

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.

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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))	-1
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.



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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.

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**AMERISOURCEBERGEN SPECIALTY GROUP, LLC**

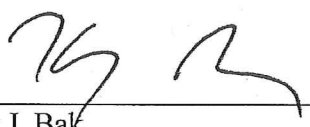
**SECRETARY'S CERTIFICATE**

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 according 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.

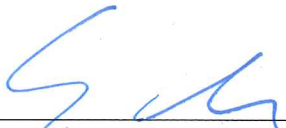
- B. ABSG may submit a timely written request for an extension of time to provide the certifications or board resolution required above. A written request is timely if it received by the U.S. Attorney's Office for the Eastern District of New York at least five business days prior to the date by which 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:**

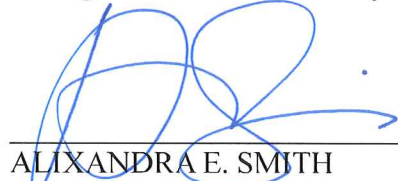
FOR AMERISOURCEBERGEN SPECIALTY GROUP, LLC:

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

9/27/17  
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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AMEET B. KABRAWALA  
Assistant U.S. Attorneys  
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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