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

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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UNITED STATES OF AMERICA

- against -

AMERISOURCEBERGEN SPECIALTY GROUP, LLC,

Defendant.

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INFORMATION

Cr. No. 17-507 (NG)
(T. 18, U.S.C., §§ 2 and 3551 et seq.; T. 21, U.S.C., §§ 331(a), 333(a)(1), 334(a)(1), 352(o), 360 and 853(p); T. 28, U.S.C., § 2461(c))

THE UNITED STATES ATTORNEY CHARGES:

INTRODUCTION

Unless stated otherwise, at all times relevant to this Information:

I. Defendant and Relevant Entities

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 Brunswick Corporation and Amerisource Health Corporation. ABC was the second-largest distributor of pharmaceuticals in the United States and was listed in 2017 as number 11 on Fortune's list of the 500 largest companies in the United States. In 2016, ABC had revenues of approximately $148 billion.

2. Defendant AMERISOURCEBERGEN SPECIALTY GROUP, LLC ("ABSG") was a subsidiary of ABC, with corporate headquarters located in Frisco, Texas. ABSG was 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 ("OSC"), which also did business as "ASD Healthcare, Inc.," 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 OSC and, at various times, did business under the names Oncology Supply Pharmacy Services 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 acquired by Bergen Brunswick in 1998, and was acquired by ABC following the merger in 2001. MII was a pre-filler of pharmaceuticals for oncology patients and operated a physical facility in Dothan, Alabama. There, MII and OSC created, sold and shipped millions of pre-filled syringes containing oncology drugs between 2001 and January 2014.

5. The United States Food and Drug Administration (the "FDA") was the federal agency responsible for protecting the health and safety of the public by enforcing the Federal Food, Drug, and Cosmetic Act ("the FDCA" or "the Act"), by ensuring that drugs — including biologics, that were also drugs — intended for use in humans were safe and effective for their intended uses, and by ensuring that the labeling of such drugs bore true and

accurate information. Pursuant to that responsibility, the FDA published and administered regulations relating to the approval, manufacture, labeling and distribution of drugs.

II. Requirements of the FDCA

A. Definitions

6. A "drug" was, in relevant part, an article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in human beings and an article (other than food) intended to affect the structure or any function of the body of humans or other animals. 21 U.S.C. §§ 321(g)(1)(B) and (C).

7. A "biological product" or "biologic" was a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings. 42 U.S.C. § 262(h)(3)(i).

8. The term "label" was defined as a display of written, printed or graphic matter upon the immediate container of any article. 21 U.S.C. § 321(k). The term "labeling" was broader and included all labels and other written, printed or graphic matter upon any article, including drugs, or any of its containers or wrappers, or on any written, printed or graphic matter accompanying such article. 21 U.S.C. § 321(m).

9. A drug was a "new drug" if it was "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness

of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof[.]" 21 U.S.C. § 321(p)(1).

B. Unapproved New Drugs

10. Introducing an unapproved new drug into interstate commerce was illegal. 21 U.S.C. § 331(d). The FDCA prohibited causing the introduction or delivery for introduction into interstate commerce or introducing or delivering for introduction into interstate commerce "new drugs," including biologic products, unless an approved new drug application ("NDA"), biologics license application ("BLA"), abbreviated new drug application ("ANDA"), or an investigational new drug application was in effect for such drug. 21 U.S.C. § 355, 42 U.S.C. § 262(a).

11. The process for obtaining approval for a new drug pursuant to an NDA included, among other requirements: (i) full reports of investigations that had been made to show whether such drug was safe for use and effective in use; (ii) a full list of the articles used as components of such drug; (iii) a full statement of the composition of the drug; and (iv) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug. In addition, manufacturers were required to make the FDA aware of, and obtain approval for, certain changes in the conditions established in an approved application. BLA applications had similar requirements. See 21 C.F.R. § 601.2.

12. The manufacturers of the FDA-approved products purchased by OSC for use in the pre-filled syringe program described in Section III below — Aloxi®, Anzemet®, generic versions of granisetron injection, Kytril®, Neupogen® and Procrit® —

obtained either NDAs or BLAs for those products in their glass vial containers. Accordingly, those products were FDA-approved in glass vial containers and could be distributed in interstate commerce.

13. A drug product compounded for an "identified individual patient based on the receipt of a valid prescription order" may have qualified for an exemption from the requirement that "new drugs" be the subject of an approved marketing application. 21 U.S.C. § 353a(a). However, commercial repackaging of FDA-approved sterile injectable drugs or biologics from their original containers (i.e., glass vials) into syringes, using a process that contradicted the instructions for the approved drug, did not constitute compounding eligible for this exemption, and in any event doing so without obtaining patient specific prescriptions for such repackaged products required filing of a new NDA or BLA.

14. Vials of Aloxi®, Anzemet®, generic versions of granisetron injection and Kytril® that were purchased by OSC for use in its pre-filled syringe program were drugs. Vials of Neupogen® and Procrit® that were purchased by OSC for use in its pre-filled syringe program were biological products as well as drugs.

C. Registration Requirement

15. The FDCA also required any entity that engaged in the "manufacture, preparation, propagation, compounding or processing" of a drug to register with the FDA. 21 U.S.C. § 360(b). The requirement to register with the FDA applied to entities engaged in "repackaging" or "otherwise changing the container, wrapper, or labeling of any drug package or device package in furtherance of the distribution of the drug or device from the

original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user[.]" 21 U.S.C. § 360(a)(1).

16. A drug that was manufactured, prepared, propagated, compounded or processed in an establishment in any state not duly registered with the FDA pursuant to 21 U.S.C. § 360 was deemed misbranded. 21 U.S.C. § 352(o).

17. An entity operating as a pharmacy may have qualified for an exemption from the registration requirement if it met all three of the following conditions: (i) it "maintain[ed] establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine;" (ii) it "regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice;" and (iii) it "[did] not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail." 21 U.S.C. § 360(g)(1).

III. The Pre-Filled Syringe Program

18. Between 2001 and January 2014, the defendant ABSG's subsidiaries MII and OSC operated a program that created, packed and shipped millions of pre-filled syringes (also known as "PFS") to oncology centers, medical practices and physicians (collectively, "healthcare providers" or "customers") for use by cancer patients for supportive care in connection with chemotherapy treatment. To create PFS, MII removed FDA-approved drug products from their original glass vial containers and repackaged them into plastic syringes via a process that allowed MII to profit from accessing and selling

excess drug product it was able to extract from the vials. However, the processes used to repackage, ship and assign PFS to patients exposed PFS to a greater risk of contamination, and did not ensure that each PFS was provided to an identified patient in a dosage appropriate for such patient. As a result, PFS created by MII in some instances contained unknown particulate; tested positive for bacteria; were subject to conditions in contravention of the FDA-approved labels for the original drug product in the vials; and were dispensed to individuals in excess of safe dosing or in the absence of a valid prescription.

A. Business Model

19. In general, drug products intended for injection produced by manufacturers in vials contained the FDA-approved dose, as well as an approved small amount of extra drug product known as "overfill." Overfill was included by the manufacturer to ensure, among other things, that when the contents of a vial were pulled into a syringe for administration to a patient, there was sufficient drug product to create the correct dosage, taking into account (i) the possibility of air bubbles forming during the syringe filling process and (ii) the viscosity of certain drugs (which made them difficult to draw into a syringe). The business model adopted by MII and OSC for pre-filled syringes took advantage of the excess drug contained in the vials and turned it into profit.

20. First, OSC obtained FDA-approved drug products directly from manufacturers, which were manufactured and packaged in glass vials in accordance with approved marketing applications. These vials were then transferred from OSC to MII, where they would be used to create PFS. These PFS were sold to healthcare providers in all 50 states, including to approximately 37 healthcare providers located in the Eastern District of

New York, based on orders placed by those providers. For each PFS ordered by a healthcare provider, OSC would bill the provider for a vial of drug product, and then MII would deliver a corresponding PFS to OSC, which was shipped to the healthcare provider by OSC.

21. OSC marketed MII's "Pre-Filled Syringe Program" (or "PFS Program") — which was, in fact, MII's entire operation — as a way for healthcare providers to save time and money by outsourcing the work of drawing drug product into syringes from vials at a significant discount. However, MII and OSC failed to disclose to healthcare providers that, in creating PFS, it utilized the overfill in the vials to create "extra" syringes of drug product, which were then sold to healthcare providers. This process allowed MII to salvage unopened vials (referred to herein as the "Unopened Vials") of drug product. MII and OSC also failed to disclose to healthcare providers the process by which overfill was extracted from the vials, or how such process exposed the previously sterile, FDA-approved drug product removed from the vials to an increased risk of contamination (as detailed below in Sections III.B and III.D).

22. For example, a 10mL dosage vial of drug product that had 10% overfill actually contained 11mL of drug product, i.e., the dose plus 10% overfill. By combining the contents of more than one vial of drug product, or "pooling," the drug product from ten of these vials together, MII created 11 10mL PFS from only ten 10mL vials. Then, by repeating this process on a massive scale, MII generated Unopened Vials. To create 110 PFS, for example, MII would only need 100 vials. Those extra ten Unopened Vials — which had already been paid for by one of MII's customers — constituted profit, as the Unopened Vials could be re-sold to a second customer at no cost to ABC. In practice, some of the

Unopened Vials were sent to other ABC subsidiaries for resale; other Unopened Vials were cycled back through OSC and sold a second or even a third time to customers via the PFS Program.

23. Because the amount of overfill in the vials determined the profitability of the PFS Program, which constituted MII's entire business, MII created and dispensed PFS only for drug products that had vials with a high percentage of overfill. As a result, MII offered only the following drugs for sale: Aloxi®, Anzemet®, generic versions of granisetron injection, Kytril®, Neupogen® and Procrit®.

24. At the time of MII's purchase by ABC in 2001, MII created and sold hundreds of thousands of PFS per year. Following an expansion of MII's physical facility in 2006, MII started to sell more than one million PFS per year. At the height of its operations, MII generated more than $14 million in profit for ABC per year. In addition, MII's PFS Program and its attendant discounts were marketed by OSC to both recruit customers to OSC and to retain existing customers (as OSC faced competition from other drug distributors).

25. This business model for the PFS Program remained consistent during the entire time of its operation, between 2001 and January 2014. It was known to and approved at the highest levels of ABSG and ABC. Responsibility for compliance and oversight of the PFS Program run by MII and OSC was tasked to both ABC's Corporate Security and Regulatory Affairs division and to the defendant ABSG's legal department.

B. MII's Process for Creating, Packing and Shipping PFS

26. MII repackaged FDA-approved drug products from their original glass containers into plastic syringes inside its facility in Dothan, Alabama. The resulting PFS

were then packed and shipped to healthcare providers from an adjoining warehouse administered by OSC.

27. MII did not usually create PFS to order for a particular physician or practice. That is, MII did not wait to receive an order form for a specific number of PFS in specific dosages, and subsequently fill that order by creating PFS that matched what had been requested. Instead, MII mass-produced PFS in anticipation of potential orders in a process known as a "batching" or "pre-draws." These batches of PFS were created continuously throughout the day prior to the receipt of order forms from healthcare providers, and at the end of the day to ensure that sufficient PFS were available at the start of the next day. PFS that were produced but not shipped to healthcare providers in a given day were kept in a refrigerator and used for orders on the following day.

28. To create these large batches of PFS — and, significantly, to ensure that all of the overfill from the vials could be harvested for profit, as described above — MII pooled FDA-approved sterile drug products that it had received in vials from drug manufacturers. These vials were de-capped (that is, opened) and pooled into IV bags or larger syringes, depending on the type of drug. Many of the vials used by MII for this process were designated by the manufacturer as "single use" vials, meaning that the manufacturer could not guarantee sterility of the drug product if the vial was entered more than once. However, in the pooling process, MII's technicians frequently re-entered vials multiple times after the vials were de-capped. This process introduced significantly greater risks of contamination than had MII simply prepared one syringe from one vial.

29. For example, for Procrit®, MII technicians opened and breached the sterility of entire cases of vials, and then used a large syringe or a blunt cannula to draw up as much drug product as possible from each vial in succession. The contents of the larger syringe — comprising drug product from many vials — would then be used to make a series of PFS. In order to ensure that all of the drug product was extracted from the vials, MII's technicians used two successive methods. Initially, MII staff opened vials of Procrit®, made an initial draw, and then left the opened vials in non-sterile containers overnight, so that any remaining drug product could collect in the vials and be used to fill PFS. Subsequently, MII's technicians changed their method of extracting drug product: once an initial draw was made from the vials, the containers holding the vials were tilted so that the excess drug product pooled more quickly. In either case, MII's technicians subsequently entered the vials for a second or even third time (post-resting or tilting) with another large syringe to capture this remaining drug product. MII adopted this process despite the fact that (i) the FDA-approved label for Procrit® stated: "Discard unused portions of Procrit® in preservative-free vials. Do not re-enter preservative-free vials," and (ii) MII was also explicitly advised by Ortho Biotech, the licensee/distributor of Procrit®, that the sterility of single use vials of Procrit® could not be guaranteed if multiple entries were made into a single vial.

30. An incentive program was put into place to ensure that MII's technicians were creating as many PFS as possible in the shortest amount of time. MII technicians received bonuses for meeting or exceeding targets for creating a certain number of PFS per day, and technicians were also given bonuses for increasing overfill percentages.

No bonuses were awarded to MII staff for error reduction, cleanliness, or any other metric of quality improvement or safety.

31. To create PFS, MII used syringes made by a single manufacturer ("Manufacturer 1"), an entity the identity of which is known to the United States Attorney. Manufacturer 1's syringes were plastic, as opposed to the glass vials that contained the original drug product, and were typically used to administer injectable drugs but were not designed for extended storage. Product instructions for Manufacturer 1's 3mL syringes stated that products placed therein should be "administered as soon as possible" after removal from original containers.

32. Once PFS were created by MII's technicians, MII's pharmacists visually inspected the PFS using a light box for issues or errors, including the presence of particulate, bubbles or volume errors. PFS that had passed MII's pharmacists' visual inspection were then grouped according to drug and dosage, and placed into plastic bins. PFS were then collected from the plastic bins to fill an order, and placed in plastic bags. Each plastic bag was given a label that included MII's contact information, the number of PFS in the bag, the dosage and drug product for the PFS, a use-by date, and, in some instances, an individual's name. The bags were subsequently wrapped in bubble wrap and placed into a box with a coolant. The packaging did not contain a temperature indicator. The boxes were subsequently mailed by OSC for overnight delivery via Federal Express.

33. MII failed to conduct any tests to ensure that its processes for removing the drug product from the FDA-approved vials and subsequently creating, packaging and shipping PFS preserved the sterility, stability and potency of the original drug product that

had been removed from the vials, or that the PFS would not leak, crack or be subject to uncontrolled conditions during transit.

34. ABC, ABSG, OSC and MII did not submit to the FDA an NDA or BLA seeking FDA approval for any of the pre-filled syringes created in the PFS Program.

C. MII's Process for Filling PFS Orders

35. MII did not require the receipt of a valid prescription for an identified individual patient prior to distributing a PFS. Instead, to purchase PFS, healthcare providers submitted order forms provided by OSC either to OSC or to MII; those forms that were submitted to OSC were subsequently conveyed to MII. Order forms were submitted via fax, e-mail or phone. In addition, certain healthcare providers had Nucleus or Pyxis machines, which were located at the healthcare providers' offices and had the ability both to store PFS and communicate electronically to MII and OSC the need for additional orders.

36. The order forms received by OSC and MII detailed the drug type(s), dose size(s) and number of PFS needed by the customer. However, approximately three-quarters of the order forms accepted by OSC and MII did not include the names of individual patients, nor did they contain other information required to be valid prescriptions under state law. While state prescription requirements varied from state to state, they often included, among other requirements, a doctor's signature; a patient's address; and an indication as to whether a pharmacy may substitute a generic drug for an enumerated prescription drug.

37. Instead, MII and OSC accepted order forms that, among other things: provided no patient names; provided a single name for the entire order; provided only patient initials or provided the name of a staff member of the healthcare provider, as opposed to a

patient name. In addition, when healthcare providers used Nucleus or Pyxis machines to advise MII that a new order was needed, the data provided by the machines to MII listed only the number and type of PFS needed and not the names of patients to whom the PFS would be administered. In some cases, where patient names were not included with the order form — and in most cases for healthcare providers whose additional orders were placed using Nucleus or Pyxis machines — MII pharmacists randomly selected patient names from prior orders and matched them to PFS for new orders. In such instances, one patient name from a prior order was generally selected by MII and matched to a bag of four PFS, rather than to an individual dose intended for a specific patient.

38. MII implemented its process for matching PFS to order forms — including accepting orders that had no names or actively matching sets of PFS to the names of prior patients — without regard to whether the individual named in an order form or assigned to a particular PFS or set of PFS was in fact a patient, and, if so, was still being seen at the practice, was still alive, or was still prescribed to receive the same drugs or dosage. Because MII did not have a direct relationship with the patients who ultimately were administered PFS, it did not submit claims directly to insurance companies, nor maintain patient records or monitor for allergies or other contraindications with respect to patients. MII also had no way to know whether PFS assigned to a particular individual were ever administered to such individual.

39. In addition, on certain occasions when an order form requested a quantity of PFS that did not match the number of vials in a box set, MII would "round up" the order and add extra PFS to the order. The bags with PFS that contained extra PFS were

either (i) labeled with the phrase "extra syringe" or "office use," or (ii) randomly assigned an individual patient's name from either the current or a prior order. Accordingly, these extra PFS were always dispensed to physicians without a valid prescription for a specific patient.

D. Problems Resulting from Operation of the PFS Program

40. There were numerous problems that resulted from the operation of the PFS Program, including the following: non-aseptic conditions in MII's cleanroom; the presence of bacteria and/or floaters of unknown origin and composition in PFS; PFS that had a different volume (and thus a different strength) than as labelled; issues with PFS leakage, cracking and/or temperature exposure resulting from shipping processes; and the distribution of PFS to individuals who were not in fact patients and/or to patients in doses that were in excess of plausible and/or safe use.

1. Non-Aseptic Conditions in MII's Cleanroom

41. MII's cleanroom contained laminar flow hoods (an ISO-5 air quality area) under which sterile drug product was removed from vials and pooled, as detailed above, to create PFS. During that process, MII's technicians wore gowns and gloves. Prior to approximately 2010, MII did not conduct any environmental (microbial) monitoring of the hoods, the air in the cleanroom and in the anterooms, or on technicians' gloved fingertips to evaluate the efficacy of their hand-washing and garbing techniques and gloved-hand sanitation.

42. Starting in late 2010, MII began to conduct some microbial monitoring of the laminar flow hoods to determine if they were contaminated. On multiple occasions over a period of several years, MII's hoods tested positive for bacteria in excess of

acceptable levels. While MII cleaned the hoods after positive tests were returned, MII did not conduct any immediate follow-up microbial sampling to determine if the bacterial contamination had been effectively removed by the cleaning. MII also did not determine the source of the bacterial contamination on the hoods, or determine if the sterility of any PFS had been compromised. Nor did MII contact healthcare providers who received PFS created during periods when positive tests were returned either to recall the PFS or to advise them of the risk of contamination.

43. After 2010, once viable air sampling commenced in MII's cleanroom and anterooms, tests were positive for fungal contamination and/or bacterial contamination in excess of acceptable levels on multiple occasions. While MII also cleaned the facility after tests showed contamination above acceptable limits, it did not cease operations during cleaning or conduct any immediate follow-up microbial sampling to determine if the bacterial and/or fungal contamination had been effectively removed. MII also did not determine the source of the bacterial or fungal contamination in the air, or determine if the sterility of any PFS had been compromised. Nor did MII contact healthcare providers who received PFS created during periods when positive tests were returned either to recall the PFS or to advise them of the risk of contamination.

44. Similarly, once MII began conducting gloved fingertip testing on MII's technicians in 2010 — the individuals who actually handled the sterile drug product as it was repackaged from vials to PFS — there were multiple gloved fingertip samples taken over several years that were positive for bacterial contamination. MII did not conduct any follow-up microbial sampling to determine the source of the bacterial contamination, or to determine

if the sterility of any PFS had been compromised. Nor did MII contact healthcare providers who received PFS created during periods when positive gloved fingertip microbial samples were returned either to recall the PFS or to advise them of the risk of contamination.

45. MII technicians wore non-sterile gowns in the cleanroom and while preparing PFS. However, some MII or OSC staff entered the MII cleanroom and anterooms without wearing any gowns at all. In addition, MII staff wore exposed jewelry, makeup, nail polish and street clothing in the cleanroom while preparing purportedly sterile PFS.

46. Additionally, non-sterile items were present in MII's cleanroom within reach of the laminar flow hoods where sterilized drug product was removed from vials and pooled to make PFS. These items included, among others, compressed air canisters containing non-sterile air and chemicals, open Band-Aids, iPods and exposed earbuds, skin lotion, aloe gel, chewing gum, lip balm, non-sterile mops, non-sterile seat cushions, and non-sterile elbow cushions abutting the laminar flow hood entrances.

2. PFS Containing Bacteria and/or Floaters

47. MII's process for creating PFS resulted in some PFS that contained particulate or foreign matter, which employees colloquially referred to as "floaters" (hereinafter "floaters" or "particulate"). MII tracked the number of PFS containing floaters for approximately six years, between 2007 and 2013, although floaters were identified in PFS prior to that period. From 2007 and 2013, approximately 32,539 PFS were identified as containing floaters. On average, MII identified well over 100 PFS each week that contained floaters.

48. The majority of PFS containing floaters were PFS made from Procrit® vials. The FDA-approved label for Procrit® stated: "Parenteral [injectable] drug products should be inspected visually for particulate matter and discoloration prior to administration. Do not use any vials exhibiting particulate matter or discoloration." (Emphasis supplied). Thus, in accordance with the label, vials or syringes of Procrit® containing particulate were required to be destroyed.

49. MII did not destroy PFS containing floaters. Instead, MII technicians employed a process to filter out the visible particulate, in contravention of the FDA-approved label for Procrit®. These filtered PFS were then sent to unknowing healthcare providers to be administered to immunocompromised cancer patients.

50. MII never took any steps to determine, nor did it determine, the cause, composition, sterility, or size(s) of the floaters. MII did not take any steps to identify, nor did it identify, what might have caused the particulate matter to enter the PFS so that it could prevent such particulate in the future. MII did not test the particulate extracted from filtered PFS to determine whether any subvisible remnants not extracted might still cause a risk to patients, such as subvisible protein particles or contaminants. MII did not assess whether its filtration process impacted the sterility, stability, purity, strength or composition of the drug contents of its PFS. Finally, MII did not conduct any assessment to determine the error rate, i.e., the rate of PFS sold to healthcare providers in which particulate was present but not detected via visual inspection.

51. Of the approximately nine million PFS that MII created, MII only submitted a total of 82 PFS for sterility testing by an outside laboratory on three occasions,

once each in 2009, 2011 and 2012. Several of the PFS submitted for outside testing in 2009 and 2011 tested positive for bacteria. Following these positive test results, MII did not conduct any follow-up tests to determine the source of the bacterial contamination. MII did not report the failed tests to the FDA or any state board of pharmacy. No recall or customer notification was issued to healthcare providers who may have purchased PFS from the same lots as the PFS that tested positive for bacteria.

3. PFS Volume Issues

52. PFS were intended to contain the exact labeled dosage (i.e., no intentional overfill), and to be directly administered to the patient without additional dose adjustments by the provider. Therefore, in the process of MII filling PFS, there was no margin for error. The PFS volume had to be exact or the patient would either get a short dose or be given too much of the drug.

53. However, MII had no objective process to ensure that PFS contained the proper volume of drug product. Rather than applying any industry standard, MII staff simply "eyeballed" the PFS volume and had differing views as to the correct level of fill for the syringe. Some technicians would draw a drug product into the syringe just below the line signifying the ordered dosage, while others would draw the product to the line of the ordered dosage. These practices changed over the years and also varied amongst MII's staff.

54. Moreover, as described above, MII had an "incentive program" for staff that paid higher bonuses to technicians who produced higher overfill percentages, i.e., had extra drug remaining from the vials they opened to fill more PFS. Thus, placing less drug product in the PFS would increase the technicians' overfill production percentages and

earn them higher bonuses. MII staff, therefore, had a direct financial incentive to put as little of the drug as possible into each PFS. In fact, MII supervisors complained that short dosing occurred because technicians were "pushing the limit" to increase overfill percentages.

55. In addition, MII did not test its processes for packing and shipping PFS to ensure that the stoppers used to close the syringes would remain secure during transport in order to avoid either the introduction of air bubbles or contaminants into PFS or the leakage of drug product from PFS. Nor did MII test its processes for packing and shipping PFS to ensure that the syringes would not be damaged during transport.

56. As a result of MII's processes for creating, packing and/or shipping PFS, some healthcare providers received PFS that contained less drug product than the labeled dosage. In some instances, the short dose appeared to be related to an issue with packing and/or shipping; for example, healthcare providers received syringes that were leaking from hairline cracks, had air bubbles or had stoppers that were loose or disconnected. In other instances, the syringes appeared intact, but healthcare providers noticed that the syringes contained less drug product than listed on the label.

4. Exposure of PFS to Temperature Variations, Light and Shaking

57. The FDA-approved labels on the drug products used to make PFS have instructions regarding storage and handling to ensure the safety and efficacy of the drug product. While these instructions varied by drug product, many of them provided guidance about the appropriate temperature range, handling process and light exposure for the drug product.

58. For example, Procrit® was a so-called "cold chain" drug and its label required that the drug be stored at 36° to 46° Fahrenheit. The label stated "Do not Freeze" and specified that "[w]hen traveling, transport PROCRIT® in its original carton in an insulated container with a coolant such as blue ice. To avoid freezing, make sure the PROCRIT® vial does not touch the coolant." In addition, the Procrit® label stated: "DO NOT SHAKE," and explained that "[s]haking may denature the glycoprotein, rendering it biologically inactive." Finally, the label for Procrit® included instructions to protect the drug product from light exposure.

59. MII's processes for creating, packing and/or shipping PFS resulted in the handling of Procrit® PFS in contravention of these label instructions. For example, MII did not ensure that the coolant with which PFS were packaged for distribution to healthcare providers would not touch the PFS when shipped and in transit. On a number of occasions, healthcare providers received Procrit® PFS that felt warm to the touch upon arrival.

60. MII also failed to conduct any testing to ensure that its method of packaging PFS for shipping — which consisted of placing PFS wrapped in bubble wrap in a box with coolant — would prevent PFS repackaged from Procrit® from coming into contact with the coolant, or that the syringes would not be shaken in that box during transit. In fact, when several healthcare providers received PFS with hairline cracks, MII staff speculated that the syringes in question may have been damaged by contact with the coolant during takeoff or landing of the airplanes transporting PFS.

61. Finally, MII took no steps to ensure that PFS repackaged from Procrit® were not exposed to light. To the contrary, MII staff created PFS repackaged from Procrit®

in a room with typical room lighting; placed such PFS inside a light box to inspect them for floaters and other issues; and packaged such PFS for shipping in a brightly lit room.

5. MII Dispensed PFS to Non-Patients and in Excess of Plausible Use

62. MII's practices of dispensing PFS in response to order forms that listed only a single name, and/or assigning names at random to PFS that were shipped in response to order forms submitted without any names, resulted in PFS being dispensed in the name of individuals who were not in fact patients, as well as in excess of plausible and/or safe use. 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 PFS. In some instances, the individual's name assigned to the set of PFS was a staff member at the healthcare provider (such as a nurse or office manager); in other instances, the individual was no longer a patient of the healthcare provider, either because the individual was no longer receiving treatment and/or because the individual was deceased.

63. 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 PFS. For example, Procrit® had a Black Box warning on the label — the most serious warning the FDA can require to be placed on a drug product — which required the use of the lowest possible dose 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.

64. In one instance in 2012, MII dispensed to a single individual a total of 34 PFS repackaged from Procrit® vials in dosages ranging from 20K to 60K units/1mL, all of which were ostensibly to be administered to that individual within a 14-day period before the use-by date. As the recommended dosage for an average adult on chemotherapy is one dose of Procrit® 40K per week, this was far in excess of the dosage that could safely be administered to a patient. Prior to dispensing the 34 PFS prepared from Procrit® vials, MII did not contact the healthcare provider to clarify whether all 34 PFS were meant for that one individual (and, if so, to counsel the physician that such overutilization of Procrit® could increase the risk of death), or for another patient, or whether the number was simply a mistake.

IV. ABSG's Avoidance of FDA Regulatory Oversight

65. In and about and between 2001 and January 2014, the defendant ABSG: (i) introduced, and caused the introduction of, misbranded drugs into interstate commerce, as such drugs were manufactured, prepared, propagated, compounded, and processed in an establishment not duly registered with the FDA; and (ii) introduced, and caused the introduction of, unapproved new drugs in commerce. In so doing, ABSG violated the FDCA and created serious risks for patients who were being treated for cancer and other illnesses who were administered pre-filled syringes.

A. Misbranding Caused by ABSG's Failure to Register MII with the FDA

66. The defendant ABSG did not register MII as a repackager or manufacturer with the FDA in order to avoid the agency's regulatory oversight. Instead,

defendant ABSG inaccurately portrayed MII to both its customers and to state agencies as a state-regulated pharmacy that was in the business of dispensing drugs pursuant to valid prescriptions and otherwise in compliance with local state law. However, MII was required to register with the FDA because MII did not function in accordance with local state laws, and functioned solely to repackage drug product from vials to PFS on a massive commercial scale.

67. As detailed above in Section III, MII's entire 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 large quantities of 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. MII thus changed the container, wrapper and labeling of the original drug product — the glass vials — to create PFS, which clearly constitutes repackaging under the FDCA.

68. MII did not qualify for any exception to the registration requirement in the FDCA because it was not in conformance with applicable local laws regulating the practice of pharmacy. For example, to qualify as a pharmacy under Alabama 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). Not only did MII not maintain this information, as detailed above, MII did not even know the patients to whom PFS were ultimately dispensed. In addition, MII routinely dispensed PFS without receiving prescriptions signed by practitioners.

B. PFS Constituted Unapproved New Drugs

69. The defendant ABSG unlawfully introduced unapproved new drugs into interstate commerce via its PFS Program, which engaged in the removal of FDA-approved drug product from glass vials and the repackaging of that product into plastic syringes. The repackaged PFS of Aloxi®, Anzemet®, generic versions of granisetron injection, Kytril®, Neupogen® and Procrit® were not the same FDA-approved drugs as those approved by the FDA in glass vial form, manufactured in the facilities and according to the specifications approved by the FDA.

70. Neither the defendant ABSG nor any other entity submitted to the FDA an NDA or BLA for any of the syringes created in the PFS Program. As a result, defendant ABSG did not submit any safety, stability or sterility data to the FDA, nor did it submit any information showing that the safety or efficacy of the drug product would not be affected by (i) the processes used to create syringes, (ii) the new packaging of the PFS, (iii) the container closure system, or (iv) the shipping methods. Defendant ABSG thus did not demonstrate to the FDA that the drug product extracted from the FDA-approved vials and repackaged into syringes was repackaged in a manner that would ensure the safety and efficacy of the drug product.

71. As described above, the processes by which MII created, packaged and shipped PFS had the substantial potential to — and on numerous occasions, did — adversely affect the strength, quality, purity and/or potency of the original drug product in the glass vials. This is evidenced by, among other things, the fact that some PFS had floaters; tested positive for bacteria; had inadequate volume for the marked dosages; and were exposed to

unapproved temperature and handling conditions. Moreover, these processes changed the drug product container closure system (from a sealed vial to a stoppered syringe), as well as the composition of the packaging of the original drug product (from glass to plastic).

72. The PFS created by MII also did not qualify for any exemption from the new drug approval requirement in the FDCA because MII, which created the PFS, did not compound the drug product for an "individual identified patient based on the receipt of a valid prescription order." As detailed above, MII did not dispense PFS pursuant to a prescription that identified the individual who would actually receive each PFS. Rather, MII matched PFS to order forms, the majority of which did not even provide the identities of individual patients.

INTRODUCTION OF MISBRANDED DRUGS INTO INTERSTATE COMMERCE

73. The allegations contained in paragraphs one through 72 are realleged and incorporated as though fully set forth in this paragraph.

74. In or about and between January 2005 and January 2014, both dates being approximate and inclusive, within the Eastern District of New York and elsewhere, the defendant ABSG, together with others, did introduce into interstate commerce, deliver for introduction into interstate commerce and cause the introduction and delivery for introduction into interstate commerce of drugs, including biological products, that were misbranded because they were manufactured, prepared, propagated, compounded and

processed in an establishment in the state of Alabama that was not duly registered with the FDA.

(Title 21, United States Code, Sections 331(a), 333(a)(1), 352(o) and 360; Title 18, United States Code, Sections 2 and 3551 et seq.)

CRIMINAL FORFEITURE ALLEGATION

75. The United States hereby gives notice to the defendant that, upon its conviction of the offense charged herein, the government will seek forfeiture in accordance with Title 21, United States Code, Section 334(a)(1) and Title 28, United States Code, Section 2461(c), which permit the forfeiture to the United States of any article of food, drug, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale after shipment in interstate commerce.

76. If any of the above-described forfeitable property, as a result of any act or omission of the defendant:

(a) cannot be located upon the exercise of due diligence;

(b) has been transferred or sold to, or deposited with, a third party;

(c) has been placed beyond the jurisdiction of the court;

(d) has been substantially diminished in value; or

(e) has been commingled with other property which cannot be divided without difficulty;

it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p),

to seek forfeiture of any other property of the defendant up to the value of the forfeitable property described in this forfeiture allegation.

(Title 21, United States Code, Sections 334(a)(1) and 853(p); Title 28, United States Code, Section 2461(c))

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EASTERN DISTRICT OF NEW YORK