SETTLEMENT AGREEMENT

This Settlement Agreement (Agreement) is entered into among the United States of America, acting through the United States Department of Justice, and on behalf of the Drug Enforcement Administration (DEA), the Office of Inspector General (OIG-HHS) of the Department of Health and Human Services (HHS), and the Defense Health Agency (DHA), acting on behalf of the TRICARE Program (collectively, the "United States"), Dunn Meadow Pharmacy LLC ("Dunn Meadow") and Allegheny Pharma LLC ("Allegheny Pharma"), collectively, "the Parties," through their authorized representatives.

RECITALS

- A. Dunn Meadow is a New Jersey Limited Liability Corporation that operated as a "mail-order" pharmacy located in Fort Lee, New Jersey until June 30, 2021.
- B. Allegheny Pharma is a holding company located in Fort Lee, New Jersey that wholly owns DMP Group, LLC. DMP Group, LLC is a holding company that wholly owns Dunn Meadow.
- C. Dunn Meadow dispensed prescriptions for some of the most potent and expensive opioid products on the market, including Subsys, Abstral, Levorphanol Tartrate ("Levorphanol"), and Oxycodone. Dunn Meadow had contracts with and received payments from pharmaceutical companies that marketed and sold opioids, including INSYS Pharma, Inc. ("Insys") and Company 1.
- D. Subsys, a sublingual spray, and Abstral, a sublingual tablet, are Transmucosal Immediate-Release Fentanyl ("TIRF") medications which are designed to administer an immediate dose of fentanyl. Prescription fentanyl is an opioid that is 80 to 100 times more powerful than morphine and is among the most potent opioids available for human use. Subsys and Abstral are approved by the United States Food and Drug Administration ("FDA") for the

treatment of breakthrough pain in opioid-tolerant cancer patients (referred to as "breakthrough cancer pain"). Subsys and Abstral are Schedule II narcotics under the Controlled Substances Act, 21 U.S.C. § 801 *et seq*.

- E. Levorphanol, an opioid tablet, is 4 to 8 times more powerful than morphine. Levorphanol is approved by the FDA for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Levorphanol is a Schedule II narcotic under the Controlled Substances Act, 21 U.S.C. § 801 et seq.
- F. Oxycodone is an opioid tablet that is 1.5 times more powerful than morphine. Oxycodone products (such as Oxycontin and Xtampza ER) are approved by the FDA for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Oxycodone is a Schedule II narcotic under the Controlled Substances Act, 21 U.S.C. § 801 *et seq*.
- G. Schedule II narcotics, such as the opioids dispensed by Dunn Meadow, have a high potential for abuse and, if abused, may cause severe psychological and physical dependence. 21 U.S.C. § 812(b)(2). Because they are considered dangerous, Schedule II narcotics are highly regulated. Based on Dunn Meadow's dispensing records, between June 2015 and December 2020, the majority of Dunn Meadow's revenues (84.3%) were from Schedule II narcotics. Schedule II narcotics sold by Insys (Subsys) and Company 1 (Abstral and Levorphanol) constituted a majority (69.4%) of all Dunn Meadow revenues and a substantial majority (82.3%) of Dunn Meadow revenues from Schedule II narcotics.
- H. Dunn Meadow will plead guilty to a two-count Information to be filed by the United States in *United States v. Dunn Meadow Pharmacy LLC*, Criminal Action No. [to be determined] (D.N.J.) (the "Criminal Action") on such date as may be determined by the U.S. District Court for the District of New Jersey, pursuant to Rule 11(c)(1)(C) of the Federal Rules

of Criminal Procedure. The Criminal Action will allege: (1) conspiracy to knowingly distribute and to knowingly dispense, outside the usual course of professional practice and not for a legitimate medical purpose, 400 grams or more of a mixture and substance containing a detectable amount of fentanyl, a Schedule II controlled substance, contrary to 21 U.S.C. §§ 841(a)(1) and (b)(1)(A)(vi) and 21 C.F.R. § 1306.04, in violation of 21 U.S.C. § 846; and (2) conspiracy to knowingly violate the Federal Anti-Kickback Statute, contrary to 42 U.S.C. § 1320a-7b(b)(2)(A), in violation of 18 U.S.C. § 371.

- I. The United States contends that Dunn Meadow submitted or caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll ("Medicare"); and the TRICARE Program, 10 U.S.C. §§ 1071-1110b ("TRICARE").
- J. The United States contends that it has certain civil claims against Dunn Meadow arising from the conduct described in this Paragraph J under the Controlled Substances Act ("CSA"), 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.04(a), and under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-33. The United States alleges that from June 2015 through December 2020, Dunn Meadow engaged in the following conduct:
 - 1. Dunn Meadow dispensed opioid medications in violation of the CSA by filling prescriptions that were not issued for a legitimate medical purpose and were outside the usual course of the professional practice of a pharmacy. Dunn Meadow dispensed opioid medications: (a) without valid prescriptions; (b) for unsafe, medically unnecessary uses; and (c) to individuals displaying red flags of abuse and addiction, including for patients who routinely sought and received early refills; patients who received dangerous combinations of controlled substances (including the high-risk "holy trinity" drug combination of at least one opioid, benzodiazepine, and muscle relaxant

sought by addicts); patients who received multiple short-acting opioids—including multiple TIRF medications—at the same time; and patients who received excessive quantities and dosages of controlled substances for extended periods of time. In addition, Dunn Meadow filled prescriptions for opioid medications written by prescribers whom Dunn Meadow had reason to know were writing prescriptions outside of the usual course of professional practice.

- 2. Dunn Meadow knowingly submitted claims for opioid medications to Medicare and TRICARE that were not eligible for coverage because they were for non-covered uses, including for patients who lacked a valid prescription, for patients who were suffering addiction to opioids and for whom the medications were medically unreasonable and unnecessary, and for patients who were receiving TIRF medications for uses other than for breakthrough cancer pain, which are not covered uses by the Medicare and TRICARE programs. 42 U.S.C. § 1395w-102(e)(1) & (e)(4)(A)(ii); 32 C.F.R. § 199.2; 32 C.F.R. § 199.4(g)(15)(i)(A)(Note).
- 3. Dunn Meadow knowingly submitted claims for opioid medications to Medicare and TRICARE in violation of the federal Anti-Kickback statute, 42 U.S.C. § 1320a-7b(b), that resulted from (a) remuneration from drug companies to doctors, (b) remuneration from Company 1 to Dunn Meadow, including payments for alleged "shipping fees" for Levorphanol and Abstral, although Dunn Meadow was a mail order pharmacy that routinely shipped medications without manufacturer payment, and (c) remuneration, such as meals and entertainment, provided by Dunn Meadow sales personnel to prescribers and pharmaceutical sales representatives for Insys and Company 1.

Collectively, this conduct is referred to below as the "Covered Conduct."

K. This Settlement Agreement is neither an admission of liability by Dunn Meadow nor a concession by the United States that its claims are not well founded, except that Dunn Meadow admits the United States' allegations in Paragraph J to the extent they are reflected in Dunn Meadow's guilty plea in the Criminal Action.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

- 1. Dunn Meadow shall pay to the United States the sums specified in this Paragraph (collectively, the Settlement Amount), under the terms and conditions specified herein.
 - a. On behalf of Dunn Meadow, Allegheny Pharma shall pay to the United States
 \$225,000, as restitution, in accordance with Dunn Meadow's obligations in the
 Criminal Action, which will be credited to the civil Settlement Amount.
 - b. Dunn Meadow shall pay to the United States 50% of revenues generated in excess of \$221,000 after August 31, 2021, if any, in quarterly payments for a total period of 5 years, up to a total Settlement Amount of \$50,000,000, \$9,000,000 of which is restitution to the United States, and \$4,498,920.82 of which is also criminal restitution. For the avoidance of doubt, the term "revenues" as used in the immediately preceding sentence includes, without limitation: (i) all cash or cash equivalents generated from the sale or transfer of any tangible and intangible property; (ii) all cash or cash equivalents generated from the collection of accounts receivable; and (iii) all cash or cash equivalents through the resolution by way of judgment, award, settlement, or otherwise of any claim held by Dunn Meadow against any other entity. Furthermore, in the event of future revenues on

or after August 31, 2021, Dunn Meadow must provide a quarterly revenue report to the US Attorney's Office Financial Litigation Unit by May 15th for the first quarter, August 15th for the second quarter, November 15th for the third quarter and February 15th for the fourth quarter of the prior year, commencing for the calendar quarter in which this Agreement is fully executed. These quarterly revenue statements must be signed under penalty of perjury by an officer or director or other authorized corporate representative of Dunn Meadow.

- 2. Subject to the exceptions in Paragraph 3 (concerning reserved claims) below, and subject to Paragraph 5 (concerning disclosure of assets), Paragraph 13 (concerning default), and Paragraph 14 (concerning bankruptcy) below, and upon the United States' receipt of the Settlement Amount, the United States releases Dunn Meadow from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; the Controlled Substances Act, 21 U.S.C. § 841(a) and 21 C.F.R. § 1306.04(a); or the common law theories of payment by mistake, unjust enrichment, and fraud.
- 3. Notwithstanding the releases given in Paragraph 2 of this Agreement, or any other term of this Agreement, the following claims and rights of the United States are specifically reserved and are not released:
 - a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
 - b. Any criminal liability;
 - c. Except as explicitly stated in this Agreement, any administrative liability or enforcement right, including mandatory exclusion from Federal health care programs;

- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Any liability of individuals;
- g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- h. Any liability for failure to deliver goods or services due;
- Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.
- 4. Notwithstanding the releases given in Paragraph 2 of this Agreement, or any other term of this Agreement, OIG-HHS and Dunn Meadow agree as follows:
- (a) In compromise and settlement of the rights of OIG-HHS to exclude Dunn Meadow pursuant to: (1) 42 U.S.C. § 1320a-7(a)(1), based upon Dunn Meadow's guilty plea to conspiracy to violate the Federal Anti-Kickback Statute, contrary to 42 U.S.C. § 1320a-7b(b)(2)(A), in violation of 18 U.S.C. § 371 in the U.S. District Court for the District of New Jersey; (2) 42 U.S.C. § 1320a-7(a)(4), based upon Dunn Meadow's guilty plea to conspiracy to knowingly distribute and to knowingly dispense, outside the usual course of professional practice and not for a legitimate medical purpose, 400 grams or more of a mixture and substance containing a detectable amount of fentanyl, a Schedule II controlled substance, contrary to 21 U.S.C. §§ 841(a)(1) and (b)(1)(A)(vi) and 21 C.F.R. § 1306.04, in violation of 21 U.S.C. § 846 in the U.S. District Court for the District of New Jersey; and (3) 42 U.S.C. § 1320a-7(b)(7), based upon the Covered Conduct, Dunn Meadow agrees to be excluded under these statutory provisions from Medicare, Medicaid, and all other Federal health care programs, as defined in 42

- U.S.C. § 1320a-7b(f) for a period of 30 years. The exclusion shall be effective upon the Effective Date of this Agreement.
- (b) Such exclusion shall have national effect. Federal health care programs shall not pay anyone for items or services, including administrative and management services, furnished, ordered, or prescribed by Dunn Meadow in any capacity while Dunn Meadow is excluded. This payment prohibition applies to Dunn Meadow and all other individuals and entities (including, for example, anyone who employs or contracts with Dunn Meadow, and any hospital or other provider where Dunn Meadow provides services). The exclusion applies regardless of who submits the claim or other request for payment. Violation of the conditions of the exclusion may result in criminal prosecution, the imposition of civil monetary penalties and assessments, and an additional period of exclusion. Dunn Meadow further agrees to hold the Federal health care programs, and all federal beneficiaries and/or sponsors, harmless from any financial responsibility for items or services furnished, ordered, or prescribed to such beneficiaries or sponsors after the effective date of the exclusion. Dunn Meadow waives any further notice of the exclusion and agrees not to contest such exclusion either administratively or in any state or federal court.
- (c) Reinstatement to program participation is not automatic. If Dunn Meadow wishes to be reinstated, Dunn Meadow must submit a written request for reinstatement to the OIG-HHS in accordance with the provisions of 42 C.F.R. §§ 1001.3001-.3005. Such request may be made to the OIG-HHS no earlier than 90 days prior to the expiration of the 30-year period of exclusion. Reinstatement becomes effective upon application by Dunn Meadow, approval of the application by the OIG-HHS, and notice of reinstatement by the OIG-HHS. Obtaining another license, moving to another state, or obtaining a provider number from a Medicare contractor, a

state agency, or a Federal health care program does not reinstate Dunn Meadow's eligibility to participate in these programs.

5. Dunn Meadow has provided sworn financial disclosures and Dunn Meadow and Allegheny Pharma have each provided supporting financial documents (together "Financial Disclosures") to the United States and the United States has relied on the accuracy and completeness of those Financial Disclosures in reaching this Agreement. Dunn Meadow and Allegheny Pharma warrant that the Financial Disclosures are complete, accurate, and current as of the Effective Date of this Agreement. If the United States learns of asset(s) in which Dunn Meadow and/or Allegheny Pharma had an interest of any kind as of the Effective Date of this Agreement (including, but not limited to, promises by insurers or other third parties to satisfy Dunn Meadow's or Allegheny Pharma's obligations under this Agreement) that were not disclosed in the Financial Disclosures, or if the United States learns of any false statement or misrepresentation by Dunn Meadow and/or Allegheny Pharma on, or in connection with, the Financial Disclosures, and if such nondisclosure, false statement, or misrepresentation changes the estimated net worth set forth in the Financial Disclosures by \$20,000 or more, the United States may at its option: (a) rescind this Agreement and file suit based on the Covered Conduct or (b) collect the full Settlement Amount in accordance with the Agreement plus one hundred percent (100%) of the net value of Dunn Meadow's and/or Allegheny Pharma's previously undisclosed assets. Dunn Meadow and Allegheny Pharma agree not to contest any collection action undertaken by the United States pursuant to this provision, and agree that it will immediately pay the United States the greater of (i) a ten-percent (10%) surcharge of the amount collected in the collection action, as allowed by 28 U.S.C. § 3011(a), or (ii) the United States' reasonable attorneys' fees and expenses incurred in such an action. In the event that the United States rescinds this Agreement pursuant to this Paragraph, Dunn Meadow and Allegheny Pharma waive and 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 (a) are filed by the United States within 120 calendar days of written notification to Dunn Meadow and Allegheny Pharma that this Agreement has been rescinded, and (b) relate to the Covered Conduct, except to the extent these defenses were available on the effective date of this Agreement.

- 6. Dunn Meadow waives and shall not assert any defenses Dunn Meadow 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.
- 7. Dunn Meadow fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Dunn Meadow has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct or the United States' investigation or prosecution thereof.
- 8. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (*e.g.*, Medicare Administrative Contractor, fiscal intermediary, or carrier), TRICARE carrier or payer, or any state payer, related to the Covered Conduct; and Dunn Meadow agrees not to resubmit to any Medicare contractor, TRICARE carrier or payer, or any state payer any previously denied claims

related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

- 9. Dunn Meadow agrees to the following:
- a. <u>Unallowable Costs Defined</u>: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Dunn Meadow, its present or former officers, directors, employees, shareholders, and agents in connection with:
 - (1) the matters covered by this Agreement and any related plea agreement;
 - (2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;
 - (3) Dunn Meadow's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);
 - (4) the negotiation and performance of this Agreement and any Plea

 Agreement; and
 - (5) the payment Dunn Meadow makes to the United States pursuant to this

 Agreement

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs).

b. <u>Future Treatment of Unallowable Costs</u>: Unallowable Costs shall be separately determined and accounted for by Dunn Meadow, and Dunn Meadow shall not charge

such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Dunn Meadow or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. <u>Treatment of Unallowable Costs Previously Submitted for Payment:</u>

Dunn Meadow further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Dunn Meadow or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Dunn Meadow agrees that the United States, at a minimum, shall be entitled to recoup from Dunn Meadow any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Dunn Meadow or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Dunn Meadow or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

- d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Dunn Meadow's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.
- 10. Dunn Meadow and Allegheny Pharma agree to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Dunn Meadow and Allegheny's cooperation will include: (1) making disclosures of all relevant facts about any individuals who were involved in the misconduct; (2) to the extent possible, making witnesses available for interviews and providing the United States relevant documentary evidence; and (3) voluntary disclosure of other wrongdoing identified by Dunn Meadow. Dunn Meadow and Allegheny Pharma further agree to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in their possession, custody, or control concerning any investigation of the Covered Conduct that they have undertaken, or that have been performed by another on their behalf. The United States will determine in its sole discretion whether information it seeks from Dunn Meadow and Allegheny as part of their cooperation is relevant to the United States' investigations. Notwithstanding any provision of this Agreement, (1) Dunn Meadow and Allegheny are not required to request that their current or former officers, agents, or employees forgo seeking the advice of an attorney or act contrary to that advice; (2) Dunn Meadow and Allegheny are not required to take any action against their officers, agents, or employees for following their attorney's advice; and (3) Dunn Meadow and Allegheny are not required to waive any privilege or claim of work product protection.

- 11. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 12 (waiver for beneficiaries paragraph), below.
- 12. Dunn Meadow agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.
- 13. The Settlement Amount represents the amount the United States is willing to accept in compromise of its civil claims arising from the Covered Conduct due solely to Dunn Meadow's and Allegheny Pharma's financial conditions as reflected in the Financial Disclosures referenced in Paragraph 5.
- a. In the event that Dunn Meadow and Allegheny Pharma fail to pay the Settlement Amount as provided in the payment schedule set forth in Paragraph 1 above, Dunn Meadow and Allegheny Pharma shall be in Default of Dunn Meadow's and Allegheny Pharma's payment obligations ("Default"). The United States will provide a written Notice of Default, and Dunn Meadow and Allegheny Pharma shall have an opportunity to cure such Default within seven (7) calendar days from the date of receipt of the Notice of Default by making the payment due under the payment schedule and paying any additional interest accruing under the Settlement Agreement up to the date of payment. Notice of Default will be delivered to Dunn Meadow and Allegheny Pharma, or to such other representative as Dunn Meadow and Allegheny Pharma shall designate in advance in writing. If Dunn Meadow and Allegheny Pharma fail to cure the Default within seven (7) calendar days of receiving the Notice of Default and in the absence of an agreement with the United States to a modified payment schedule ("Uncured Default"), the remaining unpaid balance of the Settlement Amount shall become immediately due and payable,

and interest on the remaining unpaid balance shall thereafter accrue at the rate of 12% per annum, compounded daily from the date of Default, on the remaining unpaid total (principal and interest balance).

h. In the event of Uncured Default, Dunn Meadow and Allegheny Pharma agree that the United States, at its sole discretion, may (i) retain any payments previously made, rescind this Agreement and bring any civil and/or administrative claim, action, or proceeding against Dunn Meadow and Allegheny Pharma for the claims that would otherwise be covered by the releases provided in Paragraph 2 above, with any recovery reduced by the amount of any payments previously made by Dunn Meadow and Allegheny Pharma to the United States under this Agreement; (ii) take any action to enforce this Agreement in a new action; (iii) offset the remaining unpaid balance from any amounts due and owing to Dunn Meadow and Allegheny Pharma and/or affiliated companies by any department, agency, or agent of the United States at the time of Default or subsequently; and/or (iv) exercise any other right granted by law, or under the terms of this Agreement, or recognizable at common law or in equity. The United States shall be entitled to any other rights granted by law or in equity by reason of Default, including referral of this matter for private collection. In the event the United States pursues a collection action, Dunn Meadow and Allegheny Pharma agree to immediately pay the United States the greater of (i) a ten-percent (10%) surcharge of the amount collected, as allowed by 28 U.S.C. § 3011(a), or (ii) the United States' reasonable attorneys' fees and expenses incurred in such an action. In the event that the United States opts to rescind this Agreement pursuant to this Paragraph, Dunn Meadow and Allegheny Pharma waive and agree not to plead, argue, or otherwise raise any defenses of statute of limitations, laches, estoppel or similar theories, to any civil or administrative claims that (i) are filed by the United States against Dunn Meadow and Allegheny Pharma within 120 days of written notification that this Agreement has been

rescinded, and (ii) relate to the Covered Conduct, except to the extent these defenses were available on the Effective Date of this Agreement. Dunn Meadow and Allegheny Pharma agree not to contest any offset, recoupment, and /or collection action undertaken by the United States pursuant to this Paragraph, either administratively or in any state or federal court, except on the grounds of actual payment to the United States.

- c. In the event of Uncured Default, OIG-HHS may exclude Dunn Meadow and Allegheny Pharma from participating in all Federal health care programs until Dunn Meadow and Allegheny Pharma pay the Settlement Amount, with interest, as set forth above (Exclusion for Default). OIG-HHS will provide written notice of any such exclusion to Dunn Meadow and Allegheny Pharma. Dunn Meadow and Allegheny Pharma waive any further notice of the exclusion under 42 U.S.C. § 1320a-7(b)(7), and agree not to contest such exclusion either administratively or in any state or federal court. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, Dunn Meadow or Allegheny Pharma wish to apply for reinstatement, they must submit a written request for reinstatement to OIG-HHS in accordance with the provisions of 42 C.F.R. §§ 1001.3001-.3005. Dunn Meadow and Allegheny Pharma will not be reinstated unless and until OIG-HHS approves such request for reinstatement. The option for Exclusion for Default is in addition to, and not in lieu of, the options identified in this Agreement or otherwise available.
- 14. In exchange for valuable consideration provided in this Agreement, Dunn Meadow and Allegheny Pharma acknowledge the following:
- a. Allegheny Pharma has reviewed its financial situation and warrants that it is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I) and shall remain solvent immediately following payment to the United States of the Settlement Amount.

- b. In evaluating whether to execute this Agreement, the Parties intend that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to Allegheny Pharma and Dunn Meadow, within the meaning of 11 U.S.C. § 547(c)(1), and the Parties conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange.
- c. The mutual promises, covenants, and obligations set forth herein are intended by the Parties to, and do in fact, constitute a reasonably equivalent exchange of value.
- d. The Parties do not intend to hinder, delay, or defraud any entity to which Allegheny Pharma or Dunn Meadow was or became indebted to on or after the date of any transfer contemplated in this Agreement, within the meaning of 11 U.S.C. § 548(a)(1). For the avoidance of doubt, nothing in Paragraph 14(d) shall prevent Dunn Meadow from attempting in good faith, to compromise and negotiate over the amounts it owes its creditors, including applicable payment dates.
- e. If Allegheny Pharma's or Dunn Meadow's 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) or if, before the Settlement Amount is paid in full, Dunn Meadow, Allegheny Pharma, or a third party commences a case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors seeking any order for relief of Allegheny Pharma's or Dunn Meadow's debts, or to adjudicate Allegheny Pharma or Dunn Meadow as bankrupt or insolvent; or seeking appointment of a receiver, trustee, custodian, or other similar official for Allegheny Pharma or Dunn Meadow or for all or any substantial part of Allegheny Pharma's or Dunn Meadow's assets:

- (i) the United States may rescind the releases in this Agreement and bring any civil and/or administrative claim, action, or proceeding against Dunn Meadow for the claims that would otherwise be covered by the releases provided in Paragraph 2 above; and
- (ii) the United States has an undisputed, noncontingent, and liquidated allowed claim against Dunn Meadow in the amount of \$50 million less any payments received pursuant to this agreement, provided, however, that such payments are not otherwise avoided and recovered from the United States by Allegheny Pharma, Dunn Meadow, a receiver, trustee, custodian, or other similar official for Allegheny Pharma or Dunn Meadow.
- f. Dunn Meadow agrees that any civil and/or administrative claim, action, or proceeding brought by the United States under Paragraph 14.e is not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) because it would be an exercise of the United States' police and regulatory power. Dunn Meadow shall not argue or otherwise contend that the United States' claim, action, or proceeding is subject to an automatic stay and, to the extent necessary, consents to relief from the automatic stay for cause under 11 U.S.C. § 362(d)(1). Dunn Meadow waives and 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 claim, action, or proceeding brought by the United States within 120 days of written notification to Dunn Meadow 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.
- 15. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.
- 16. Each Party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

- 17. This Agreement is governed by the laws of the United States. The exclusive venue for any dispute relating to this Agreement is the United States District Court for the District of New Jersey. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.
- 18. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties. Forbearance by the United States from pursuing any remedy or relief available to it under this Agreement shall not constitute a waiver of rights under this Agreement.
- 19. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.
- 20. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.
- 21. This Agreement is binding on Dunn Meadow's successors, transferees, heirs, and assigns.
- 22. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.
- 23. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: 8/3/22

BY:

Assistant United States Attorney

United States Attorney's Office for the

District of New Jersey

BY: RISAM. RE / RMP

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Office of Inspector General

United States Department of Health and Human Services

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for General Counsel

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