

## **SETTLEMENT AGREEMENT**

This Settlement Agreement (the “Agreement”) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (“OIG-HHS”) of the Department of Health and Human Services (“HHS”), the Defense Health Agency (“DHA”), acting on behalf of the TRICARE Program; the Office of Personnel Management (“OPM”), which administers the Federal Employees Health Benefits Program (“FEHBP”); and the United States Department of Veterans Affairs (“VA”) (collectively, the “United States”), Defendants AmerisourceBergen Corporation (“AmerisourceBergen”), AmerisourceBergen Specialty Group, LLC (“ABSG”), AmerisourceBergen Drug Corporation (“ABDC”), ASD Specialty Healthcare, LLC d/b/a Oncology Supply (“OSC”), and Medical Initiatives, Inc. d/b/a Oncology Supply Pharmacy Services (“MII”), (collectively the “ABC Defendants”), and Michael Mullen, Omni Healthcare Inc., and Daniel Sypula and Kelly Hodge (collectively the “Relators”), through their authorized representatives. The foregoing hereafter are collectively referred to as “the Parties.”

### **RECITALS**

A. Defendant AmerisourceBergen is a Delaware corporation with its corporate headquarters located at 1300 Morris Drive, Chesterbrook, Pennsylvania. Defendant AmerisourceBergen does business through numerous subsidiaries or operating divisions, including Defendants ABDC, ABSG, OSC, and MII. The ABC Defendants operate and conduct business throughout the United States, Puerto Rico, and Canada. ABDC is headquartered in Chesterbrook, Pennsylvania. ABSG is headquartered at 3101 Gaylord Parkway, Frisco, Texas. OSC is a pharmaceutical distributor operated by ABSG. OSC’s principal place of business is 2801 Horace Shepard Drive, Dothan, Alabama. MII, a subsidiary of OSC, was incorporated in

the State of Florida and is still registered as a for-profit corporation in Florida. On January 31, 2014, AmerisourceBergen closed MII. Prior to its closing, MII was a pre-filler of pharmaceuticals for oncology patients. MII's principal place of business was 2801 Horace Shepard Drive, Dothan, Alabama. MII operated a facility at OSC's location in Dothan, Alabama using one or more pharmacy license(s) in the name of MII and/or Oncology Supply Pharmacy Services and/or OS Pharmacy. The ABC Defendants did not register MII with the United States Food and Drug Administration ("FDA"), as required by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360.

B. On October 21, 2010, Michael Mullen filed a *qui tam* action in the United States District Court for the Eastern District of New York captioned *United States ex rel. Michael Mullen v. AmerisourceBergen Corporation, et al.*, Civil Action No. CV-10-4856 (E.D.N.Y), pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b). An amended complaint was filed on January 24, 2011 (the "Mullen Action"). The United States intervened in part in the Mullen Action on August 31, 2017.

C. On March 9, 2012, Omni Healthcare Inc. filed a *qui tam* action in the United States District Court for the Eastern District of New York captioned *United States ex rel. Omni Healthcare Inc. v. AmerisourceBergen, et al.*, Civil Action No. CV-12- 1178 (E.D.N.Y), pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b). An amended complaint was filed on October 9, 2012 (the "Omni Action"). The United States intervened in part in the Omni Action on August 31, 2017.

D. On February 4, 2013, Daniel Sypula, RPH, and Kelly Hodge filed a *qui tam* action in the United States District Court for the Eastern District of Michigan captioned *United States ex rel. Daniel Sypula and Kelly Hodge v. AmerisourceBergen Drug Corporation, et al.*, CV-13-10439 (E.D.MI.), pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. §

3730(b). The case was transferred to the United States District Court for the Eastern District of New York by order dated September 4, 2014 and assigned Civil Action No. CV-14-5278 (E.D.N.Y.). An amended complaint was filed on January 28, 2015, and a second amended complaint was filed on July 16, 2015 (the “Sypula Action”). The United States intervened in part in the Sypula Action on August 31, 2017. The Mullen, Omni and Sypula Actions are referred to collectively hereafter in this Agreement as the “Civil Actions.”

E. On September 27, 2017, ABSG pleaded guilty to illegally distributing misbranded drugs in interstate commerce. (A copy of the Plea Agreement with Exhibits, which was filed in the United States District Court for the Eastern District of New York, is Attachment 1 to this Agreement.) ABSG agreed to pay a total of \$260 million in criminal fines and forfeiture to resolve criminal liability for its unlawful distribution of oncology supportive-care drugs. *See* Attachment 1, Plea Agreement ¶ 3.

F. The ABC Defendants admit, acknowledge and accept responsibility for the underlying conduct set forth in the Statement of Facts, attached hereto as Attachment 2.

G. The United States contends that the ABC Defendants caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 (“Medicare”); the Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 (“Medicaid”); the TRICARE Program, 10 U.S.C. §§ 1071-1110b (“TRICARE”); and the FEHBP, 5 U.S.C. §§ 8901-8914; and that the ABC Defendants caused the purchase of Covered Drugs (as defined below) by the Department of Veterans Affairs, Veterans Health Administration, 38 U.S.C. Chapter 17. These programs are referred to collectively hereafter in this Agreement as the “Federal healthcare programs.”

H. The United States contends that it has certain civil claims against the ABC Defendants arising from their operation of a Pre-Filled Syringe Program that repackaged the

following injectable drugs: Procrit®, Aloxi®, Kytril® and its generic form granisetron, Anzemet® and Neupogen® (the “Covered Drugs”). As more fully set forth below, the United States contends that the ABC Defendants, through their Pre-Filled Syringe Program, caused numerous false claims to be submitted to the Federal healthcare programs (1) for unapproved new drugs; (2) for drugs that were defective, contaminated or otherwise compromised drugs, whose quality and/or purity fell below that which they were purported or represented to possess; (3) by causing double billing for the same vial of drug product as a result of exploiting overfill; and (4) for Procrit® purchased as a result of the ABC Defendants’ kickback to physicians for Procrit® Pre-Filled Syringe purchases. The conduct set forth in this Paragraph and the subparagraphs below is referred to as “Covered Conduct.”

1. From October 21, 2001, through January 31, 2014, the ABC Defendants, through MII, repackaged the Covered Drugs from their original sterile vials into syringes and distributed those Pre-Filled Syringes to oncology practices and physicians treating vulnerable cancer patients. The ABC Defendants sought to profit from the excess drug product or overfill contained in the original FDA-approved sterile vials. To harvest the overfill, MII broke the sterility of the original sterile vials, pooled the contents, and repackaged the drugs into Pre-Filled Syringes. In so doing, MII created a greater number of Pre-Filled Syringes than the number of vials OSC purchased, which resulted in extra vials that were then sold to customers for profit.

2. From October 21, 2001, through January 31, 2014, the ABC Defendants sold Pre-Filled Syringes to customers. The Pre-Filled Syringes did not have approved New Drug Applications (“NDA”) or Biologics License Applications (“BLA”) in effect. No NDA or BLA was ever submitted to the FDA for the Pre-Filled Syringes, and the Pre-Filled Syringes were never covered by an approved NDA or BLA. Furthermore, the

ABC Defendants failed to demonstrate to the FDA that the drug vials repackaged into Pre-Filled Syringes were repackaged in a manner that would ensure the safety and efficacy of the drug product. The ABC Defendants did not submit any safety, stability or sterility data to the FDA or any information showing that the Pre-Filled Syringes' container closure system, packaging, or shipping methods would not adversely impact the safety or efficacy of the repackaged drug product. The ABC Defendants did not provide information to the FDA to establish that the Pre-Filled Syringes were generally recognized as safe and effective.

3. From October 21, 2001 through January 31, 2014, the ABC Defendants' business model was to sell to oncology practices Pre-Filled Syringes of the Covered Drugs that MII repackaged from their original sterile glass vials. To do so, MII staff broke the sterility of the original sterile vials, pooled the contents, and repackaged the drug product into plastic syringes. Some of the Pre-Filled Syringes contained visible particles of unknown origin, which MII sought to filter out before shipment. However, MII did not conduct any tests to confirm that the filtering process removed the foreign particles. The ABC Defendants represented to physician customers that MII's repackaging procedures followed aseptic technique and complied with all applicable laws when, in fact, that was not uniformly the case. On the few occasions when samples of Pre-Filled Syringes were tested for sterility, some of those samples tested positive for bacteria. The ABC Defendants never recalled any Pre-Filled Syringes.

4. From October 21, 2001 through January 31, 2014, the ABC Defendants used overfill and salvaged vials for resale, which caused double-billing for the same vial of drug product. The ABC Defendants' repackaging operation at MII allowed some vials to remain unopened (the "Unopened Vials"). The ABC Defendants resold the Unopened

Vials to other healthcare providers. These Unopened Vials were billed to payors, including the Federal healthcare programs. The second purchaser was either another physician ordering vials to be made into Pre-Filled Syringes or a hospital or pharmacy that purchased the Unopened Vials with the representation from the ABC Defendants that the Unopened Vials were purchased directly by the ABC Defendants from the manufacturer and sold directly to the second purchaser. The ABC Defendants failed to disclose to the second purchasers that the Unopened Vials were extra vials accumulated by MII as a result of the Pre-Filled Syringe Program and billed to payors, including Federal healthcare programs.

5. From June 30, 2005 to January 31, 2014, the ABC Defendants paid kickbacks to physicians to induce them to purchase Procrit® in Pre-Filled Syringes rather than the original vials by providing a rebate to physician-customers who purchased the drug in syringe form. The rebate was disguised on the invoice as a general pharmacy credit and not associated with Procrit®. Customers who bought Procrit® in a vial rather than Pre-Filled Syringes did not receive the additional rebate. The ABC Defendants did not properly disclose the rebate to customers in writing at the time of the initial sale of Procrit®.

I. Relators claim entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relators' reasonable expenses, attorneys' fees and costs.

J. The ABC Defendants will be entering into separate settlement agreements, described in Paragraph 1.b. below (the "Medicaid State Settlement Agreements") with the states (the "Medicaid Participating States") in settlement of the conduct released in those separate Medicaid State Settlement Agreements.

K. Except as otherwise expressly admitted in the Statement of Facts (Attachment 2), this Settlement Agreement is neither an admission of liability by the ABC Defendants nor a concession by the United States or Relators that their claims are not well founded.

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:

1. TERMS AND CONDITIONS

1. The ABC Defendants shall pay to the United States and the Medicaid Participating States, collectively, \$625,000,000 together with interest accrued thereon as follows: at a rate of 2.375% per annum from December 1, 2017, continuing until and including the day before payment is made (collectively the “Settlement Amount”). Payment shall be made no later than 10 days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney’s Office for the Eastern District of New York. The Settlement Amount shall constitute a debt immediately due and owing to the United States and the Medicaid Participating States on the Effective Date of this Agreement. The debt shall be discharged by payments to the United States and the Medicaid Participating States, under the following Terms and Conditions:

- a. AmerisourceBergen Corporation shall pay the United States the sum of \$581,809,006.00 plus accrued interest (the “Federal Settlement Amount”), of which \$313,631,942.91 is restitution, within ten (10) days of the Effective Date of this Agreement.
- b. AmerisourceBergen Corporation shall pay the Medicaid Participating States the sum of \$43,190,994.00 plus accrued interest (the “State Settlement Amount”)

pursuant to the terms of the Medicaid State Settlement Agreements that the ABC Defendants have or will enter into with the Medicaid Participating States.

2. Conditioned upon the United States receiving the Federal Settlement Amount from AmerisourceBergen Corporation and as soon as feasible after receipt, the United States shall pay the sum of \$93,089,441.00 plus accrued interest to Relator Mullen. No other relator payments shall be made by the United States with respect to the matters covered by this Agreement.

3. AmerisourceBergen Corporation agrees to pay Relators' attorneys' fees and costs, as required by 31 U.S.C. § 3730(d), within ten days of the Effective Date of this Agreement, as to which the Relators and AmerisourceBergen Corporation will be entering into separate settlement agreements covering the amount and payment of such fees and costs to Relators.

4. Subject to the exceptions in Paragraph 9 (concerning excluded claims) below, and conditioned upon AmerisourceBergen Corporation's full payment of the Settlement Amount, the United States releases the ABC Defendants, together with their current and former parent corporations; direct and indirect subsidiaries; brother or sister corporations; divisions; current or former corporate owners; and the corporate successors and assigns of any of them, 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; or the common law theories of payment by mistake, unjust enrichment, and fraud.

5. Conditioned upon AmerisourceBergen Corporation's full payment of the Settlement Amount and of the Relators' attorneys' fees and costs, each Relator, for himself, herself, or itself, and for his/her/its respective heirs, successors, attorneys, agents, assigns, executors, administrators and/or estates, hereby irrevocably releases, acquits and forever



discharges the ABC Defendants, their predecessors, parents, divisions, related or affiliated entities and subsidiaries, and current and former owners, officers, employees, shareholders, successors and assigns of the foregoing entities (“the ABC Defendant Releasees”) from any civil monetary claim the Relator has on behalf of the United States under the False Claims Act, 31 U.S.C. §§ 3729-3733, any claim for expenses or attorneys’ fees or costs under 31 U.S.C. § 3730(d), on behalf of any state, or political subdivision or municipality, under any state, political subdivision or municipality False Claims Act or similar law, and from all charges, complaints, liabilities, obligations, promises, agreements, controversies, damages, suits, rights, costs, losses, debts, expenses, claims, demands, actions, or causes of action whatsoever, whether known or unknown, fixed or contingent, in law or in equity, in contract, in tort or otherwise, under any federal or state statute or regulation, or in common law, that each Relator and his/her/its respective heirs, successors, attorneys, agents and assigns otherwise has or would have standing to bring as of the Effective Date of this Agreement; and including, but not limited to, any liability arising from or relating to the claims such Relator asserted or could have asserted in his/her/its Civil Action, and all claims for, or in any matter related to or arising from the following non-exclusive list: breach of express or implied contract; promissory estoppel; fraud, deceit, or misrepresentation; whistleblower claims; claims under any False Claims Act or similar statute, including, but not limited to, retaliation; claims under any state or federal Anti-Kickback Statute or similar statute; unjust, wrongful, or constructive dismissal claims; intentional, reckless, or negligent infliction of emotional distress; defamation or libel, breach of any express or implied covenant of employment, including the covenant of good faith and fair dealing; interference with contractual or advantageous relations; discrimination on any basis or retaliation under federal, state, or local law, including without limitation, Title VII of the Civil Rights Act of 1964, as amended, the Americans with Disabilities Act, as amended, the Age Discrimination in

Employment Act, as amended; misclassification of Relator's employment status; any and all dismissed claims; and claims for costs, expenses, and attorneys' fees with respect thereto. Each Relator's release herein shall be effective whether or not such Relator releases claims that are currently known, unknown, foreseen or unforeseen. Each Relator represents and warrants that he/she/it is not currently aware of any claims that exist or could lawfully be brought at this time against any of the ABC Defendant Releasees other than those encompassed within the Covered Conduct and in the Civil Actions, for which a full release is granted herein.

a. Each Relator further represents and warrants that neither Relator, nor anyone on his/her/its behalf, has filed any claims, complaints or charges against the ABC Defendant Releasees with any local, state or federal court or agency, and that neither Relator, nor anyone on his/her/its behalf, has any pending claims, complaints or charges with any local, state or federal court or agency. Each Relator additionally represents and warrants that he/she/it has not assigned or transferred to any person or entity any claims or any part or portion thereof.

b. Each Relator further agrees that neither he or she or it, nor anyone on his/her/its behalf, will hereafter pursue any claims against any of the ABC Defendant Releasees (including without limitation any claims seeking reinstatement with, or damages of any nature, severance, incentive or retention pay, attorneys' fees or costs) by filing a lawsuit in any local, state, or federal court for or on account of anything which has occurred up to the Effective Date of this Agreement as a result of the Civil Actions and/or any claim for attorneys' fees or costs related to the Civil Actions.

6. In consideration of the obligations of AmerisourceBergen Corporation in this Agreement and the Corporate Integrity Agreement (CIA), entered into between OIG-HHS and AmerisourceBergen Corporation and conditioned upon AmerisourceBergen Corporation's full payment of the Settlement Amount, the OIG-HHS agrees to release and refrain from instituting,

directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against AmerisourceBergen Corporation under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in this Paragraph and in Paragraph 9 (concerning excluded claims), below. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude AmerisourceBergen Corporation from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 9, below.

7. In consideration of the obligations of the ABC Defendants set forth in this Agreement, and conditioned upon AmerisourceBergen Corporation's full payment of the Settlement Amount, DHA agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the TRICARE Program against the ABC Defendants under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in Paragraph 9 (concerning excluded claims), below, and as reserved in this Paragraph. DHA expressly reserves authority to exclude the ABC Defendants from the TRICARE Program under 32 C.F.R. §§ 199.9 (f)(1)(i)(A), (f)(1)(i)(B), and (f)(1)(iii), based upon the Covered Conduct. Nothing in this Paragraph precludes DHA or the TRICARE Program from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 9, below.

8. In consideration of the obligations of the ABC Defendants in this Agreement, and conditioned upon the ABC Defendants' full payment of the Settlement Amount, OPM agrees to

release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the FEHBP against the ABC Defendants under 5 U.S.C. § 8902a or 5 C.F.R. Part 890 Subpart J or Part 919 for the Covered Conduct, except as reserved in this Paragraph and in Paragraph 9 (concerning excluded claims), below, and except if excluded by the OIG-HHS pursuant to 42 U.S.C. § 1320a-7(a). OPM expressly reserves all rights to comply with any statutory obligation to debar the ABC Defendants from the FEHBP under 5 U.S.C. § 8902a(b) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes OPM from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 9, below.

9. Notwithstanding the releases given in paragraphs 4, 5, 6, 7 and 8 of this Agreement, or any other term of this Agreement, the following claims 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, including mandatory exclusion from Federal healthcare 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; and

- i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

10. Relators and their heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon Relator Mullen's receipt of the payment described in Paragraph 2, Relators and their heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims related to or arising from each of their respective Civil Actions or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the claims arising from the Civil Actions.

11. The ABC Defendants waive and shall not assert any defenses the ABC Defendants 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.

12. The ABC Defendants fully and finally release the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that any ABC Defendant 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 and the United States' investigation and prosecution thereof.

13. The ABC Defendants, for themselves and their predecessors, parents, divisions, related or affiliated entities, subsidiaries, and current and former owners, officers, employees, shareholders, successors and assigns of the foregoing entities, fully and finally release the Relators, and their past, present, and future officers, agents, directors, attorneys, employees, heirs, successors, assigns, and servants (“the Relator Releasees”) from any claims (including attorneys’ fees, costs, and expenses of every kind and however denominated) that the ABC Defendants have asserted, could have asserted, or may assert in the future against the Relators and/or the Relator Releasees, related to the Covered Conduct, the claims in the Civil Actions, the Relators’ investigation and prosecution thereof, and from all charges, complaints, liabilities, obligations, promises, agreements, controversies, damages, suits, rights, costs, losses, debts, expenses, claims, demands, actions, or causes of action whatsoever, whether known or unknown, fixed or contingent, in law or in equity, in contract, in tort or otherwise, under any federal or state statute or regulation, or in common law, that any ABC Defendant or its respective heirs, successors, attorneys, agents and assigns otherwise has or would have standing to bring as of the Effective Date of this Agreement; and including, but not limited to, any liability arising from or relating to the claims such ABC Defendant or its respective heirs, successors, attorneys, agents and assigns asserted or could have asserted in the Civil Actions, and all claims for, or in any matter related to or arising from the following non-exclusive list: breach of express or implied contract; promissory estoppel; fraud, deceit, or misrepresentation; intentional, reckless, or negligent infliction of emotional distress; defamation or libel, breach of any express or implied covenant of employment, including the covenant of good faith and fair dealing; interference with contractual or advantageous relations; any and all dismissed claims; and claims for costs, expenses, and attorneys’ fees with respect thereto. Each ABC Defendant’s release herein shall be effective whether or not such ABC Defendant releases claims that are currently known,

unknown, foreseen or unforeseen. Each ABC Defendant represents and warrants that it is not currently aware of any claims that exist or could lawfully be brought at this time against any of the Relators (and/or the Relators' Releasees).

a. Each ABC Defendant further represents and warrants that neither it, nor anyone on its behalf, has filed any claims, complaints or charges against the Relators (and/or the Relator Releasees) with any local, state or federal court or agency, and that neither it, nor anyone on its behalf, has any pending claims, complaints or charges with any local, state or federal court or agency. Each ABC Defendant additionally represents and warrants that it has not assigned or transferred to any person or entity any claims or any part or portion thereof.

b. Each ABC Defendant further agrees that neither it, nor anyone on its behalf, will hereafter pursue any claims against any Relator and/or the Relator Releasees (including without limitation any claims seeking damages of any nature, attorneys' fees or costs) by filing a lawsuit in any local, state, or federal court for or on account of anything which has occurred up to the Effective Date of this Agreement as a result of the Civil Actions and/or any claim for attorneys' fees or costs related to the Civil Actions.

14. 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, carrier) TRICARE or FEHBP carrier or any state payor, related to the Covered Conduct; and the ABC Defendants agree not to resubmit to any Medicare contractor, TRICARE or FEHBP carrier or any state payer any previously denied claims related to the Covered Conduct, agree not to appeal any such denials of claims, and agree to withdraw any such pending appeals.

15. The ABC Defendants agree to the following:

a. Unallowable Costs Defined: 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. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of the ABC Defendants, their present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement and the related Plea Agreement;
- (2) the United States' audit(s) and civil and criminal investigation(s) of the matters covered by this Agreement;
- (3) the ABC Defendants' 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 attorney's fees);
- (4) the negotiation and performance of this Agreement and the related Plea Agreement;
- (5) the payment AmerisourceBergen Corporation makes to the United States pursuant to this Agreement and any payments that AmerisourceBergen Corporation makes to Relators, including costs and attorneys' fees; and
- (6) the negotiation of, and obligations undertaken pursuant to the CIA to: (i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (ii) prepare and submit reports to the OIG-HHS are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and FEHBP (hereinafter referred to as Unallowable Costs). However, nothing in Paragraph



15.a (6) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to AmerisourceBergen Corporation.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by the ABC Defendants, and the ABC Defendants 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 the ABC Defendants or any of their subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: The ABC Defendants further agree that within 90 days of the Effective Date of this Agreement they 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 the ABC Defendants or any of their 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. The ABC Defendants agree that the United States, at a minimum, shall be entitled to recoup from the ABC Defendants 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 the ABC Defendants or any of their subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on the ABC Defendants or any of their 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 the ABC Defendants' books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

16. 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 17 (waiver for beneficiaries paragraph), below.

17. The ABC Defendants agree that they waive 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.

18. Upon receipt of the Settlement Amount described in Paragraph 1 above, and the attorneys' fees and costs described in Paragraph 3 above, the United States and Relators shall promptly sign and file in each of the Civil Actions a Joint Stipulation of Dismissal with prejudice of the federal claims against the ABC Defendants in the Civil Actions as to the Covered Conduct pursuant to Rule 41(a)(1). As for any other claims in the Civil Actions against any ABC Defendants beyond those in the Covered Conduct, the United States and Relators shall promptly

sign and file in each of the Civil Actions a Joint Stipulation of Dismissal with prejudice as to the Relators, but without prejudice as to the United States.

19. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement, except as provided in Paragraph 3 above (Relators' attorneys' fees and costs).

20. Each party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

21. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Eastern District of New York. 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.

22. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

23. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

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

25. This Agreement is binding on the ABC Defendants' successors, transferees, heirs, and assigns.

26. This Agreement is binding on Relators' successors, transferees, heirs, and assigns.

27. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.


28. 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.

**FOR THE UNITED STATES OF AMERICA**

DATED: 9/28/2018

RICHARD P. DONOGHUE  
United States Attorney  
Eastern District of New York

BY:

  
DEBORAH B. ZWANY  
MATTHEW SILVERMAN  
Assistant U.S. Attorneys

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

SANJAY M. BHAMBHANI  
JOHN HENEBERRY  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

LISA M. RE  
Assistant Inspector General for Legal  
Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
United States Department of Health and  
Human Services

*Signature Page, Settlement Agreement United States v. AmerisourceBergen Corp., et al.*

FOR THE UNITED STATES OF AMERICA

DATED: \_\_\_\_\_


RICHARD P. DONOGHUE  
United States Attorney  
Eastern District of New York

BY:

\_\_\_\_\_  
DEBORAH B. ZWANY  
MATTHEW SILVERMAN  
Assistant U.S. Attorneys

DATED: 9/26/2018

BY:

  
\_\_\_\_\_  
SANJAY M. BHAMBHANI  
JOHN HENEBERRY  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

DATED: \_\_\_\_\_

BY:

\_\_\_\_\_  
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Office of Inspector General  
United States Department of Health and  
Human Services

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**FOR THE UNITED STATES OF AMERICA**

DATED: \_\_\_\_\_

RICHARD P. DONOGHUE  
United States Attorney  
Eastern District of New York

BY:

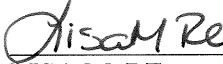
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MATTHEW SILVERMAN  
Assistant U.S. Attorneys

DATED: \_\_\_\_\_

BY:

\_\_\_\_\_  
SANJAY M. BHAMBHANI  
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United States Department of Justice

DATED: 9/28/2018 BY:

  
\_\_\_\_\_  
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Office of Inspector General  
United States Department of Health and  
Human Services

*Signature Page, Settlement Agreement United States v. AmerisourceBergen Corp., et al.*

DATED: 09/26/2018

BY: BLEY.PAUL.NICHOLA Digitally signed by  
S.1099873821 BLEY.PAUL.NICHOLAS.1099873821  
Date: 2018.09.26 16:35:46 -04'00'

LEIGH A. BRADLEY  
for General Counsel  
Defense Health Agency  
United States Department of Defense

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

EDWARD M. DeHARDE  
Assistant Director of Federal Employee  
Insurance Operations  
Healthcare and Insurance  
United States Office of Personnel  
Management

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

ROBIN M. RICHARDSON  
Acting Assistant Inspector General for Legal  
Affairs  
United States Office of Personnel  
Management

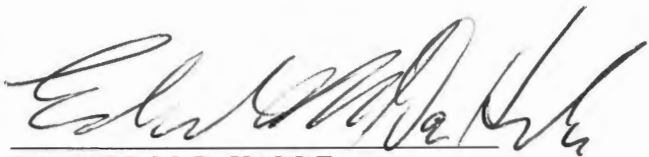
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DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
LEIGH A. BRADLEY  
General Counsel  
Defense Health Agency  
United States Department of Defense

DATED: 9/27/18

BY:   
EDWARD M. DeHARDE  
Assistant Director of Federal Employee  
Insurance Operations  
Healthcare and Insurance  
United States Office of Personnel  
Management

DATED:

BY: \_\_\_\_\_  
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DATED: \_\_\_\_\_

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BY: \_\_\_\_\_  
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United States Office of Personnel  
Management

DATED:

*9/27/18*

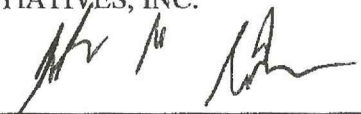
BY:

  
ROBIN M. RICHARDSON PAUL N. ST. HILLAIRE  
Acting Assistant Inspector General for Legal  
Affairs  
United States Office of Personnel  
Management

**FOR THE ABC DEFENDANTS**

AMERISOURCEBERGEN CORPORATION, AMERISOURCEBERGEN  
DRUG CORPORATION, AMERISOURCEBERGEN SPECIALTY GROUP,  
LLC, ASD SPECIALTY HEALTHCARE, LLC D/B/A ONCOLOGY  
SUPPLY AND MEDICAL INITIATIVES, INC.


DATED: 9/27/18

BY: 

STEVEN H. COLLIS  
Chairman, President and Chief Executive Officer

MORGAN, LEWIS & BOCKIUS LLP

DATED: 9/27/18

BY: 

ERIC W. SITARCHUK, ESQ.  
JOHN J. PEASE III, ESQ.  
KELLY A. MOORE, ESQ.  
RYAN P. McCARTHY, ESQ.  
1701 Market Street  
Philadelphia, PA 19103  
Counsel for the ABC Defendants

FOR RELATOR MICHAEL MULLEN

DATED: 9/24/18

BY:   
MICHAEL MULLEN

DATED: 9/26/18

THOMAS & ASSOCIATES  
20 Park Plaza Suite 438  
Boston, Massachusetts 0221002116

BY:   
ROBERT M. THOMAS, JR.


DATED: 9/26/18

DURRELL LAW OFFICE  
180 Williams Avenue  
Milton, Massachusetts 02186

BY:   
SUZANNE E. DURRELL

DATED: 9/27/18

KELLOGG, HANSEN, TODD,  
FIGEL & FREDERICK, P.L.L.C.  
1615 M Street, N.W. Suite 400  
Washington, D.C. 20036

BY:   
SILVIA A. STRIKIS  
JOSEPH S. HALL  
ANDREW C. SHEN

**FOR RELATOR OMNI HEALTHCARE INC.**

OMNI HEALTHCARE INC.

DATED: 9/26/18

BY:   
\_\_\_\_\_  
MARK BOBANGO  
Chief Financial Officer

DATED: \_\_\_\_\_

VEZINA LAW, PLC  
280 N. Old Woodward Avenue, Suite LL20  
Birmingham, Michigan 48009

BY: \_\_\_\_\_  
J. MARC VEZINA  
Counsel for Relator Omni Healthcare Inc.

DATED: \_\_\_\_\_

VEZINA LAW, PLC  
280 N. Old Woodward Avenue, Suite LL20  
Birmingham, Michigan 48009

BY: \_\_\_\_\_  
MONICA P. NAVARRO  
Counsel for Relator Omni Healthcare Inc.

*Signature Page, Settlement Agreement United States v. AmerisourceBergen Corp., et al.*

**FOR RELATOR OMNI HEALTHCARE INC.**

OMNI HEALTHCARE INC.

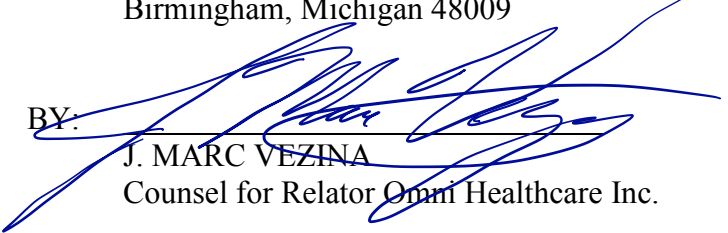
DATED: \_\_\_\_\_

BY: \_\_\_\_\_

MARK BOBANGO  
Chief Financial Officer

DATED: 09/26/18

VEZINA LAW, PLC  
280 N. Old Woodward Avenue, Suite LL20  
Birmingham, Michigan 48009

BY:   
\_\_\_\_\_  
J. MARC VEZINA  
Counsel for Relator Omni Healthcare Inc.


DATED: 9/26/18

VEZINA LAW, PLC  
280 N. Old Woodward Avenue, Suite LL20  
Birmingham, Michigan 48009

BY:   
\_\_\_\_\_  
MONICA P. NAVARRO  
Counsel for Relator Omni Healthcare Inc.

**FOR RELATORS DANIEL SYPULA AND KELLY HODGE**

DATED: 9/26/2018

BY:   
DANIEL SYPULA, RPH

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
KELLY HODGE

DATED: \_\_\_\_\_

HERTZ SCHRAM PC  
1760 Telegraph Road, Suite 300  
Bloomfield Hills, MI 48302-0183

BY: \_\_\_\_\_  
PATRICIA A. STAMLER  
Counsel for Relators Sypula and Hodge

*Signature Page, Settlement Agreement United States v. AmerisourceBergen Corp., et al.*

**FOR RELATORS DANIEL SYPULA AND KELLY HODGE**

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
DANIEL SYPULA, RPH

DATED: 9/26/18

BY:   
KELLY HODGE

DATED: \_\_\_\_\_

HERTZ SCHRAM PC  
1760 Telegraph Road, Suite 300  
Bloomfield Hills, MI 48302-0183

BY: \_\_\_\_\_  
PATRICIA A. STAMLER  
Counsel for Relators Sypula and Hodge

*Signature Page, Settlement Agreement United States v. AmerisourceBergen Corp., et al.*



**FOR RELATORS DANIEL SYPULA AND KELLY HODGE**

DATED: \_\_\_\_\_

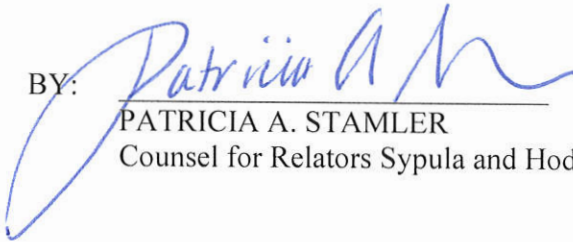
BY: \_\_\_\_\_  
DANIEL SYPULA, RPH

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
KELLY HODGE

DATED: 9/26/18

HERTZ SCHRAM PC  
1760 Telegraph Road, Suite 300  
Bloomfield Hills, MI 48302-0183

BY:   
\_\_\_\_\_  
PATRICIA A. STAMLER  
Counsel for Relators Sypula and Hodge

*Signature Page, Settlement Agreement United States v. AmerisourceBergen Corp., et al.*

# Attachment 1

JMK/SCJ:AES/ABK  
F. # 2012R00978

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

-----X

UNITED STATES OF AMERICA

PLEA AGREEMENT

- against -

17 CR 507 (NG)

AMERISOURCEBERGEN SPECIALTY  
GROUP, LLC,

Defendant.

-----X

Pursuant to Rule 11 of the Federal Rules of Criminal Procedure, the United States Attorney's Office for the Eastern District of New York and the United States Department of Justice, by and through the Consumer Protection Branch (collectively, the "United States") and AMERISOURCEBERGEN SPECIALTY GROUP, LLC ("defendant ABSG"), acting through its counsel, Eric W. Sitarchuk, Esq., pursuant to authority granted by its Board of Directors, conditioned as confirmed in the certification attached hereto as Exhibit A, agree to the following:

1. Defendant ABSG will waive indictment and plead guilty to Count One of an Information to be filed in this district, charging a violation of 21 U.S.C. §§ 331(a) and 333(a)(1). The count carries the following statutory penalties:
  - a. Maximum fine: \$200,000 or twice the gross pecuniary gain or loss, whichever is greater (18 U.S.C. §§ 3571(c)(5) and (d)).
  - b. Restitution: The United States and ABSG agree that no restitution will be ordered in this criminal case because (a) the

offense of conviction is not one for which restitution is mandatory under 18 U.S.C. § 3663A; and (b) there is a substantial agreed upon fine and forfeiture payment. The parties stipulate that nothing in this Plea Agreement, including this paragraph, is binding for civil, administrative or regulatory purposes, which may be the subject of other or further proceedings, including but not limited to proceedings under the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, and that the fine and forfeiture amounts set forth in this Plea Agreement shall not offset or reduce any civil, administrative or regulatory damages, penalties and/or interest for which the defendant may be liable. The parties further stipulate that the Plea Agreement is not, nor is intended to be, a full and fair resolution of the issue of loss to the government arising from the conduct covered in this Plea Agreement. The parties also stipulate that in any civil, administrative or regulatory proceedings relating to the conduct covered by this Plea Agreement, the defendant shall not assert or rely in any way upon the absence of restitution in this Plea Agreement as proof or support for any argument that the United States is not entitled to recover losses arising from the conduct covered in this Plea Agreement. The United States, by agreeing that no restitution will be ordered in this criminal case, does not agree that there is no loss to the United States arising from the conduct covered in this Plea Agreement.

- c. Criminal forfeiture: \$52,000,000, as set forth in paragraphs 6-11 below.  
(21 U.S.C. §§ 334 and 853(p), and 28 U.S.C. § 2461(c)).
- d. \$125 special assessment  
(18 U.S.C. § 3013(a)(1)(B)(iii)).

2. Defendant ABSG understands that although imposition of a sentence in accordance with the United States Sentencing Guidelines (the “Guidelines” and “U.S.S.G.”) is not mandatory, the Guidelines are advisory and the Court is required to consider any applicable Guidelines provisions as well as other factors enumerated in 18 U.S.C. § 3553(a) to arrive at an appropriate sentence in this case. The United States will advise the Court and the Probation Department of information relevant to sentencing, including criminal activity

engaged in by the defendant, and such information may be used by the Court in determining the defendant's sentence. See 18 U.S.C. § 3661 ("No limitation shall be placed on the information concerning the background, character, and conduct of a person convicted of an offense which a court of the United States may receive and consider for the purpose of imposing an appropriate sentence."). Defendant ABSG admits, agrees and stipulates that the factual allegations set forth in the attached Exhibit B are true and correct, and will not contradict anything in the attached Exhibit B in any proceeding by the United States, including any trial, guilty plea or sentencing proceeding. Defendant ABSG further agrees not to contradict the factual allegations in the Information at any sentencing proceeding in this case; provided, however, that the parties agree that the facts set forth in the Information are not necessary for defendant ABSG's guilty plea and that, by agreeing not to contest them at sentencing, defendant ABSG is not admitting to them for any purpose. Furthermore, except with regard to the facts that are set forth in Exhibit B, the parties agree that defendant ABSG may challenge, contest and refute the factual allegations in the Information in any subsequent proceeding. The parties agree that the calculation of the fine range set forth below is correct and is consistent with the provisions of 18 U.S.C. §§ 3553 and 3572. The parties calculate that the fine range is \$195,025,414 to \$390,050,829, which is predicated on the following Guidelines calculation:

Base Fine

Base Fine: \$121,890,884, based on a pecuniary gain to ABSG of approximately that amount  
(U.S.S.G. § 8C2.4(a)(2))

Culpability Score

Base Culpability Score (U.S.S.G. § 8C2.5(a))	5
ABSG Had 1,000 or More Employees and An Individual Within High-Level Personnel Participated In, Condoned, or Was Willfully Ignorant of the Offense (U.S.S.G. § 8C2.5(b)(1)(A)(i))	+4
ABSG Clearly Demonstrated Recognition and Affirmative Acceptance of Responsibility for its Criminal Conduct (U.S.S.G. § 8C2.5(g)(2))	<u>-1</u>
Total Culpability Score:	8

Maximum and Minimum Fine Range

Minimum Fine \$121,890,884 base fine x 1.6 multiplier (U.S.S.G. §§ 8C2.6 and 8C2.7(a))	\$195,025,414
Maximum Fine \$121,890,884 base fine x 3.2 multiplier (U.S.S.G. §§ 8C2.6 and 8C2.7(b))	\$390,050,829

Defendant ABSG stipulates to this fine range.

3. The government and defendant ABSG agree, pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure, that the following constitutes an appropriate disposition of this case: (i) a criminal fine in the amount of \$208,000,000; (ii) criminal forfeiture in the amount of \$52,000,000; and (iii) a mandatory special assessment of \$125 pursuant to 18 U.S.C. § 3013(a)(1)(B)(iii). Conditioned upon the execution of the Compliance Program and Certifications executed contemporaneously with this Plea Agreement, between the United States and defendant ABSG (attached hereto as Exhibit C), defendant ABSG will not be placed on probation. Defendant ABSG agrees to pay the

criminal fine, the criminal forfeiture and the mandatory special assessment within ten business days (not including any bank holidays) after the imposition of sentence.

4. Defendant ABSG's plea will be tendered pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure. Defendant ABSG cannot withdraw its plea of guilty unless the sentencing judge rejects this agreement or fails to impose the stipulated sentence referenced above. If the sentencing judge rejects this agreement, the agreement shall be null and void at the option of either the government or defendant ABSG. Defendant ABSG and the government waive the preparation of a Presentence Report and intend to seek a sentencing by the Court immediately following the Rule 11 plea hearing in the absence of a Presentence Report. Defendant ABSG understands that the decision whether to proceed immediately following the plea hearing with the sentencing proceeding, and to do so without a Presentence Report, is exclusively that of the Court.

5. Defendant ABSG agrees not to file an appeal or otherwise challenge by petition pursuant to 28 U.S.C. § 2255 or any other provision the conviction or sentence in the event that the Court imposes a total fine of \$390,050,829 or less. This waiver is binding without regard to the sentencing analysis used by the Court. In the event that (a) the sentencing judge rejects this agreement, (b) defendant ABSG's conviction is vacated for any reason, (c) defendant ABSG violates this agreement, or (d) defendant ABSG's plea is later withdrawn, any prosecution that is not time-barred on the date that this agreement is signed, including, without limitation, prosecutions that are not time-barred by operation of any tolling agreements entered into by the parties, may be commenced against defendant ABSG notwithstanding the expiration of any statute of limitations or the rescission, cancellation or

expiration of any tolling agreement upon or subsequent to the signing of this agreement. Defendant ABSG waives any right to additional disclosure from the government in connection with the guilty plea. Defendant ABSG agrees that with respect to all charges referred to in paragraphs 1 and 12(a), (a) it is not a “prevailing party” within the meaning of the “Hyde Amendment,” 18 U.S.C. § 3006A note, and will not file any claim under that law, and (b) to waive any claim under the Double Jeopardy Clause of the Fifth Amendment to the United States Constitution.

6. As a result of this guilty plea, defendant ABSG consents to the entry of a forfeiture money judgment in the amount of \$52,000,000 dollars in United States currency (the “Forfeiture Money Judgment”), pursuant to 21 U.S.C. §§ 334 and 853(p), and 28 U.S.C. § 2461(c). The Forfeiture Money Judgment shall be made payable to the “United States Marshals Service” pursuant to wire instructions provided by the United States.

7. The Forfeiture Money Judgment shall be paid within ten business days (not including any bank holidays) after the imposition of sentence (the “Final Due Date”). Should the defendant ABSG fail to pay any portion of the Forfeiture Money Judgment on or before the Final Due Date, defendant ABSG consents to the forfeiture of any other property up to the amount of the Forfeiture Money Judgment, pursuant to 21 U.S.C. § 853(p).

8. Defendant ABSG agrees that the value of the quantities of drugs which were misbranded in violation of 21 U.S.C. § 331(a) totaled at least \$52,000,000 in United States currency. Defendant ABSG acknowledges and agrees that the quantities of the drugs which were misbranded in violation of 21 U.S.C. § 331(a) cannot be located upon exercise of



due diligence, or have been transferred or sold to, or deposited with, a third party, placed beyond then jurisdiction of the Court, substantially diminished in value, or commingled with other property which cannot be divided without difficulty. Accordingly, defendant ABSG agrees that the government is entitled to forfeit as substitute assets any other assets of defendant ABSG up to the value of the now missing directly forfeitable assets, pursuant to 21 U.S.C. § 853(p). The government and defendant ABSG agree that payment in full of the Forfeiture Money Judgment shall satisfy any and all forfeiture obligations that defendant ABSG may have as a result of this guilty plea. Defendant ABSG consents to the entry of an Order of Forfeiture pursuant to Rule 32.2 of the Federal Rules of Criminal Procedure forfeiting the above-referenced Forfeiture Money Judgment.

9. Defendant ABSG agrees to fully assist the government in effectuating the payment of the Forfeiture Money Judgment. Defendant ABSG agrees not to file or interpose any claim or to assist others to file or interpose any claim to any property against which the government seeks to execute the Forfeiture Money Judgment in any administrative or judicial proceeding.

10. Defendant ABSG knowingly and voluntarily waives its right to any required notice concerning the forfeiture of the assets and monies forfeited hereunder, including notice set forth in an indictment or information. In addition, defendant ABSG knowingly and voluntarily waives its right, if any, to a jury trial on the forfeiture of the assets and monies forfeited hereunder, and waives all constitutional, legal and equitable defenses to the forfeiture of said assets, including, but not limited to, any defenses based on principles of double jeopardy, the Ex Post Facto clause of the Constitution, any applicable statute of

limitations, venue, or any defense under the Eighth Amendment, including a claim of excessive fines.

11. Defendant ABSG agrees that the forfeiture of the above sum of money is not to be considered a fine or a payment on any income taxes that may be due.

12. The United States agrees that, subject to the acceptance of defendant ABSG's guilty plea to the Court:

- a. no further criminal charges will be brought against defendant ABSG, its present and former parents, affiliates, divisions and subsidiaries, with respect to the conduct covered by the Information filed in this case, or facts otherwise known to the United States prior to the date of this Plea Agreement regarding (i) the sale of drugs via the Pre-Filled Syringe Program by defendant ABSG's subsidiaries Medical Initiatives, Inc. ("MII") and Oncology Supply ("OS") that were adulterated; (ii) the sale of drugs via the Pre-Filled Syringe Program by MII and OS that were misbranded; (iii) the sale of drugs via the Pre-Filled Syringe Program via MII and OS that constituted the introduction of unapproved new drugs in commerce for which no FDA-approved marketing or investigational application was in effect; (iv) communications by defendant ABSG, AmerisourceBergen Corporation, MII and OS with third parties regarding the Pre-Fill Syringe Program; and (v) the payment to Pre-Filled Syringe Program customers by OS of a kickback in connection with an undisclosed rebate relating to Procrit, it being understood that this agreement does not bar the use of such conduct as a predicate act or as the basis for a sentencing enhancement in a subsequent prosecution including, but not limited to, a prosecution pursuant to 18 U.S.C. §§ 1961 *et seq.*

and, based upon information now known to the United States, it will

- b. advocate before the Court for the agreed-upon sentence set forth in paragraph 3.

If information relevant to sentencing, as determined by the United States, becomes known to the United States after the date of this agreement, the United States will not be bound by

paragraph 12(b). Should it be judged by the United States that defendant ABSG has violated any provision of this agreement, defendant ABSG will not be released from its plea of guilty but this United States will be released from its obligations under this agreement, including but not limited to the provisions of paragraphs 12(a)-(b).

13. This agreement is binding upon the Attorney General of the United States, the United States Department of Justice, and all United States Attorneys on the matters set forth in paragraph 12, but cannot and does not bind the Tax Division of the United States Department of Justice or the Internal Revenue Service of the United States Department of the Treasury. Defendant ABSG also understands that this agreement does not bind any state or local prosecuting authority. The parties agree that the fine and forfeiture amounts determined for criminal purposes are not binding for civil, administrative or regulatory purposes and are exclusive of civil, administrative or regulatory damages, penalties and interest.

14. No promises, agreements or conditions have been entered into by the parties other than those set forth in this agreement and none will be entered into unless memorialized in writing and signed by all parties. This agreement supersedes all prior

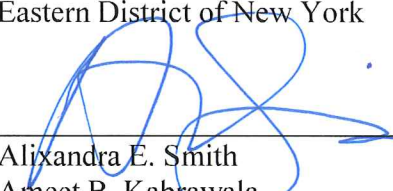
promises, agreements or conditions between the parties. To become effective, this agreement must be signed by all signatories listed below.

Dated: Brooklyn, New York  
September 27, 2017


BRIDGET M. ROHDE

Acting United States Attorney  
Eastern District of New York

By:

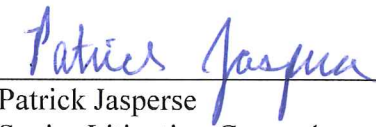
  
\_\_\_\_\_  
Alixandra E. Smith  
Ameet B. Kabrawala  
Assistant United States Attorneys

Approved by:


  
\_\_\_\_\_  
Jacquelyn M. Kasulis  
Shannon C. Jones  
Supervising Assistant U.S. Attorneys

JILL P. FURMAN  
Deputy Director  
Consumer Protection Branch  
U.S. Department of Justice

By:

  
\_\_\_\_\_  
Patrick Jasperse  
Senior Litigation Counsel

On behalf of defendant ABSG, I am entering into this agreement knowingly and voluntarily, on the basis of express authority granted to me by defendant ABSG's Board of Directors, as confirmed in the attached certification.



---

Eric W. Sitarchuk, Esq.

Kelly A. Moore, Esq.

John J. Pease III, Esq.

Morgan, Lewis & Bockius LLP

Counsel to Defendant ABSG

# **EXHIBIT A**

AMERISOURCEBERGEN CORPORATION


SECRETARY'S CERTIFICATE

I, Hyung J. Bak, do hereby certify that I am Secretary of AmerisourceBergen Corporation, a Delaware corporation (the "Company"), and do hereby further certify that:

Attached hereto are true, correct, and complete resolutions of the Board of Directors of the Company adopted as of the sixth day of September, 2017. These resolutions have not been modified, amended or rescinded and remain in full force and effect as of the date hereof.

IN WITNESS WHEREOF, I have executed this Secretary's Certificate on behalf of the Company on this 6<sup>th</sup> of September, 2017.

AMERISOURCEBERGEN CORPORATION

By:   
Name: Hyung J. Bak  
Title: Secretary



**AMERISOURCEBERGEN CORPORATION**

**MEETING OF THE BOARD OF DIRECTORS**

**September 6, 2017**

**Plea Agreement**

**RESOLVED**, that the Board of Directors of AmerisourceBergen Corporation, a Delaware corporation (“ABC”), has been presented with an executive summary and a draft of a Plea Agreement (the “Plea Agreement”) to be entered into by AmerisourceBergen Specialty Group, LLC, a Delaware limited liability company and a wholly owned indirect subsidiary of ABC (“ABSG”), regarding the former operations of Medical Initiatives, Inc., a Delaware corporation and a wholly owned subsidiary of ABSG (“MII”), and hereby authorizes and directs ABSG to enter into the Plea Agreement to resolve a criminal investigation by the United States Attorney’s Office for the Eastern District of New York; and further

**RESOLVED**, that ABSG is hereby authorized and directed to plead guilty to the charge specified in the Plea Agreement in the United States District Court for the Eastern District of New York; and further

**RESOLVED**, that legal counsel for ABC and ABSG (in-house and/or external counsel), and/or any other corporate officer or senior executive of ABSG, is hereby authorized and directed to execute the Plea Agreement and all other documents necessary to carry out the provisions of the Plea Agreement; and further

**RESOLVED**, that legal counsel for ABC and ABSG (in-house and/or external counsel) and/or any other corporate officer or senior executive of ABSG is hereby authorized and directed to appear on behalf of ABSG and enter such guilty plea; and further

**RESOLVED**, that legal counsel for ABC and ABSG (in-house and/or external counsel) and/or any other corporate officer or senior executive of ABSG is hereby authorized and directed to acknowledge on behalf of ABSG that the Plea Agreement and related documents (the “Documents”) fully set forth the agreement made between ABSG and the United States, and that no additional promises or representations have been made to ABSG by any officials of the United States in connection with the Plea Agreement, other than those set forth in the Documents; and further

**RESOLVED**, that (i) the President and Chief Executive Officer of ABC, (ii) the Executive Vice President and Chief Legal & Business Officer of ABC, (iii) the Executive Vice President and Chief Financial Officer of ABC, (iv) the Vice President and Corporate Treasurer of ABC, (v) the Senior Vice President and Corporate Controller of ABC or (vi) any of their written designees, respective successors or current or future officers of ABC or ABSG holding the same or similar titles are authorized and directed to make any payments required in connection with the Plea Agreement.



**General Authority**

**RESOLVED**, that the officers of ABC and ABSG be, and each of them hereby is, authorized and empowered, in the name and on behalf of ABC or ABSG, respectively, to make all such arrangements, to do and perform all such acts and things, and to execute and deliver all such certificates and such other instruments and documents as they may deem appropriate in order to effectuate fully the purpose of each and all of the foregoing resolutions, and that any and all actions taken heretofore and hereafter to accomplish such purposes, all or singular, be, and they hereby are approved, ratified and confirmed; and further

**RESOLVED**, that any actions taken by any of the officers of ABC or ABSG prior to the date of the foregoing resolutions adopted hereby that are within the authority conferred hereby are ratified, confirmed and approved as the act and deed of ABC or ABSG, respectively.

###

**AMERISOURCEBERGEN SPECIALTY GROUP, LLC**

**SECRETARY'S CERTIFICATE**

I, Hyung J. Bak, do hereby certify that I am Secretary of AmerisourceBergen Specialty Group, LLC, a Delaware limited liability company (the "Company"), and do hereby further certify that:

Attached hereto are true, correct, and complete resolutions of the Board of Managers of the Company adopted as of the sixth day of September, 2017. These resolutions have not been modified, amended or rescinded and remain in full force and effect as of the date hereof.

IN WITNESS WHEREOF, I have executed this Secretary's Certificate on behalf of the Company on this 6<sup>th</sup> of September, 2017.

AMERISOURCEBERGEN SPECIALTY GROUP, LLC



By: \_\_\_\_\_  
Name: Hyung J. Bak  
Title: Secretary

**AMERISOURCEBERGEN SPECIALTY GROUP, LLC**

**WRITTEN CONSENT OF THE BOARD OF MANAGERS**

**September 6, 2017**

In conformity with the Delaware Limited Liability Company Act and the Limited Liability Company Operating Agreement of AmerisourceBergen Specialty Group, LLC, a Delaware limited liability company ("ABSG"), the undersigned, being all the members comprising the Board of Managers of ABSG, hereby consent in writing to and adopt the following resolutions and take the following actions with the same force and effect as if such resolutions had been duly adopted and such actions duly taken at a meeting duly called and convened for such purpose on the date first set forth above, with a full quorum present and acting throughout:

**Plea Agreement**

**RESOLVED**, that the Board of Managers of ABSG has been presented with an executive summary and a draft of a Plea Agreement (the "Plea Agreement") to be entered into by ABSG regarding the former operations of Medical Initiatives, Inc., a Delaware corporation and a wholly owned subsidiary of ABSG ("MI"), and hereby authorizes and directs ABSG to enter into the Plea Agreement to resolve a criminal investigation by the United States Attorney's Office for the Eastern District of New York; and further

**RESOLVED**, that ABSG is hereby authorized and directed to plead guilty to the charge specified in the Plea Agreement in the United States District Court for the Eastern District of New York; and further

**RESOLVED**, that legal counsel for ABSG (in-house and/or external counsel), and/or any other corporate officer or senior executive of ABSG, is hereby authorized and directed to execute the Plea Agreement and all other documents necessary to carry out the provisions of the Plea Agreement; and further

**RESOLVED**, that legal counsel for ABSG (in-house and/or external counsel) and/or any other corporate officer or senior executive of ABSG is hereby authorized and directed to appear on behalf of ABSG and enter such guilty plea; and further

**RESOLVED**, that legal counsel for ABSG (in-house and/or external counsel) and/or any other corporate officer or senior executive of ABSG is hereby authorized and directed to acknowledge on behalf of ABSG that the Plea Agreement and related documents (the "Documents") fully set forth the agreement made between ABSG and the United States, and that no additional promises or representations have been made to ABSG by any officials of the United States in connection with the Plea Agreement, other than those set forth in the Documents; and further

**RESOLVED**, that (i) the President and Chief Executive Officer of ABSG, (ii) the Executive Vice President and General Counsel of ABSG, (iii) the Executive Vice President and Chief Financial Officer of ABSG, (iv) the Vice President and Corporate Treasurer of ABSG or (v) any of their written designees, respective successors or future officers of ABSG holding the same

or similar titles are authorized and directed to make any payments required in connection with the Plea Agreement.

**General Authority**

**RESOLVED**, that the officers of ABSG be, and each of them hereby is, authorized in the name and on behalf of ABSG to make all such arrangements, to do and perform all such acts and things, and to execute and deliver all such instruments and documents as such officer(s) deems necessary or appropriate in order to effectuate fully the purpose of each and all of the foregoing resolutions, and any and all actions taken heretofore and hereafter to accomplish such purposes, are hereby approved, ratified and confirmed; and further

**RESOLVED**, that any actions taken by any of the officers of ABSG prior to the date of the foregoing resolutions adopted hereby that are within the authority conferred hereby are ratified, confirmed and approved as the act and deed of ABSG; and further

**RESOLVED**, that this Written Consent of the Board of Managers may be (a) executed in counterparts and all such counterparts shall constitute one consent, notwithstanding that all managers may not be signatories to the same counterpart; and (b) executed and delivered by facsimile and upon such delivery the facsimile signature will be deemed to have the same effect as if the original signature had been delivered; and further

**RESOLVED**, that any officer of ABSG is hereby directed to file a signed copy of this Written Consent of the Board of Managers in the minute book of ABSG.

# **EXHIBIT B**

## **EXHIBIT B**

### **STATEMENT OF FACTS**

1. AmerisourceBergen Corporation (“ABC”) was a pharmaceutical company incorporated in the State of Delaware, with corporate headquarters located in Chesterbrook, Pennsylvania. ABC was formed in 2001 following a merger between Bergen Brunswig Corporation and AmeriSource Health Corporation.
2. Defendant AMERISOURCEBERGEN SPECIALTY GROUP, LLC (“ABSG”) was a subsidiary of ABC, with corporate headquarters located in Frisco, Texas. ABSG served as the parent entity for a series of companies serving the specialty pharmaceutical market, including in the areas of biotechnology, blood-plasma and oncology, as well as pharmaceutical manufacturers, healthcare organizations, physicians, payors and patients. ABSG employed more than 1,000 individuals.
3. Oncology Supply Company d/b/a ASD Healthcare, Inc. (“OSC”) was both an unincorporated subsidiary of and operated by ABSG. OSC’s principal place of business was located at 2801 Horace Shepard Drive, Dothan, Alabama. OSC was a pharmaceutical distributor to community oncologists and distributed chemotherapy and supportive care drugs throughout the United States.
4. Medical Initiatives Inc. (“MII”) was a subsidiary of ABSG and, at various times, did business under the names Oncology Supply Pharmacy Services and/or OS Pharmacy. MII was incorporated in the State of Florida and, like OSC, had its principal place of business at 2801 Horace Shepard Drive, Dothan, Alabama. It was a pre-existing business of Bergen Brunswig, and was acquired by ABC in connection with the merger in 2001. MII was a pre-filler of pharmaceuticals for oncology patients, and operated a physical facility in Dothan, Alabama.

5. Defendant ABSG's subsidiaries MII and OSC operated a program that created, packed and shipped pre-filled syringes (also known as "PFS") to oncology practices for administration to cancer patients for supportive care during their chemotherapy treatment. Pursuant to written agreements, for each PFS ordered by a practice, OSC would bill the practice for a vial of drug product, and then MII would prepare, and OSC would ship, the practice a corresponding PFS by Federal Express. Between 2001 and January 2014, millions of PFS were sold and shipped to oncology practices, including to 37 practices located in the Eastern District of New York.

6. MII's business model was to remove FDA-approved drug product from glass vials, transfer it into plastic syringes, and sell those syringes to oncology practices. To do so, MII's staff opened sterile vials, pooled the drug product from the vials, and then transferred the drug product into smaller PFS. Those PFS were then matched to orders; placed into plastic bags; new labels were affixed to those bags; and the bags were packaged and shipped to customers.

7. MII often dispensed PFS in response to order forms that were not prescriptions signed by practitioners. Those order forms often listed only a single name, and/or assigned names at random to PFS that were shipped in response to order forms submitted without any names, which resulted in PFS being dispensed in the name of individuals who were not in fact patients. On many occasions, MII assigned the name of an individual to a set of PFS, and subsequently shipped PFS that were in a bag labeled with that individual's name, despite the fact that the individual was not in fact a patient who was to be administered one or more syringes. In some instances, the individual's name assigned to the set of PFS was a staff member at a physician customer (such as a nurse or office manager); in others, the individual who was no

longer a patient of the physician customer, either because the individual was no longer receiving treatment and/or because the individual was deceased.

8. In addition, MII often filled orders that had been submitted with a single patient name, and/or assigned a single individual's name to an order of PFS, in excess of plausible and/or safe use of the drug product contained in the syringes. For example, Procrit® had a Black Box warning on the label which required the use of the lowest possible dose sufficient to avoid red blood cell transfusion. However, MII routinely dispensed multiple syringes repackaged from Procrit® vials in a single individual's name far beyond the dosage permitted by the label, and beyond the dosage that could plausibly and safely be administered to that individual in the time period before the beyond use date on the PFS.

9. The defendant ABSG did not register MII with the United States Food and Drug Administration ("FDA"), as required by the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 360.

10. MII did not qualify for the exemption to the registration requirement in 21 U.S.C. § 360(g)(1) for pharmacies that maintained establishments in conformance with applicable local laws regulating the practice of pharmacy. For example, to fully comply with Alabama pharmacy law, MII was required to maintain the medication history, diagnosis, laboratory data and other pertinent information for the patients to whom PFS were administered. See Ala. Admin. Code §680-X-2-19 (7)(b) and (d).

11. In and about and between 2005 and January 2014, the defendant ABSG introduced, or caused the introduction of, misbranded drugs into interstate commerce, as such drugs were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered with the FDA pursuant to 21 U.S.C. § 360.



# **EXHIBIT C**

**EXHIBIT C**  
**COMPLIANCE PROGRAM AND CERTIFICATIONS**

Defendant AmerisourceBergen Specialty Group, LLC (“ABSG”) agrees to the provisions set forth in this exhibit to the Plea Agreement between the United States Attorney’s Office for the Eastern District of New York and the Consumer Protection Branch of the Department of Justice (collectively, the “DOJ”) and ABSG in the matter captioned United States v. AmerisourceBergen Specialty Group, LLC, 17 CR 507 (NG). These provisions apply to “Legacy ABSG” operating segments, as defined below, and shall be in effect for three (3) years following entry of a guilty plea by ABSG in this matter.

**I. Background and Definitions**

The agreement set forth in this exhibit is referred to below as “Exhibit C.”

ABSG is a subsidiary of AmerisourceBergen Corporation (“ABC”). ABC is in the process of reorganizing various operating segments under a new operating unit to be known as Pharmaceutical Distribution and Strategic Global Sourcing (“PDSGS”). The provisions of Exhibit C will apply to the following ABSG operating segments: ASD Healthcare, Besse Medical, Oncology Supply, ION Solutions, IntrinsicQ Specialty Solutions, and US Bioservices. These operating segments are collectively referred to in the Compliance Agreement as “Legacy ABSG.”

**II. Compliance and Ethics Program**

ABSG has in place and will maintain a Compliance and Ethics Program, which applies to the business operations of Legacy ABSG in the United States. The purpose of the Compliance and Ethics Program is to: (a) prevent, detect, and correct violations of law and company policy and procedures; (b) assure the continuation of compliance-related policies and procedures for business operations; (c) assure the continued development of training and other programs designed to educate employees regarding applicable policies, procedures, and standards; (d) conduct auditing and monitoring of the effectiveness of applicable policies, procedures, and standards; (e) assure that there is a mechanism for internal reporting of questionable or inappropriate activities to enable timely investigation and resolution; and (f) assure that appropriate corrective action is taken to prevent recurrence of misconduct. The Compliance and Ethics Program does and will continue to contain policies and procedures designed to prevent, detect, and correct violations of federal healthcare program requirements and the Federal Food, Drug, and Cosmetic Act (“FDCA”). These policies and procedures will be designed to ensure that Legacy ABSG complies with, among other things, the FDCA’s registration requirements applicable to entities that are engaged in the manufacture (including

repackaging), preparation, propagation, compounding, or reprocessing of a drug, and the FDCA's prohibitions against causing the introduction into interstate commerce of a drug that is adulterated, misbranded, or unapproved.

The Compliance and Ethics Program is overseen by the Chief Compliance Officer ("CCO") for ABC, who reports to the Chief Legal and Business Officer and the ABC Board of Directors. ABC's Compliance and Ethics Program includes a Compliance Committee comprised of senior executives, including Legacy ABSG representatives, and which meets bi-weekly, a comprehensive set of policies and procedures governing the conduct of its employees, a training program focused on the company's compliance policies and procedures, a hotline to allow employees to report potential violations of law or potential violations of the company's compliance policies and procedures, an anti-retaliation policy, and a monitoring and auditing program designed to deter and detect compliance issues. The CCO is responsible for overseeing the administration and implementation of the Compliance and Ethics Program. The CCO has direct access to senior executives vested with the authority to direct and implement compliance-related changes in the organization as necessary. The CCO has the authority to exercise independent judgment in assessing compliance-related matters. The CCO has authority to seek advice from independent legal counsel or other outside experts when appropriate. The CCO is authorized to report compliance-related or other issues, of any kind, directly to officers and directors of ABC.

### III. Notice

Within thirty (30) days after the entry of the guilty plea in this matter and for a period of one hundred and eighty (180) days thereafter, defendant ABSG shall post on the "Contact Us" or "About Us" portions of its website, [www.absg.com](http://www.absg.com), a notice containing the language set forth below:

We are committed to maintaining our comprehensive compliance and ethics program and provide this notice to customers to remind them that they are encouraged to report any questionable practices by the company and/or our employees to AmerisourceBergen Corporation's Compliance Department, at 1-800-241-5689 or [Compliance@amerisourcebergen.com](mailto:Compliance@amerisourcebergen.com).

The CCO (or a designee) shall maintain a log (the "Log") of all calls and messages received by the Compliance and Ethics Program that report questionable practices by employees of Legacy ABSG and its subsidiaries, including any such calls or messages made in response to the notice above. The Log shall include a record and summary of each call and message received (whether anonymous or not), the status of the call or message, and any corrective action taken in response to the call or message.

ABSG shall produce the Log to the DOJ within ten (10) days of a written request for such production, for a period of three (3) years after the entry of ABSG's guilty plea in this matter.

#### **IV. Certifications and Board Resolution**

##### **A. Certification of the Log by the President of PDSGS**

The President of PDSGS shall conduct a review of the Log during the period that Exhibit C is in effect. Based on that review, the President shall submit to the DOJ a certification (the "Log Certification") stating (1) that, to the best of his or her knowledge, during the preceding review period, ABC maintained the Log pursuant to this agreement, and (2) the total number of calls and messages received. The review periods and the deadlines for filing the Log Certifications are defined in Section IV.D below.

##### **B. Certification of the Effectiveness of the Compliance and Ethics Program by the President of PDSGS**

The President of PDSGS shall have a review conducted of the effectiveness of the Compliance and Ethics Program with respect to Legacy ABSG during the period that Exhibit C is in effect. The President may, in his or her discretion, rely on an outside consultant or reviewer to perform the review. Based on the review, the President shall submit to the DOJ a signed certification ("the Compliance and Ethics Program Certification") stating that, to the best of his or her knowledge based on a reasonable inquiry into the operations of the Compliance and Ethics Program with respect to Legacy ABSG, during the preceding review period, the Compliance and Ethics Program was effective in implementing policies and procedures reasonably designed to identify and prevent violations of federal healthcare program requirements and, where applicable, the FDCA. The certification shall summarize the review described above. If the President is unable to certify that the Compliance and Ethics Program was effective in implementing policies and procedures reasonably designed to identify and prevent violations of federal healthcare program requirements and the FDCA, he or she shall provide a detailed explanation of why the Compliance and Ethics Program was not effective, and will state the steps Legacy ABSG is taking to ensure the effectiveness of the Compliance and Ethics Program. The review periods and the deadlines for filing the Compliance and Ethics Program Certifications are defined in Section IV.D below.

##### **C. Resolution by PDSGS' Board of Directors**

The Board of Directors of PDSGS, or a designated Committee thereof (the "Board"), shall review the effectiveness of the Compliance and Ethics Program with respect to Legacy ABSG during the period that Exhibit C is in effect. This review shall

include, at a minimum, updates and reports by the PDSGS CCO and other personnel regarding compliance matters, and the review conducted by the PDSGS President. The Board shall evaluate the effectiveness of the Compliance and Ethics Program with respect to Legacy ABSG, including, among other means, by receiving updates about the activities of the CCO and the ABC Compliance Committee and updates about the adoption and implementation of policies, procedures, and practices to ensure compliance with applicable federal healthcare program requirements and, where applicable, the FDCA. The Board review shall not require the retention of third party experts. The Board shall, based on its review, submit to the DOJ a resolution that summarizes its review and oversight of Legacy ABSG's compliance with federal healthcare program requirements and, where applicable, the FDCA. The resolution shall, at a minimum, include the following language:

The Board of Directors of PDSGS, or a designated Committee thereof, has made a reasonable inquiry, as described in Section IV.C of the Compliance Agreement, into the operations of the Compliance and Ethics Program with respect to Legacy ABSG for the preceding 12 months, including the performance of the Chief Compliance Officer and the ABC Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Legacy ABSG has implemented an effective compliance program, as set forth in the Compliance Agreement that was Exhibit C to the Plea Agreement with ABSG and as defined in the United States Sentencing Commission Guidelines Manual, Chapter 8: Sentencing of Organizations, to meet the requirements of federal healthcare programs and, where applicable, the Federal Food, Drug, and Cosmetic Act.

If the Board is unable to provide any part of this statement, it shall include in the resolution a written explanation of the reasons why it is unable to provide such a statement. The review periods and the deadlines for filing the Board's resolutions are defined in Section IV.D below.

#### **D. Filing of the Certifications and Resolutions**

The certifications referenced above in paragraphs IV.A and IV.B shall be sworn to under penalty of perjury and shall set forth that the representations contained therein may be provided to, relied upon, and material to the government of the United States, and that a knowing false statement could result in criminal or civil liability for the signatory.<sup>1</sup>

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<sup>1</sup> Consistent with the Department of Justice's Freedom of Information Act ("FOIA") procedures, the government shall make reasonable effort to notify ABSG prior to any release by DOJ of information submitted by ABSG pursuant to its obligations

The review periods referenced above in sections IV.A, IV.B, and IV.C and the deadlines for filing the certifications and resolutions required above in sections IV.A, IV.B, and IV.C are as follows:

1. The first review period covers the first six (6) months following entry of the guilty plea by ABSG. The deadline for submitting the certifications and resolution is thirty (30) days after the end of this review period.
2. The second review period is one year and covers the seventh (7th) through eighteenth (18th) months following entry of the guilty plea by ABSG. The deadline for submitting the certifications and resolution is thirty (30) days after the end of this review period.
3. The third review period is one year and covers the nineteenth (19th) through thirtieth (30th) months following entry of the guilty plea by ABSG. The deadline for submitting the certifications and resolution is thirty (30) days after the end of this review period.

The certifications referenced in sections IV.A and IV.B and the resolutions referenced above in section IV.C should be sent to:

Chief, Criminal Division  
U.S. Attorney's Office,  
Eastern District of New York  
271 Cadman Plaza East  
Brooklyn, NY 11201

Director, Consumer Protection Branch  
U.S. Department of Justice  
P.O. Box 386  
Washington, D.C. 20044

## **V. Breach of this Exhibit**

ABSG recognizes that each of the terms in this Compliance Agreement constitutes a material term of the Compliance Agreement. As a contractual remedy, ABSG and the DOJ agree that failure to comply with the obligations set forth in this Exhibit may lead to the imposition of the following monetary penalties (hereafter "Stipulated Penalties") in accordance with the following provisions:

- A. A Stipulated Penalty of \$5,000 per day for each day Legacy ABSG (1) fails to maintain a Compliance and Ethics Program as set forth in section I above; or (2) fails to timely supply the certifications and board resolution

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under this Plea Agreement and identified upon submission by ABSG as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, ABSG shall have the rights set forth under said procedures.

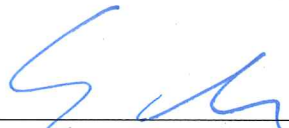
as set forth in section III above. With regard to the certifications and board resolution, the Stipulated Penalty will begin to accrue on the first day after the date the document was due, subject to the provisions for extension of time for compliance and the opportunity to cure set forth below.

- B. ABSG may submit a timely written request for an extension of time to provide the certifications or board resolution required above. A written request is timely if it received by the U.S. Attorney's Office for the Eastern District of New York at least five business days prior to the date by which the Certification or board resolution is due. Timely requests for extension will not be unreasonably denied. If an extension of time is granted in writing, Stipulated Penalties shall not accrue until one day after ABSG fails to meet the revised deadline. If not granted, Stipulated Penalties shall not begin to accrue until three business days after ABSG receives the DOJ's written denial of such request or the original deadline, whichever is later.
  
- C. Upon the DOJ's reasonable determination that ABC has failed to comply with any of the obligations described herein, the DOJ shall notify ABSG in writing of ABSG's failure to comply and the DOJ's exercise of its contractual right to demand payment of the Stipulated Penalties ("the Demand Letter"). The Demand Letter shall set forth: (1) the provision(s) breached; (2) the date of the breach; (3) a description of the breach sufficient to permit ABSG to cure (as described below); and (4) the amount of Stipulated Penalties claimed by the DOJ as of the date of the Demand Letter. Within thirty (30) days after receipt of the Demand Letter, or such other period as the DOJ may agree in writing, ABSG shall cure the breach to the DOJ's reasonable satisfaction ("Cure Period"). If ABSG cures the breach within the Cure Period, no Stipulated Penalties shall be due. If ABSG fails to cure the breach during the Cure Period, Stipulated Penalties calculated from the date of breach to the date of payment shall be immediately payable to the United States Treasury. The Stipulated Penalties shall be paid by electronic fund transfer according to wire instructions that will be provided by the DOJ. A joint reasonable determination by the United States Attorney for the Eastern District of New York and the Assistant Attorney General for the Civil Division of the Department of Justice regarding ABSG's failure to comply with any of the obligations described herein will be final and non-appealable. ABSGC agrees that the United States District Court for the Eastern District of New York shall have jurisdiction over any action to collect such a penalty.

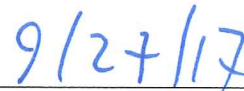
The absence of violation notice from the DOJ is not, and shall not be construed as, evidence of compliance with this agreement, federal healthcare program requirements, the FDCA, or other applicable laws, policies or procedures.

**AGREED:**

FOR AMERISOURCEBERGEN SPECIALTY GROUP, LLC:



MORGAN, LEWIS & BOCKIUS LLP  
Eric W. Sitarchuk, Esq.  
Kelly A. Moore, Esq.  
John J. Pease III, Esq.

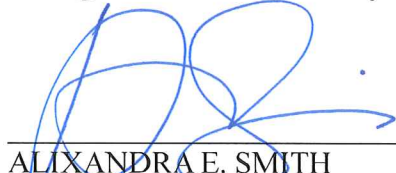


Date



FOR THE UNITED STATES ATTORNEY'S OFFICE  
FOR THE EASTERN DISTRICT OF NEW YORK:

BRIDGET M. ROHDE  
Acting United States Attorney



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ALIXANDRA E. SMITH  
AMEET B. KABRAWALA  
Assistant U.S. Attorneys  
Eastern District of New York  
271 Cadman Plaza East  
Brooklyn, NY 11201

9/27/17  
Date

FOR THE UNITED STATES DEPARTMENT OF JUSTICE,  
CONSUMER PROTECTION BRANCH:

JILL P. FURMAN  
Deputy Director



---

PATRICK JASPERSE  
Senior Litigation Counsel  
U.S. Department of Justice  
Consumer Protection Branch  
P.O. Box 386  
Washington, DC 20044

9-18-17  
Date

# Attachment 2

## STATEMENT OF FACTS

1. AmerisourceBergen Corporation (“ABC”) is a pharmaceutical company incorporated in the State of Delaware, with its corporate headquarters located in Chesterbrook, Pennsylvania. ABC was formed in 2001 following a merger between Bergen Brunswig Corporation and AmeriSource Health Corporation.

2. AmerisourceBergen Specialty Group, LLC (“ABSG”) is a subsidiary of ABC, with corporate headquarters located in Frisco, Texas. ABSG serves as the parent entity for a series of companies serving the specialty pharmaceutical market, including in the areas of biotechnology, blood-plasma and oncology, as well as pharmaceutical manufacturers, healthcare organizations, physicians, payors and patients.

3. AmerisourceBergen Drug Corporation (“ABDC”) is a subsidiary of ABC. ABDC serves institutional healthcare providers such as hospitals and retail pharmacies. ABDC is headquartered in Chesterbrook, Pennsylvania.

4. ASD Specialty Healthcare, LLC d/b/a Oncology Supply (“OSC”) is both an unincorporated subsidiary of and operated by ABSG. OSC’s principal place of business is located at 2801 Horace Shepard Drive, Dothan, Alabama. OSC is a pharmaceutical distributor to community oncologists and distributes chemotherapy and supportive care drugs throughout the United States.

5. Medical Initiatives Inc. (“MII”) was an operating subsidiary of ABSG and, at various times, did business under the names Oncology Supply Pharmacy Services and/or OS Pharmacy. MII is incorporated in the State of Florida and, like OSC, had its principal place of business at 2801 Horace Shepard Drive, Dothan, Alabama. It was a pre-existing business of Bergen Brunswig, and was acquired by

ABC in connection with the above-referenced merger in 2001. MII was a pre-filler of pharmaceuticals for oncology patients, and operated a physical facility in Dothan, Alabama.

6. ABC, ABSG, ABDC, OSC and MII are collectively referred to hereafter as “the ABC Defendants.”

7. ABSG’s subsidiaries MII and OSC operated a program that created, packed and shipped pre-filled syringes (also known as “PFS”) to oncology practices for administration to cancer patients for supportive care during their chemotherapy treatment. Pursuant to written agreements, for each PFS ordered by a practice, OSC would bill the practice for a vial of drug product, and then MII would prepare, and OSC would ship to the practice a corresponding PFS by Federal Express. Between 2001 and January 2014, millions of PFS were sold and shipped to oncology practices, including to 37 practices located in the Eastern District of New York.

8. The drugs used in the PFS Program were Procrit®, Aloxi®, Kytril®, generic versions of granisetron injection, Anzemet® and Neupogen®.

9. MII’s business model was to remove FDA-approved drug product from glass vials, transfer it into plastic syringes, and sell, through OSC, those syringes to oncology practices. To do so, MII’s staff opened sterile vials, pooled<sup>1</sup> the drug product from the vials, and then transferred the drug product into smaller PFS. Those PFS were then matched to orders from practices; placed into plastic bags; new labels were affixed to those bags; and the bags were packaged and shipped to customers.

10. MII often prepared PFS in response to order forms that were not

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<sup>1</sup> In this context, pooling is the combination of the contents of two or more vials of drug product.

prescriptions signed by practitioners. Those order forms often listed only a single name, and/or assigned names at random to PFS that were shipped in response to order forms submitted without any names, which resulted in PFS being prepared and labeled bearing the names of individuals who were not in fact patients. On many occasions, MII assigned the name of an individual to a set of PFS, and OSC subsequently shipped PFS that were in a bag labeled with that individual's name, despite the fact that the individual was not in fact a patient who was to be administered a PFS. In some instances, the individual's name assigned to the set of PFS was a staff member at a physician customer (such as a nurse or office manager); in others, the individual was no longer a patient of the physician customer, either because the individual was no longer receiving treatment and/or because the individual was deceased.

11. In addition, MII often filled orders that had been submitted with a single patient name, and/or assigned a single individual's name to an order of PFS, in excess of plausible and/or safe use of the drug product contained in the syringes. For example, Procrit® had a Black Box warning on the label that required the use of the lowest possible dose sufficient to avoid red blood cell transfusion. However, MII routinely prepared and OSC shipped multiple syringes prepared from Procrit® vials in a single individual's name far beyond the dosage permitted by the label, and beyond the dosage that could plausibly and safely be administered to that individual in the time period before the beyond use date on the PFS.

12. The ABC Defendants did not register MII with the United States Food and Drug Administration ("FDA"), as required by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360.

13. MII did not qualify for the exemption to the registration requirement in 21 U.S.C. § 360(g)(1) for pharmacies that maintained establishments in conformance with applicable local laws regulating the practice of pharmacy. For example, to fully comply with Alabama pharmacy law, MII was required to maintain the medication history, diagnosis, laboratory data and other pertinent information for the patients to whom PFS were administered. See Ala. Admin. Code §680-X-2-19 (7)(b) and (d).

14. On September 27, 2017, ABSG pleaded guilty to introduction of misbranded drugs into interstate commerce, as such drugs were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered with the FDA pursuant to 21 U.S.C. § 360.

15. All vials of Aloxi®, Anzemet®, generic versions of granisetron injection, Kytril®, Neupogen® and Procrit® that the ABC Defendants purchased for use in its PFS Program are drugs within the meaning of 21 U.S.C. § 321(g)(1). The vials of Neupogen® and Procrit® are biological drug products.

16. The ABC Defendants did not submit to FDA a New Drug Application (“NDA”) or Biologics License Application (“BLA”) for any of the PFS used in the Pre-Filled Syringe Program and did not obtain approvals for such applications.

17. From about October 21, 2001 through January 31, 2014, the ABC Defendants sold PFS to physicians throughout the United States.

18. MII pooled the drug product from the vials, including the overfill<sup>2</sup> in those

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<sup>2</sup> The term “overfill” is a frequently used term in the pharmaceutical industry generally meaning the amount of extra drug above and beyond the labeled dose that is contained in an FDA-approved vial of drug. The overfill is not listed on the FDA-approved drug label. The reason manufacturers put overfill in each vial of drug is to ensure that the health care provider administering the drug will be able to extract the full labeled dose from the vial to give to the patient. *See, e.g.*, 75 Fed. Reg. 73170, 73466-67 (Nov 29, 2010). It is also not included in the price of the vial.

vials. This process resulted in extra vials remaining after the PFS were filled, which the ABC Defendants sold either to an OSC/MII customer or to other subsidiaries of ABC that would then re-sell the extra vials. The sale of the extra vials represented the profit from the PFS Program.

19. Beginning June 30, 2005 and continuing until the close of MII on January 31, 2014, the ABC Defendants provided rebates to physicians in connection with the purchase of Procrit® in PFS rather than vials. The rebate was identified on the invoice only as a general pharmacy credit, not associated with Procrit®.