs dispensed by the pharmacies, were engaging in opioid diversion. RDC frequently failed to conduct such further investigation. Several physicians who wrote a large number of prescriptions filled by RDC customers were subsequently arrested and prosecuted for diversion. RDC failed to maintain effective controls to prevent such diversion and failed to report frequent unexplained sharp spikes in opioid orders.

c. Through reports that RDC received reflecting the controlled substances that its pharmacy customers had dispensed, on-site visits of its customers, and other sources, RDC internally identified "red flags" suggesting that certain pharmacy customers were dispensing controlled substances that were not for legitimate medical purposes. For example, several of RDC's largest pharmacy customers exhibited the following dispensing patterns:

i. A high percentage of the pharmacy's controlled substance sales, and particularly sales of oxycodone 30-milligram tablets, were paid for in cash as opposed to through insurance. Oxycodone 30-milligram tablets are the most commonly abused form of oxycodone.

ii. An unusually high proportion of the pharmacy's overall dispensing consisted of controlled substances.

iii. A disproportionate percentage of the pharmacy's controlled substance purchases were for highly-abused drugs, such as oxycodone 30-milligram tablets or fentanyl patches or spray.

iv. The pharmacy filled prescriptions for controlled substances for many patients who lived great distances from the pharmacy.

v. The pharmacy frequently filled prescriptions for quantities or dosages of controlled substances that were higher than accepted medical standards.

Notwithstanding these "red flags," RDC did not file suspicious order reports with the DEA for orders placed by these pharmacy customers.

d. RDC maintained an internal list that identified prescribers who had been arrested, investigated by state or federal government agencies, subject to state administrative proceedings, or whom RDC compliance personnel had identified as engaging in suspicious prescribing activities ("Suspicious Prescriber List"). Several of RDC's largest pharmacy customers filled large numbers of prescriptions written by prescribers on the Suspicious Prescriber List, and RDC continued to sell controlled substances to these pharmacies well after placing the prescribers on the list.

e. RDC developed and implemented a system to identify "orders of interest." The system automatically generated an alert each time a pharmacy customer's order for a drug in a particular category of controlled substances exceeded a monthly purchase threshold that RDC had set for drugs in that category. The monthly thresholds were calculated based on a multiple of the pharmacy customer's average purchases of the relevant drugs over the preceding 12 months. Accordingly, for a customer's drug purchases to exceed the monthly threshold, there would need to have been a significant spike in the customer's ordering of the relevant drugs during that month. RDC's system identified approximately 7,800 "orders of interest" from January 2013 through the end of the Covered Period. RDC filled nearly all these "orders of interest," frequently without taking reasonable steps to determine whether there was a legitimate explanation for the significant spike in the pharmacy customer's order volume. RDC rarely contacted the pharmacy that placed the "order of interest" to obtain the reason for the increased ordering, and regularly failed to obtain recent controlled substance dispensing information from the customer before releasing the order to be shipped. RDC did not report any of the approximately 7,800 "orders of interest" to the DEA. Instead, to prevent the generation of future "orders of interest," RDC often raised the purchase thresholds for certain high-volume customers so that these customers could continue to increase their opioid purchases and dispensing over time.

f. RDC failed to implement an adequate due diligence program to prevent the diversion of controlled substances by its pharmacy customers. RDC failed to devote sufficient resources to its compliance program and employed compliance personnel who lacked necessary qualifications and relevant experience when they were hired. RDC compliance personnel and contractors did not conduct field visits for most of its pharmacy customers, and

failed to consistently obtain and review updated and complete dispensing reports that would have allowed it to better detect troubling dispensing patterns. In addition, RDC frequently began selling controlled substances to new pharmacy customers without conducting an adequate review of the pharmacy's operations, background, and historical dispensing patterns. RDC's sales staff were involved in screening and approving new customers despite the fact that they received payments for each new customer enrolled.

g. RDC's top customer during the Covered Period was a specialty pharmacy located in Woodbury, New York. This pharmacy was one of the largest providers of Subsys, a highly-addictive fentanyl spray that is approved by the FDA only for use by cancer patients with breakthrough pain. This pharmacy was also a large provider of oxycodone; between October 2012 and October 2013, the pharmacy went from purchasing approximately 70,000 units of oxycodone per month to purchasing over 200,000 units per month. This pharmacy filled a high volume of prescriptions written by prescribers included on RDC's Suspicious Prescriber List, including numerous physicians who were subsequently arrested for diversion.

3. RDC shall pay to the United States a civil penalty of $20,000,000 (the "Settlement Amount"). RDC may satisfy its obligation to pay the Settlement Amount by complying with its obligations under Paragraphs 3-6 of the DPA, including but not limited to consenting to the forfeiture of $20,000,000 and paying this amount to the United States in accordance with the schedule set forth in the DPA.

4. RDC shall be in default if it fails to pay the Settlement Amount as set forth in Paragraph 3 ("Default"). The Government shall provide written notice to RDC of any Default in the manner set forth in Paragraph 28 below. RDC shall then have an opportunity to cure the Default within ten (10) calendar days from the date of delivery of the notice of Default. In the event that a Default is not fully cured within ten (10) calendar days of the delivery of the notice of Default ("Uncured Default"), interest shall accrue at the rate specified in Paragraph 6 of the DPA on the remaining unpaid principal balance of the Settlement Amount. In the event of an Uncured Default, RDC shall agree to entry of a consent judgment in favor of the United States against RDC in the amount of the Settlement Amount as attached hereto as Exhibit A; in the event that RDC has paid a portion of the Settlement Amount prior to the Uncured Default, RDC

may, within ten (10) business days of the Uncured Default, execute and deliver to the United States a substitute consent judgment that includes only the amount of the unpaid portion of the Settlement Amount. The United States may also, at its option, (a) rescind this Stipulation and reinstate the claims asserted against RDC in the Complaint; (b) seek compliance with this Stipulation; (c) offset the remaining unpaid balance of the Settlement Amount from any amounts due and owing RDC by any department, agency, or agent of the United States; or (d) exercise any other rights granted by law, or under the terms of this Stipulation, or recognizable at common law or in equity. RDC shall not contest any offset imposed or any collection undertaken by the Government pursuant to this Paragraph, either administratively or in any federal or state court. In addition, RDC shall pay the Government all reasonable costs of collection and enforcement under this Paragraph, including attorneys' fees and expenses. In the event that the United States opts to rescind this Stipulation pursuant to this Paragraph, RDC shall not 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 relate to the Covered Conduct.

5. RDC shall promptly report to the DEA all suspicious orders as defined in the CSA and its implementing regulations, including but not limited to 21 C.F.R. § 1301.74. RDC shall promptly report to the DEA any of its customers that it knows or has reason to believe are distributing controlled substances outside the scope of professional practice and not for a legitimate medical purpose.

6. RDC shall voluntarily submit to DEA inspections conducted pursuant to 21 C.F.R. § 1316.03 at any time without condition and without advance notice.

7. RDC shall maintain and implement a Controlled Substances Monitoring Program that meets the requirements set forth in the Compliance Addendum attached as Exhibit B to this Stipulation. All of the terms sets forth in the Compliance Addendum are incorporated herein and shall be deemed part of this Stipulation. As set forth in the DPA, RDC shall retain an independent compliance monitor (the "Monitor") who, among other things, will be responsible for assessing and monitoring compliance with the Compliance Addendum. The manner in which the Monitor will be selected, the Monitor's responsibilities and mandate, and the Monitor's reporting obligations are set forth in Exhibit E to the DPA.

8. Defendant agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Stipulation, including but not limited to any investigation of current or former RDC employees or any pharmacy that purchased controlled substances from RDC. Upon reasonable notice, Defendant shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Defendant further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

9. Subject to the exceptions in Paragraphs 11 and 15 below (concerning excluded claims and bankruptcy proceedings), and conditioned upon Defendant's full compliance with the terms of this Stipulation, including full payment of the Settlement Amount to the United States pursuant to Paragraph 3 above, the United States releases Defendant from any civil claim for

penalties that the United States has for the Covered Conduct under 21 U.S.C. § 842. For avoidance of doubt, this Stipulation does not release any current or former officer, director, employee, or agent of Defendant from liability of any kind.

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

11. Notwithstanding the releases given in Paragraph 9 above, or any other term of this Stipulation, the following claims of the Government are specifically reserved and are not released by this Stipulation:

a. any liability arising under Title 26, United States Code (Internal Revenue Code);

b. any criminal liability;

c. any administrative claims and liability, including but not limited to any and all administrative claims within DEA's enforcement authority under 21 U.S.C. §§ 823 and 824, for mandatory or permissive exclusion from federal healthcare 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-7b (permissive exclusion), and for suspension or debarment from participating in transactions with federal agencies;

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 Stipulation; and

f. any liability of individuals.

12. RDC has provided Financial Information to the United States and the United States has relied on the accuracy and completeness of that Financial Information in reaching this Stipulation. RDC warrants that the Financial Information is complete, truthful, and accurate. If the United States learns of any misrepresentation in the Financial Information, or of assets in which RDC had an interest at the time of this Stipulation that were not disclosed in the Financial Information, and if such nondisclosure or misrepresentation changes the stated net income set forth in the Financial Information by $500,000 or more or the value of the stated assets set forth in the Financial Information by 5% or more, the United States may at its option: (i) rescind this Stipulation and reinstate the claims asserted against RDC in the Complaint, or (ii) let the Stipulation stand and collect the full Settlement Amount plus one hundred percent (100%) of the value of the net income or assets that were previously not disclosed. RDC agrees not to contest any collection action undertaken by the United States pursuant to this provision, and immediately to pay the United States all reasonable costs incurred in such an action, including attorneys' fees and expenses.

13. RDC waives and shall not assert any defenses RDC 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 Stipulation bars a remedy sought in such criminal prosecution or administrative action.

14. RDC, having truthfully admitted to the facts set forth in Paragraph 2, agrees that it shall not, through its attorneys, agents, or employees, make any statement, in litigation or otherwise, contradicting the facts set forth in Paragraph 2 or its representations in this Stipulation. Consistent with this provision, RDC may raise defenses and/or assert affirmative claims and defenses in any proceedings brought by private and/or public parties as long as doing so does not contradict the facts set forth in Paragraph 2 or such representations. Any such contradictory statement by RDC or its present or future attorneys, agents, or employees shall constitute a violation of this Stipulation. The decision as to whether any such contradictory statement will be imputed to RDC for the purpose of determining whether RDC has violated this Stipulation shall be within the sole discretion of the Office of the United States Attorney for the Southern District of New York (the "Office"). Upon the Office's notifying RDC of any such contradictory statement, RDC may avoid a finding of violation of this Agreement by repudiating such statement both to the recipient of such statement and to the Office within four business days after having been provided notice by the Office. RDC consents to the public release by the Office, in its sole discretion, of any such repudiation. Nothing in this Stipulation is meant to affect the obligation of RDC or its officers, directors, agents or employees to testify truthfully to the best of their personal knowledge and belief in any proceeding. Nothing in this paragraph applies to statements made, in litigation or otherwise, by any present or former officers, directors, agents or employees of RDC that are made solely in an individual capacity, and not on behalf of RDC.

15. RDC represents and warrants that it has reviewed its financial situation, that it currently is not insolvent as such term is defined in 11 U.S.C. § 101(32), and that it reasonably believes that it shall remain solvent following payment to the Government of the Settlement

Amount. Further, the Parties warrant that, in evaluating whether to execute this Stipulation, they (a) have intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to RDC, within the meaning of 11 U.S.C. § 547(c)(1); and (b) have concluded that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which RDC was or became indebted to on or after the date of this Stipulation, within the meaning of 11 U.S.C. § 548(a)(1).

16. If within 91 days of the Effective Date of this Stipulation or any payment made under this Stipulation, RDC commences any case, action, or other proceeding under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors or a third party commences any case, action, or other proceeding under any law related to bankruptcy, insolvency, reorganization, or relief of debtors (a) seeking an order for relief of RDC's debts, or seeking to adjudicate RDC as bankrupt or insolvent; or (b) seeking appointment of a receiver, trustee, custodian, or other similar official for RDC or for all or part of RDC's assets, RDC agrees as follows:

a. RDC's obligations under this Stipulation may not be avoided pursuant to 11 U.S.C. § 547, and RDC shall not argue or otherwise take the position in any such case, action, or proceeding that (i) RDC's obligations under this Stipulation may be avoided under 11 U.S.C. § 547; (ii) RDC was insolvent at the time this Stipulation was entered into; or (iii) the mutual promises, covenants, and obligations set forth in this Stipulation do not constitute a

contemporaneous exchange for new value given to RDC.

b. If any of RDC's obligations under this Stipulation are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the Government, at its option, may rescind the release in this Stipulation and bring any civil and/or administrative claim, action, or proceeding against RDC for the claims that would otherwise be covered by the release in Paragraph 9 above. RDC agrees that (i) any such claim, action, or proceeding brought by the Government would not be subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the case, action, or proceeding described in the first sentence of this Paragraph, and RDC shall not argue or otherwise contend that the Government's claim, action, or proceeding is subject to an automatic stay; (ii) RDC shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any claim, action, or proceeding that is brought by the Government within 60 calendar days of written notification to RDC that the release has been rescinded pursuant to this Paragraph, except to the extent such defenses were available on the Effective Date; and (iii) the Government has a valid claim against RDC in the amount of the Settlement Amount and the Government may pursue its claim in the case, action, or proceeding described in the first sentence of this Paragraph, as well as in any other case, action, or proceeding.

c. RDC acknowledges that the agreements in this Paragraph are provided in exchange for valuable consideration provided in this Stipulation.

17. Defendant agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Office of Management and Budget ("OMB") Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards published at 2 C.F.R. §§ 200 *et seq.*; the Department of Health and Human Services adoption of the OMB Guidance provided at 45 C.F.R. § 75, subpart E *et seq.*; the Federal Acquisition Regulation, 48 C.F.R. §§ 31.205-47 where applicable; or otherwise as specified by federal statutes, regulations or the terms and conditions of a federal award) incurred by or on behalf of Defendant, including its present or former officers, directors, employees, and agents in connection with:

(1) the matters covered by this Stipulation;

(2) the United States' audit(s) and civil or criminal investigation(s) of matters covered by this Stipulation;

(3) Defendant's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil or criminal investigation(s) in connection with matters covered by this Stipulation (including attorneys' fees);

(4) the negotiation and performance of this Stipulation; and

(5) any payment Defendant makes to the United States pursuant to this Stipulation, including expenses, costs and attorneys' fees;

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 Defendant, and Defendant shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Within 90 days of the Effective Date of this Stipulation, Defendant shall identify and repay by adjustment to future claims for payment or otherwise any Unallowable Costs (as defined in this Paragraph) included in payments previously sought by Defendant from the United States. Defendant agrees that the United States, at a minimum, shall be entitled to recoup from Defendant any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted requests for payment. Any payments due shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States, including the Department of Justice and/or the affected agencies, reserves its right to audit, examine, or re-examine Defendant's books and records and to disagree with any calculation submitted by Defendant or any of its subsidiaries or affiliates regarding any Unallowable Costs included in payments previously sought by Defendant, or the effect of any such Unallowable Costs on the amounts of such payments.

d. Nothing in this Stipulation shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Defendant's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

18. This Stipulation 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 as otherwise provided herein.

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

20. Any failure by the Government to insist upon the full or material performance of any of the provisions of this Stipulation shall not be deemed a waiver of any of the provisions hereof, and the Government, notwithstanding that failure, shall have the right thereafter to insist upon the full or material performance of any and all of the provisions of this Stipulation.

21. This Stipulation is governed by the laws of the United States.

22. The Court shall retain jurisdiction over the enforcement and interpretation of this Stipulation and all disputes that arise thereunder.

23. For purposes of construing this Stipulation, this Stipulation shall be deemed to have been drafted by all Parties to this Stipulation and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

24. This Stipulation constitutes the complete agreement between the Parties with respect to the subject matter hereof. No prior agreements, oral representations or statements shall be considered part of this Stipulation. This Stipulation may not be amended except by written consent of the Parties. Any amendment to the Compliance Addendum agreed to in writing by the Parties shall not require Court approval.

25. The undersigned counsel and other signatories represent and warrant that they are fully authorized to execute this Stipulation on behalf of the persons and the entities indicated below.

26. This Stipulation is binding on RDC and RDC's successors, transferees, and assigns.

27. This Stipulation may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Stipulation. E-mails that attach signatures in PDF form or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Stipulation.

28. Any notice pursuant to this Stipulation shall be in writing and shall, unless expressly provided otherwise herein, be delivered by hand, express courier, or e-mail transmission followed by postage-prepaid mail, and shall be addressed as follows:

TO THE UNITED STATES:

Jeffrey K. Powell
Jacob M. Bergman
Assistant United States Attorneys
United States Attorney's Office
Southern District of New York
86 Chambers Street, Third Floor
New York, New York 10007
Telephone: (212) 637-2706/2776
Email: Jeffrey.Powell@usdoj.gov
Jacob.Bergman@usdoj.gov

TO DEFENDANT RDC:

Douglas B. Farquhar, Esq.
Hyman, Phelps & McNamara, P.C.
700 13th Street, NW, Suite 1200
Washington, D.C. 20005
Telephone: (202) 737-9624
Email: DFarquhar@hpm.com

29. The effective date of this Stipulation is the date upon which the Stipulation is approved by the Court (the "Effective Date").

Dated: Apr 23, 2019

GEOFFREY S. BERMAN
United States Attorney for the
Southern District of New York
Attorney for Plaintiff United States of America

By: _____

JEFFREY K. POWELL
JACOB M. BERGMAN
Assistant United States Attorneys
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New York, New York 10007
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ROCHESTER DRUG CO-OPERATIVE, INC.

By: _____

JOHN KINNEY
Interim Chief Executive Officer

HYMAN, PHELPS, & MCNAMARA, P.C.
Attorneys for ROCHESTER DRUG CO-OPERATIVE, INC.

By: _____

DOUGLAS B. FARQUHAR, ESQ.
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Washington, D.C. 20005
Telephone: (202) 737-9624
Email: DFarquhar@hpm.com

SO ORDERED:

_____, 2019

_____
HONORABLE _____, U.S.D.J.

Exhibit A

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, Plaintiff, v. ROCHESTER DRUG CO-OPERATIVE, INC., Defendant.	19 Civ. 3568 (___)

CONSENT JUDGMENT

Upon the consent of Plaintiff the United States of America and Defendant Rochester Drug Co-operative, Inc. ("Defendant,"), it is hereby

ORDERED, ADJUDGED and DECREED: that plaintiff the United States of America is awarded judgment in the amount of $20,000,000 as against Defendant, as well as post-judgment interest at the rate of 12% per annum compounded daily.

Agreed to by:

Dated: _____, 2019

GEOFFREY S. BERMAN
United States Attorney for the
Southern District of New York
Attorney for Plaintiff United States of America

By: _____

JEFFREY K. POWELL
JACOB M. BERGMAN
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ROCHESTER DRUG COOPERATIVE, INC.

By: _____

JOHN KINNEY
Interim Chief Executive Officer

HYMAN, PHELPS, & MCNAMARA, PC
Attorneys for ROCHESTER DRUG COOPERTAIVE, INC.

By: _____

DOUGLAS B. FARQUHAR, ESQ.
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Telephone: (212) 841-0681
Telephone: 202-737-9624
Email: DFarquhar@hpm.com

SO ORDERED:

_____, 2019

_____
HONORABLE _____, U.S.D.J.

Exhibit B

Compliance Addendum

1. RDC shall maintain and implement a Controlled Substance Monitoring Program ("CSMP") that is designed to identify and report suspicious orders and maintain effective controls against the diversion of controlled substances. The CSMP shall meet the requirements set forth in this Compliance Addendum. The CSMP shall apply to all DEA-registered RDC distribution centers.

2. The effective date of the Compliance Addendum shall be the date upon which the Stipulation and Order of Settlement and Dismissal is approved by the Court. The obligations contained in this Compliance Addendum shall remain in full force and effect for a period of three years from the Effective Date, unless otherwise specified herein.

3. RDC acknowledges and agrees that the obligations undertaken in this Compliance Addendum do not fulfill the totality of RDC's obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders of controlled substances pursuant to the Controlled Substances Act, 21 U.SC. §§ 801 *et seq.* ("the CSA"), and applicable regulations promulgated by DEA.

4. Definitions. The below terms shall be defined as follows for purposes of this Compliance Addendum:

a. The term "threshold" means the total monthly volume of a controlled substance as defined under the CSA, or a particular category of controlled substances, that RDC allows a pharmacy customer to purchase in any particular calendar month before triggering the investigation and approval process set forth in Paragraph 5(b) below.

b. The term "highly diverted controlled substances" means the controlled substances that RDC designates as being subject to the most restrictive thresholds and/or

supplemental due diligence because such substances have a higher risk of diversion compared to other controlled substances. RDC's list of highly diverted controlled substances currently includes, and shall continue to include, the following: (i) oxycodone; (ii) hydrocodone; (iii) hydromorphone; (iv) methadone; (v) morphine; (vi) carisoprodol; (vii) alprazolam; (viii) tramadol; (ix) oxymorphone; (x) fentanyl; (xi) amphetamine; and (xii) buprenorphine. RDC shall add other controlled substances to the list of highly diverted controlled substances as needed based on information obtained from DEA and other sources related to drug diversion trends.

c. The term "order" means a unique pharmacy customer request on a specific date for a certain amount of a specific dosage form or strength of a controlled substance in one given instance, regardless of other requests made concurrently with that given request. For the purposes of this definition, each line item on an invoice or DEA Form 222 is a separate order.

d. The term "dispensing activity data" means the following information regarding the controlled substances dispensed by a pharmacy during a specific period: (a) the prescription number; (b) the patient's zip code; (c) the drug's name, strength, dosage form, and National Drug Code ("NDC") number; (d) the quantity of the drug dispensed and the days supply; (e) the date the drug was dispensed; (f) the prescriber's name and DEA number; (g) the method of payment; and (h) the total number of prescriptions dispensed, broken down by controlled and non-controlled substances.

5. Within 90 days of the Effective Date, RDC shall implement improved CSMP procedures and systems to review all orders of controlled substances and to detect and report suspicious orders to DEA.

a. RDC shall review and enhance its methodology for calculating and establishing appropriate thresholds designed to detect potentially suspicious orders from pharmacy customers. These thresholds shall be based not only on the customer's historical dispensing activity data, but also on the ordering patterns of comparable pharmacy customers. RDC shall set more restrictive thresholds for orders of highly diverted controlled substances. RDC shall establish appropriate initial thresholds for new customers prior to supplying them with any controlled substances. RDC compliance personnel shall be exclusively responsible for establishing and modifying initial thresholds, and may consult with other RDC personnel to gather information relevant to such determinations.

b. RDC shall not fulfill any order that exceeds the customer's threshold without conducting a thorough and diligent investigation to determine whether the order is suspicious and must be reported to DEA. This investigation shall include, but not be limited to, contacting the customer to obtain an explanation for the increase in ordering and obtaining and reviewing a report from the customer reflecting its most recent dispensing activity data. RDC compliance personnel trained in detecting suspicious orders shall conduct this investigation and shall create documentation sufficiently specific to show the basis for their determination as to whether the order is suspicious and must be reported to DEA. Any decision that an order is not suspicious and need not be reported to DEA must be approved in writing by RDC's Chief Compliance Officer, Director of Compliance, or Assistant Director of Compliance. In addition, RDC will notify the Independent Monitor in writing of any decision that results in fulfilling an order that exceeds a customer's threshold.

c. RDC shall review and enhance its procedures and systems for evaluating and approving customer requests for increased thresholds ("Threshold Change Requests"). Prior

to approving a Threshold Change Request, RDC shall conduct a thorough and diligent investigation to determine whether the increased threshold is warranted. This investigation shall include, but not be limited to, contacting the customer to obtain the basis for the Threshold Change Request, obtaining and reviewing a report from the customer reflecting its most recent dispensing activity data, and conducting an on-site visit to the pharmacy if the pharmacy has not been subject to a site visit within the prior six months. RDC compliance personnel shall conduct this investigation and shall create documentation sufficiently specific to show the basis for their determination as to whether the Threshold Change Request should be approved. RDC shall not temporarily increase thresholds in order to circumvent the requirement to conduct Threshold Change Request investigations. Any increase in a customer's thresholds must be approved in writing by RDC's Chief Compliance Officer, Director of Compliance, or Assistant Director of Compliance. In addition, RDC will notify the Independent Monitor in writing of any decision that results in the approval of a customer's Threshold Change Request.

d. RDC shall review and enhance its procedures and systems for detecting patterns or trends in customer orders and dispensing activity that indicate a pharmacy may be dispensing controlled substances for other than a legitimate medical purpose ("Red Flags"). In the event that RDC identifies a Red Flag for a pharmacy customer, RDC shall conduct a thorough and diligent investigation to determine whether any orders or customer Red Flags should be reported to DEA. Red Flags include, but are not limited to:

(i) A high percentage of the pharmacy's controlled substance sales are paid for in cash.

(ii) The pharmacy fills prescriptions for many patients who live far from the pharmacy.

(iii) The pharmacy frequently fills prescriptions for higher quantities than the accepted medical standards.

(iv) A high percentage of the pharmacy's overall dispensing consists of controlled substances.

(v) A disproportionate percentage of the pharmacy's controlled substance sales are for highly diverted controlled substances.

(vi) The pharmacy fills prescriptions written by prescribers acting outside their practice or specialty.

(vii) The pharmacy fills prescriptions for prescribers who have been subject to discipline or a law enforcement action.

(viii) The pharmacy dispenses the same quantity of highly diverted controlled substances to most patients.

(ix) Additional red flags identified by DEA to RDC in writing or otherwise published by DEA.

Upon identification of one or more Red Flags, RDC shall suspend and not resume distribution of controlled substances to the customer unless it reasonably concludes, based on specific and articulable facts, that there is a legitimate explanation for the identified Red Flag(s). RDC compliance personnel trained in detecting suspicious orders shall conduct this investigation and shall create documentation sufficiently specific to show the basis for their determination, including its decision, if any, not to suspend distribution of controlled substances.

e. RDC shall electronically submit all suspicious orders to DEA Headquarters. DEA agrees to provide RDC with instructions and procedures for electronically submitting suspicious orders. RDC shall submit the suspicious order reports in the format as

defined by DEA pursuant to reporting requirements to the centralized database as defined in the SUPPORT Act, § 3292, or as otherwise designated by DEA. RDC shall also submit all suspicious order reports to the DEA Field Division, and these reports shall specify the basis for reporting the order. RDC shall transmit suspicious order reports, if any, to DEA Headquarters and the DEA Field Division within two business days of discovery. RDC shall not fulfill any order deemed to be suspicious.

6. Within 90 days of the Effective Date of this Stipulation, RDC shall implement improved CSMP procedures and systems for conducting due diligence reviews of pharmacy customers to prevent the diversion of controlled substances.

a. RDC shall review and enhance its customer on-boarding procedures and systems to better assess whether prospective customers dispense controlled substances for only legitimate medical purposes. RDC shall, to the extent possible, verify any information that is self-reported by the prospective customer and relied upon to make this assessment. Prior to initiating the sale of controlled substances to a pharmacy, RDC compliance personnel, or a qualified third party consultant acting on behalf of RDC, shall engage in at least the following due diligence: (i) conduct an on-site visit to the pharmacy and interview the pharmacist-in-charge; (ii) complete a report reflecting the findings based on this visit and interview and noting any areas of concern; (iii) review recent dispensing activity data for the pharmacy to identify any Red Flags; (iv) determine whether the pharmacy or the pharmacist-in-charge has been subject to any disciplinary action, and, if so, the basis for the disciplinary action; and (v) conduct a diligent inquiry to determine whether another distributor has previously suspended the pharmacy's ability to purchase controlled substances, and, if so, the reason. In the event that RDC identifies a Red Flag that does not have a legitimate explanation or RDC's due diligence reveals any other

credible information suggesting that the pharmacy may be engaging in diversion, RDC shall not sell controlled substances to the pharmacy and shall report its findings and the results of its due diligence review to the DEA Field Division within two business days.

b. RDC shall review and enhance its procedures and systems for conducting meaningful due diligence of existing customers that purchase controlled substances to better assess whether existing customers dispense controlled substances for only legitimate medical purposes. RDC compliance personnel, or a qualified third party consultant acting on behalf of RDC, must engage in at least the following due diligence for each controlled substance customer: (i) conduct on-site visits and interviews of the pharmacist-in-charge, which shall be done at least once a year for RDC's 100 largest customers of highly diverted controlled substances, as measured by total volume of sales of highly diverted controlled substances during the prior year, and at least once every three years for all other controlled substances customers; (ii) complete a report reflecting their findings based on the visit and interview and noting any areas of concern; (iii) at least three times each calendar year for RDC's 100 largest customers of highly diverted controlled substances, as measured by total volume of sales of highly diverted controlled substances during the prior year, and at least two times each calendar year for all other controlled substances customers, obtain and review the pharmacy's dispensing activity data for the prior three months to identify any Red Flags; (iv) obtain updated completed questionnaires from the pharmacy on an annual basis; and (v) conduct all necessary additional due diligence in response to any information or events raising concerns of potential diversion activities (*e.g.*, the receipt of reliable information from law enforcement about possible diversion, the receipt of information regarding the suspension or revocation of a DEA registration or state license). . Upon identification of any credible information suggesting that an existing customer may be

engaging in diversion, including the presence of one or more Red Flags, RDC shall report its findings and the results of its due diligence review to the DEA Field Division within two business days. In addition, upon identification of such evidence suggesting diversion, including the presence of one or more Red Flags, RDC shall suspend and not resume distribution of controlled substances to the customer unless it reasonably concludes, based on specific and articulable facts, that no such diversion is occurring, including that there is a legitimate explanation for the evidence suggesting diversion and the identified Red Flag(s). RDC compliance personnel trained in detecting suspicious orders shall conduct this investigation and shall create documentation sufficiently specific to show the basis for their determination, including its decision, if any, not to suspend distribution of controlled substances.

c. All steps taken with respect to the due diligence review of prospective or existing customers shall be documented in the customer's file.

7. RDC shall ensure that all policies and procedures relating to its CSMP are included in an updated version of its compliance manual ("CSMP Manual").

8. RDC shall submit periodic reports to DEA Headquarters, the United States Attorney's Office for the Southern District of New York (the "SDNY"), and the Independent Monitor. RDC shall submit its first report within 90 days of the Effective Date. After making its first report, RDC shall thereafter make a report every 180 days (a "Reporting Period"). The reports shall be submitted on or before the last day of each Reporting Period. Each report shall include the following:

a. A list of all RDC compliance personnel, as well as any third-party consultants used by RDC to perform compliance functions.

b. RDC's list of highly diverted controlled substances as of the end of the Reporting Period.

c. A list of RDC's 20 largest customers of highly diverted controlled substances, as measured by total volume of sales of highly diverted controlled substances during the Reporting Period, and a breakdown of the sales of highly diverted controlled substances to each of these customers during the Reporting Period.

d. A description of the methodology used during the Reporting Period to calculate and establish thresholds for new and existing RDC pharmacy customers, as well as any changes that were made to the methodology since the prior Reporting Period.

e. The total number of suspicious orders reported to DEA during the Reporting Period.

f. A copy of any version of the CSMP Manual that was in effect during the Reporting Period, which shall include, among other things, a description of the manner in which RDC identified and reported suspicious orders to DEA during the Reporting Period and a description of the procedures and systems in place during the Reporting Period to conduct due diligence reviews of new and existing pharmacy customers.

9. RDC agrees that DEA personnel may enter its registered locations at any time during regular business hours, without prior notice, to verify compliance with this Compliance Addendum. RDC will permit entry of DEA personnel without an Administrative Inspection Warrant. RDC personnel shall sign a Notice of Inspection when requested to do so by DEA personnel during regular business hours.

10. RDC shall maintain customer due diligence files and all other records sufficient to document compliance with this Compliance Addendum during the period from the Effective Date through six months after the last Reporting Period.

11. RDC may notify the Independent Compliance Monitor of any material provision set forth in this Compliance Addendum that it believes is unduly burdensome, inconsistent with applicable law or regulation, excessively expensive, or otherwise inadvisable, as well as the basis for such conclusion. Such notification shall be sent to the Monitor and the Office, and must include a written proposal of an alternative approach, policy, procedure or system that RDC believes will achieve the same objective or purpose as the challenged provision. The Office shall in its sole discretion, determine whether to accept RDC's proposed revision, to maintain the existing provision, or to adopt a different alternative.