JOSH STEIN
ATTORNEY GENERAL

STATE OF NORTH CAROLINA
DEPARTMENT OF JUSTICE

SETH DEARMIN
CHIEF OF STAFF

February 7, 2019

North Carolina Senate President Pro Tempore Phil Berger
North Carolina House of Representatives Speaker Tim Moore
Co-Chairs, Joint Legislative Commission on Governmental Operations

Senator Danny Earl Britt, Jr.
Senator Warren Daniel
Senator Norman W. Sanderson
Representative James Boles, Jr.
Representative Ted Davis, Jr.
Representative Allen McNeill
Representative Rena W. Turner
Co-Chairs, Appropriations Subcommittee on Justice and Public Safety

North Carolina General Assembly
Raleigh, North Carolina 27601-1096

RE: G.S. §114-2.5; Report on Settlement Agreement for AmerisourceBergen Corporation

Dear Members:

Section 114-2.5 of the North Carolina General Statutes requires the Attorney General to report to the Joint Legislative Commission on Governmental Operations and the Chairs of the Appropriations Subcommittees on Justice and Public Safety regarding all settlements and court orders which result in more than $75,000.00 being paid to the State. Pursuant to that statute, I am writing regarding the settlement of claims for Medicaid reimbursement to the state and federal governments in the above-referenced matter. Pursuant to federal law (42 C.F.R. § 433.320) recoveries in these cases are shared on a pro rata basis by the state and federal governments.

A settlement has been executed between AmerisourceBergen and the State of North Carolina.

The settlement resolves allegations that from October 21, 2001 through January 31, 2014, AmerisourceBergen failed to register as a re-packer. AmerisourceBergen adulterated the cancer drugs Procrit, Aloxi, Kytril, Anzemet, and Neupogen by "breaking the seal" and supplying the drugs in pre-filled syringes without FDA oversight.

Under the terms of North Carolina's settlement, the State of North Carolina will recover $2,915,415.79. Of that amount the federal government will receive $1,899,576.23 for North Carolina's federal portion of Medicaid recoveries. Pursuant to G.S. § 1-610, the qui tam plaintiffs whose whistleblower actions brought this matter to the government's attention will receive $160,285.43 of North Carolina's recovery. The North Carolina Medicaid Program will receive $439,444.96 as restitution and interest. In addition, pursuant to Article IX, Section 7 of the North Carolina Constitution and G.S. § 115C-457.1, the penalty portion of the settlement in the amount of $346,347.07 will be paid to the Civil Penalty Forfeiture Fund for the support of North Carolina public schools. Pursuant to G.S. § 115C-457.2 and G.S. § 1-608(c), the North Carolina Department of Justice will receive $69,762.10 for investigative costs and costs of collection.

We will be happy to respond to any questions you may have regarding this report.

Very truly yours,

Seth Dearmin
Chief of Staff

SD:ng

cc: John Poteat, NCGA Fiscal Research Division

STATE SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement (the "Agreement") is entered into between the State of North Carolina ("the State") and Defendants AmerisourceBergen Corporation ("AmerisourceBergen"), AmerisourceBergen Specialty Group, Inc. ("ABSG"), AmerisourceBergen Drug Company ("ABDC"), Oncology Supply Company d/b/a ASD Healthcare, Inc. ("OSC"), and Medical Initiatives, Inc. d/b/a Oncology Supply Pharmacy Services ("MII"), collectively the "ABC Defendants." The foregoing hereafter are collectively referred to as "the Parties."

II. PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

A. Defendant AmerisourceBergen is a Delaware corporation with its corporate headquarters located at 227 Washington Street, Conshohocken, 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 Conshohocken, 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").

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").

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").

E. The Mullen, Omni, and Sypula Actions are referred to collectively hereafter in this Agreement as the "Civil Actions."

F. On September 27, 2017, ABSG pleaded guilty to illegally distributing misbranded drugs in interstate commerce. 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.

G. The ABC Defendants admit, acknowledge, and accept responsibility for the underlying conduct set forth in the Statement of Facts, attached and incorporated hereto as Attachment 1.

H. The ABC Defendants have entered into a separate civil settlement agreement (the "Federal Settlement Agreement") with the "United States of America" (the "United States") as that term is defined in the Federal Settlement Agreement.

I. The State contends that the ABC Defendants caused claims for payment to be submitted to the State's Medicaid Program (42 U.S.C. Chapter 7 Subchapter XIX), including "managed care entities" as defined by 42 U.S.C. s1396u-2.

J. The State 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 State contends that the ABC Defendants, through their Pre-filled Syringe Program, caused numerous false claims to be submitted to the State's Medicaid program

(1) for unapproved new drugs; (2) for drugs that were defective, contaminated, or otherwise compromised, 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 had 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 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 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 the State's Medicaid Program. 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 the State's Medicaid Program.

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®.

K. Except as otherwise expressly admitted in the Statement of Facts (Attachment 1), this Settlement Agreement is neither an admission of liability by the ABC Defendants nor a concession by the State that its claims are not well-founded.

III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations set forth in this Agreement, and for good and valuable consideration as stated herein, the Parties agree as follows:

1. AmerisourceBergen agrees to pay to the United States and the Medicaid Participating States (as defined in sub-paragraph (c) and subject to the non-participating state deduction provision of sub-paragraph (d) below), collectively, the sum of $625,000,000.00 plus accrued interest (the "Settlement Amount"). 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 the Federal Settlement Agreement, as defined therein, and subject to the terms of this Agreement. The debt shall forever be discharged by payments to the United States and the Medicaid Participating States under the following terms and conditions:

(a) AmerisourceBergen shall pay to the United States the sum of $581,809,006.00 plus accrued interest pursuant to the terms of the Federal Settlement Agreement.

(b) The total Medicaid recovery for the Covered Conduct is $99,863,569.00 consisting of $43,190,994.00 for the states pursuant this Agreement and $56,672,575.00 for the United States, pursuant to the Federal Settlement Agreement. AmerisourceBergen shall pay to the Medicaid Participating States the sum of $43,190,994.00 plus accrued interest on that amount of 2.375% per annum commencing on December 1, 2017 and

continuing to and including the day before payment is made under this Agreement (the "Medicaid State Settlement Amount"), subject to the non-participating state deduction provision of sub-paragraph (d) below (the "Medicaid Participating State Settlement Amount"), no later than seven (7) business days after the expiration of the 60-day opt-in period for Medicaid Participating States described in sub-paragraph (c) below. Of the "Medicaid State Settlement Amount", $23,282,684.21 shall be considered restitution (the "Medicaid State Restitution Amount"), also subject to the non-participating state deduction provision of sub-paragraph (d) (the "Medicaid Participating State Restitution Amount"). The Medicaid Participating State Settlement Amount shall be paid and immediately deposited by electronic funds transfer to the New York State Attorney General's National Global Settlement Account pursuant to written instructions from the state negotiating team (the "State Team"), which written instructions shall be delivered to counsel for AmerisourceBergen. This electronic funds transfer shall constitute tender and negotiation of the State Amount as defined in Paragraph III. 1. (d).

(c) AmerisourceBergen shall execute a State Settlement Agreement with any State that executes such an Agreement in the form to which AmerisourceBergen and the State Team have agreed, or in a form otherwise agreed to by AmerisourceBergen and an individual State. The State shall constitute a Medicaid Participating State provided this Agreement is fully executed by the State and delivered to AmerisourceBergen's attorneys within 60 days of receiving this Agreement. AmerisourceBergen's offer to resolve this matter with the State shall become null and void absent written agreement between counsel for AmerisourceBergen and the State Team to extend the 60-day period.

(d) The total portion of the amount paid by AmerisourceBergen in settlement for the Covered Conduct for the State is $2,901,360.17, consisting of a portion paid to the State under this Agreement and another portion paid to the United States as part of the Federal Settlement Agreement. The amount allocated to the State under this Agreement is the sum of $1,001,783.94 plus applicable interest (the "State Amount"), of which $540,025.06 is restitution. If the State does not execute this Agreement within 60 days of receiving this Agreement, the State Amount shall be deducted from the Medicaid State Settlement Amount and shall not be paid by AmerisourceBergen absent written agreement between counsel for AmerisourceBergen and the State Team to extend the time period for executing this Agreement.

2. Contingent upon receipt of the State Amount, the State agrees to dismiss with prejudice any state law claims which the State has the authority to dismiss currently pending against AmerisourceBergen in State or Federal Courts for the Covered Conduct including any supplemental state law claims asserted in the Civil Action. Contingent upon receipt of the State Amount, the State, if served with the Civil Action and otherwise liable to pay a relator's share, agrees to pay the Relator(s) the amount of $160,285.43 plus applicable interest. This amount is to be paid through the State Team and has been addressed via side letter(s) with the Relators in the Civil Actions.

3. Subject to the exceptions in Paragraph 4 below, in consideration of the obligations of AmerisourceBergen set forth in this Agreement, and conditioned upon receipt by the State of the State Amount, the State agrees to release the ABC Defendants, their predecessors, and current and former parents, divisions, subsidiaries, affiliates, successors, transferees, heirs, and assigns (collectively, the "ABC Defendants' Released

Entities"), from any civil or administrative monetary cause of action that the State has for any claims submitted or caused to be submitted to the State's Medicaid Program as a result of the Covered Conduct.

4. Notwithstanding the releases given in Paragraph 3 of this Agreement, or any other term of this Agreement, the following claims of the State are specifically reserved and are not released:

(a) any criminal, civil, or administrative liability arising under state revenue codes;

(b) any criminal liability not specifically released by this Agreement;

(c) any civil or administrative liability that any person or entity, including the ABC Defendants' Released Entities, has or may have to the State or to individual consumers or state program payors under any statute, regulation, or rule not expressly covered by the release in Paragraph 3 above, including, but not limited to, any and all of the following claims: (i) State or federal antitrust violations; and (ii) claims involving unfair and/or deceptive acts and practices and/or violations of consumer protection laws;

(d) any liability to the State for any conduct other than the Covered Conduct;

(e) any liability based upon obligations created by this Agreement;

(f) except as explicitly stated in this Agreement, any administrative liability, including mandatory or permissive exclusions from the State's Medicaid Program;

(g) any liability for expressed or implied warranty claims or other claims for defective or deficient products and services, including quality of goods and services;

(h) any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;

(i) any liability for failure to deliver goods or services due; or

(j) any liability of individuals.

5. In consideration of the obligations of AmerisourceBergen set forth in this Agreement, and the Corporate Integrity Agreement (the "CIA") that AmerisourceBergen has entered into with the Office of the Inspector General of the United States Department of Health and Human Services in connection with this matter, and conditioned on receipt by the State of the State Amount, the State agrees to release and refrain from instituting, recommending, directing, or maintaining any administrative action seeking exclusion from the State's Medicaid Program against AmerisourceBergen for the conviction in the Federal Criminal Action or for the Covered Conduct, except as reserved in Paragraph 4 above. Nothing in this Agreement precludes the State from taking action against AmerisourceBergen in the event that AmerisourceBergen is excluded by the federal government, or for conduct and practices other than the Covered Conduct or the conviction in the Federal Criminal Action.

6. The ABC Defendants waive and shall not assert any defenses they 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 of the Fifth Amendment of the U.S. Constitution or the Excessive Fines Clause of the Eighth Amendment of the U.S. Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

7. In consideration of the obligations of the State set forth in this Agreement, the ABC Defendants Released Entities waive and discharge the State and any of its agencies, departments, and personnel including, but not limited to, officials, employees,

and agents, whether current or former, in their official and individual capacities, from any causes of action (including attorneys' fees, costs, and expenses of every kind and however denominated) which the AmerisourceBergen Released Entities have against the State and any of its agencies, departments, and personnel as previously referenced arising from the State's investigation and prosecution of the Covered Conduct.

8. The amount that AmerisourceBergen must pay to the State pursuant to Paragraph III.1. above will not be decreased as a result of the denial of any claims for payment now being withheld from payment by the State's Medicaid Program, or any other state program payor, for the Covered Conduct; and the ABC Defendants agree not to resubmit to the State's Medicaid Program or any other state program payor, any previously denied claims, which denials were based on the Covered Conduct, and agrees to withdraw the appeal of, or not to appeal or cause the appeal of, any such denials of claims.

9. The ABC Defendants shall not seek payment for any claims for reimbursement to the State's Medicaid Program covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third-party payors.

10. The ABC Defendants expressly warrant that they have reviewed their financial condition and that they are currently solvent, meaning that a fair valuation of their property (exclusive of exempt property) exceeds the sum of their debts.

11. The Parties each represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

12. Except as expressly provided to the contrary in this Agreement, each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

13. Except as otherwise stated in this Agreement, this Agreement is intended to be for the benefit of the Parties only, and the Parties do not release any liability as to any other person or entity.

14. Nothing in this Agreement constitutes an agreement by the State concerning the characterization of the amounts paid hereunder for purposes of the State's revenue code.

15. In addition to all other payments and responsibilities under this Agreement, AmerisourceBergen agrees to pay the State Team's reasonable expenses and fees, including travel costs, consultant expenses, and administrative fees. AmerisourceBergen will pay this amount by separate check made payable to the National Association of Medicaid Fraud Control Units, after the Medicaid Participating States execute their respective Agreements, or as otherwise agreed by the Parties.

16. This Agreement is governed by the laws of the State, except disputes arising under the CIA shall be resolved exclusively under the dispute resolution provisions of the CIA, and venue for addressing and resolving any and all disputes relating to this Agreement shall be the state courts of appropriate jurisdiction of the State.

17. The undersigned ABC Defendants' signatories represent and warrant that they are authorized as a result of appropriate corporate action to execute this Agreement. The undersigned State signatories represent that they are signing this Agreement in their

official capacities and that they are authorized to execute this Agreement on behalf of the State through their respective agencies and departments.

18. The Effective Date of this Agreement shall be the date of signature of the last signatory to this Agreement. Facsimiles of signatures shall constitute acceptable binding signatures for purposes of this Agreement.

19. This Agreement shall be binding on all successors, transferees, heirs, and assigns of the Parties.

20. This Agreement constitutes the complete agreement between the Parties with respect to this matter and shall not be amended except by written consent of the Parties.

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

22. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by the Parties to this Agreement and shall not, therefore, be construed against any of the Parties for that reason.

STATE OF NORTH CAROLINA

By: _____ Dated: 10-24-18

F. Edward Kirby, Jr.
Director, Medicaid Investigations Division
Office of the Attorney General

By: _____ Dated: 10/15/18

DAVE RICHARD
Deputy Secretary for Medical Assistance
Division of Medical Assistance

FOR THE ABC DEFENDANTS

AMERISOURCEBERGEN CORPORATION,
AMERISOURCEBERGEN DRUG COMPANY,
AMERISOURCEBERGEN SPECIALTY GROUP,
ONCOLOGY SUPPLY COMPANY AND
MEDICAL INITIATIVES, INC.

By: _____ Dated: 11/27/18

[INSERT] John G. Chou, Esq.
Executive Vice President and Chief Legal and Business Officer

MORGAN, LEWIS & BOCKIUS LLP

By: _____ Dated: 11/26/2018

ERIC W. SITARCHUK, ESQ.
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Counsel for ABC Defendants

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. Oncology Supply Company d/b/a ASD Healthcare, Inc. ("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[1] 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

[1] 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)(l) 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[2] in those

[2] 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®.