

## **SETTLEMENT AGREEMENT AND RELEASE**

### **I. PARTIES**

This Settlement Agreement and Release ("Settlement Agreement" or "Agreement") is entered into between the United States of America, acting through the United States Department of Justice ("DOJ"),<sup>1</sup> and on behalf of the Drug Enforcement Administration ("DEA") (collectively referred to herein as the "United States"), and McKesson Corporation ("McKesson").

### **II. RECITALS**

A. McKesson is a corporation organized and existing under the laws of the State of Delaware. McKesson's corporate headquarters and principal place of business is located at One Post Street, San Francisco, California.

B. McKesson is a wholesale distributor of pharmaceuticals, including controlled substances and non-controlled prescription medications. McKesson distributes pharmaceuticals through a network of distribution centers located throughout the United States, including distribution centers located in the following areas: Aurora, Colorado; Aurora, Illinois; Delran, New Jersey; La Crosse, Wisconsin; Lakeland, Florida; Livonia, Michigan; Methuen, Massachusetts; Santa Fe Springs, California; Washington Courthouse, Ohio; and West Sacramento, California. McKesson formerly distributed pharmaceuticals through a distribution center located in Landover, Maryland, which closed in January 2012 (the "Landover Distribution Center"), and in La Vista, Nebraska, which closed in October 2016. A list of all McKesson U.S. Pharmaceutical distribution

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<sup>1</sup> The Department of Justice is represented by the following 12 U.S. Attorney's Offices: Central District of California; Eastern District of California; District of Colorado; Middle District of Florida; Eastern District of Kentucky; Northern District of Illinois; District of Massachusetts; Eastern District of Michigan; District of Nebraska; District of New Jersey; Northern District of West Virginia; and Western District of Wisconsin.

centers that hold a DEA Certificate of Registration as of the Effective Date of this Agreement is attached hereto as Appendix A. Collectively, the distribution centers listed in Appendix A and the Landover Distribution Center are referred to herein as the “McKesson Distribution Centers.”

C. At times relevant to this Agreement, the McKesson Distribution Centers were required to operate in accordance with the statutory provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §§ 801 *et seq.* (the “CSA” or the “Act”), and the regulations promulgated thereunder, 21 C.F.R. Part 1300 *et seq.*

D. The DEA is the DOJ component agency primarily responsible for administering the CSA and the regulations promulgated thereunder, and is vested with the responsibility of investigating CSA violations.

E. The Attorney General, through the United States Attorneys, has primary authority to bring civil actions to enforce the CSA and the regulations promulgated thereunder. *See* 21 U.S.C. § 871 and 28 C.F.R. § 0.55(c).

F. The regulations promulgated under the CSA include a requirement to design and operate a system to detect and report “suspicious orders” for controlled substances, as that term is defined in the regulation. *See* 21 C.F.R. § 1301.74(b).

G. The CSA authorizes the imposition of a civil penalty of up to \$10,000 for each violation of 21 C.F.R. § 1301.74(b). *See* 21 U.S.C. §§ 842(a)(5) and (c)(1)(B).

### III. **COVERED CONDUCT**

The United States contends that it has certain civil claims against McKesson under 21 U.S.C. §§ 821, 823, 827, and 842(a)(5) for engaging in the following conduct (the “Covered Conduct”) from January 1, 2009, through the Effective Date as that term is defined in Section

VI(F) (the “Covered Time Period”):

A. McKesson failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels by sales to certain of its customers in violation of the CSA and the CSA’s implementing regulations at McKesson Distribution Centers, including the following specific centers:

Aurora, Colorado;  
Aurora, Illinois;  
Delran, New Jersey;  
La Crosse, Wisconsin;  
Lakeland, Florida;  
Landover, Maryland;  
La Vista, Nebraska;  
Livonia, Michigan;  
Methuen, Massachusetts;  
Santa Fe Springs, California;  
Washington Courthouse, Ohio; and  
West Sacramento, California.

B. In 2008, McKesson entered into a settlement agreement with the DOJ and a Memorandum of Agreement with the DEA (collectively referred to herein as the “2008 Agreements”) arising out of, among other things, McKesson’s failure to report suspicious orders of controlled substances to the DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). As a result of the 2008 Agreements, McKesson developed a Controlled Substance Monitoring Program (“CSMP”) in which McKesson recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to the DEA. McKesson failed to properly monitor its sales of controlled substances and/or report suspicious orders to the DEA, in accordance with McKesson’s obligations under the 2008 Agreements, the CSA, and 21 C.F.R. § 1301.74(b).

C. McKesson failed to follow the procedures and policies set forth in the McKesson

CSMP to detect and disclose suspicious orders of controlled substances. Among other things, McKesson failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers, and bypassed suspicious order reporting procedures set forth in the McKesson CSMP.

D. In addition, McKesson failed to inform the DEA Field Division Offices and/or DEA Headquarters of suspicious orders of controlled substances made by its customers during the Covered Time Period, including orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency, as required by and in violation of 21 C.F.R. §1301.74(b), 21 U.S.C. § 842(a)(5), and the 2008 Agreements.

E. McKesson failed to report suspicious orders for controlled substances in accordance with the standards identified and outlined by the DEA in three letters from the DEA's Deputy Assistant Administrator, Office of Diversion Control, sent to every registered manufacturer and distributor, including McKesson, on September 27, 2006, February 7, 2007, and December 27, 2007.

F. Certain McKesson Distribution Centers distributed controlled substances to pharmacies even though those Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a).

#### **IV. ACCEPTANCE OF RESPONSIBILITY**

A. On or about September 27, 2006, February 7, 2007, and December 27, 2007, DEA's

Deputy Assistant Administrator, Office of Diversion Control, sent letters to every entity in the United States that was registered with DEA to manufacture or distribute controlled substances, including McKesson (the "DEA Letters"). The DEA Letters contained, among other things, guidance for the identification and reporting of suspicious orders to DEA, as required by 21 C.F.R. § 1301.74(b). McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum. The Compliance Addendum is an attachment to the Administrative Memorandum of Agreement (the "2017 MOA") entered into by McKesson and DEA contemporaneously with this Agreement. The Compliance Addendum and the 2017 MOA are attached hereto as Appendix B.

B. On or about May 2, 2008, DEA and McKesson entered into an Administrative Memorandum of Agreement (the "2008 MOA"). The 2008 MOA provided, among other things, that McKesson maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b), and follow procedures established by its CSMP. McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA. McKesson has taken steps to

prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

**V. TERMS AND CONDITIONS**

In consideration of the mutual promises, covenants, and obligations set forth in this Settlement Agreement, the United States and McKesson agree as follows:

A. McKesson shall pay the United States the sum of One Hundred Fifty Million Dollars (\$150,000,000.00) (the "Settlement Amount") within five (5) business days of the Effective Date of this Settlement Agreement, by electronic funds transfer ("EFT") pursuant to written instructions to be provided by the United States.

B. In consideration of the fulfillment of the payment of the Settlement Amount, the United States agrees to:

1. Fully and finally release McKesson and all McKesson facilities, including McKesson subsidiary entities, affiliates, and registrants, (collectively, the "Released Parties") from any and all civil penalty claims under 21 U.S.C. § 842 that the United States could have asserted, or may assert in the future, against McKesson related to the Covered Conduct; and
2. Refrain from filing any action for civil penalty claims under 21 U.S.C. § 842 by any U.S. Attorney's Office and/or DOJ based on the Covered Conduct.

C. Nothing in this Settlement Agreement shall prohibit or limit any other agency within DOJ or any other law enforcement, administrative, or regulatory agency of the United States from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct. DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that has initiated or initiates an investigation, action, or proceeding involving the Covered Conduct, but will not otherwise initiate or refer any civil action to any U.S. Attorney's Office or to any

component of DOJ, based on the Covered Conduct.

D. McKesson fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including for attorney's fees, costs, and expenses of every kind and however denominated) which McKesson has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct and the investigation and prosecution thereof by the United States.

E. Notwithstanding any term of this Settlement Agreement, specifically reserved and excluded from the scope and terms of this Settlement Agreement, and the releases set forth herein, as to any entity or person (including McKesson) are the following:

1. Any potential criminal liability;
2. Any civil, criminal, or administrative liability arising under Title 26, United States Code (the Internal Revenue Code);
3. Any civil or administrative liability to the United States for any conduct other than the Covered Conduct, as described in paragraph III(A)-(F); and
4. Any liability based upon any obligation created by or arising under this Settlement Agreement.

F. Contemporaneously with the execution of this Settlement Agreement, McKesson will enter into the 2017 MOA, which will resolve administrative claims that DEA has or may have against McKesson related to the Covered Conduct. *See* Appendix B. McKesson acknowledges that it is required to comply with the controlled substance record keeping and reporting requirements of the CSA. McKesson represents that it has taken, is taking, and will be taking further good faith actions to detect and prevent diversion. *See* Compliance Addendum attached hereto in Appendix B.

G. Nothing in this Settlement Agreement shall prevent, preclude, limit, or prejudice the right of the United States to enforce the CSA by commencing a civil or administrative action against McKesson for violations of the CSA, and regulations promulgated thereunder, unrelated to the Covered Conduct as described in Section III of this Settlement Agreement or which occur after the Effective Date of this Settlement Agreement.

H. McKesson agrees that any and all costs it has, will, or may incur in connection with this matter – including payment of the Settlement Amount under this Settlement Agreement, attorney's fees, costs of investigation, negotiation, future compliance efforts, and remedial action - shall be unallowable costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) for government contracting accounting and for purposes of any government reimbursement program.

I. McKesson warrants that it has reviewed its financial situation and that it currently is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and will remain solvent following its payment to the United States of the Settlement Amount. Furthermore, the Parties warrant that, in evaluating whether to execute this Settlement Agreement, they (a) intended that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to McKesson, within the meaning of 11 U.S.C. § 547(c)(1); and (b) concluded that the mutual promises, covenants, and obligations set forth herein do, in fact, constitute such a contemporaneous exchange. In addition, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value which is not meant to hinder or delay payment to, or to



defraud any entity to which McKesson was or became indebted on or after the date of this transfer, all within the meaning of 11 U.S.C. § 548(a)(1).

J. If, within 91 days of the Effective Date of this Settlement Agreement or of any payment made hereunder, McKesson commences, or a third-party commences, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors, (i) seeking to have any order for relief of McKesson's debts, or seeking to adjudicate McKesson as bankrupt or insolvent; or (ii) seeking appointment of a receiver, trustee, custodian, or other similar official for McKesson or for all or any substantial part of McKesson's assets, McKesson agrees as follows:

1. McKesson's obligations under this Settlement Agreement may not be avoided pursuant to 11 U.S.C. §§ 547 or 548, and McKesson will not argue or otherwise take the position in any such case, proceeding, or action that: (i) McKesson's obligations under this Settlement Agreement may be avoided under 11 U.S.C. §§ 547 or 548; (ii) McKesson was insolvent at the time this Settlement Agreement was entered into, or became insolvent as a result of the payment made to the United States hereunder; or (iii) the mutual promises, covenants, and obligations set forth in this Settlement Agreement do not constitute a contemporaneous exchange for new value given to McKesson;

2. If McKesson's obligations under this Settlement Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Settlement Agreement, and bring any civil claims that would otherwise be covered by the release provided in Paragraph 2, above. McKesson agrees that (i) any such claims, actions, or proceedings brought by the United States are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the action, case, or proceeding described in the first clause of this Paragraph, and that McKesson will not argue or otherwise contend that the United States' claims, actions, or proceedings are subject to an automatic stay; (ii) that McKesson will not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceeding which are brought

by the United States within 90 calendar days of written notification to McKesson that the releases herein have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on the Effective Date of the Settlement Agreement; and (iii) the United States may pursue any and all claims it had as of July 1, 2014, in the case, action, or proceeding referenced in the first clause of this Paragraph, as well as in any other case, action, or proceeding; and

3. McKesson acknowledges that its agreements in this Paragraph are provided in exchange for valuable consideration provided by and through this Settlement Agreement.

K. Each Party to this Settlement Agreement will bear its own legal expenses and other costs incurred in connection with this matter, including those for the preparation and performance of this Settlement Agreement.

L. This Settlement Agreement is intended to be for the benefit of the Parties only.

M. McKesson represents that this Settlement Agreement is freely and voluntarily entered into, without any degree of duress or compulsion whatsoever. McKesson also acknowledges that it was represented by legal counsel of its choosing throughout the negotiation and execution of this Settlement Agreement.

N. McKesson consents to the disclosure of this Settlement Agreement, information about this Settlement Agreement, and the settlement memorialized herein by the United States to the public.

O. Nothing in this Settlement Agreement constitutes an agreement by the United States concerning characterization of the Settlement Amount for purposes of Title 26 of the United States Code (Internal Revenue Code).

## VI. GENERAL PROVISIONS

A. Governing Law: This Settlement Agreement is governed by the laws of the United States of America. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties regarding this Settlement Agreement and its terms shall be the United States District Court for the Northern District of West Virginia.

B. Headings: The section and paragraph headings in this Settlement Agreement are inserted solely for the convenience of the Parties and shall not be construed to be part of or in any way affect the substantive provisions of this Settlement Agreement.

C. Merger Clause: This Settlement Agreement, including Attachments, constitutes the complete agreement and understanding by and between the United States and McKesson with respect to the settlement of claims against McKesson arising out of the Covered Conduct and no promises, agreements, or understandings, written or oral, not contained herein shall be of any force or effect. This Settlement Agreement may be amended at any time by mutual consent of the parties hereto, with any such amendment to be invalid, unless in writing, signed by an authorized agent of McKesson and an authorized representative of the United States.

D. Counterparts: This Settlement Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same agreement. Copies or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Settlement Agreement.

E. Binding: This Settlement Agreement is binding on McKesson and its successors, transferees, and assigns.

F. Effective Date: This Settlement Agreement shall be effective when the last signatory to this Settlement Agreement executes the Agreement.


G. Drafting: For purposes of construing this Settlement Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

H. Authority to Sign: Each person who signs this Settlement Agreement in a representative capacity warrants that he or she is fully authorized to do so. The government signatories represent that they are signing this Settlement Agreement in their official capacities.

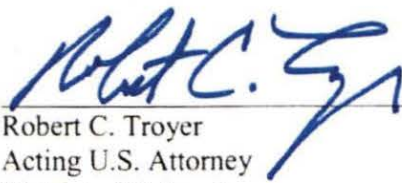
**IN WITNESS WHEREOF**, the United States and McKesson have duly executed this Settlement Agreement with the intent to be bound by the terms, conditions, and representations herein.

THE UNITED STATES OF AMERICA

Dated: 12/30/2016


  
\_\_\_\_\_  
William J. Inlenfeld, II  
U.S. Attorney  
Northern District of West Virginia

Dated: 1/17/17

  
\_\_\_\_\_  
Robert C. Troyer  
Acting U.S. Attorney  
District of Colorado

**THE UNITED STATES OF AMERICA**

Dated: 01/05/17

  
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Zachary T. Fardon  
U.S. Attorney  
Northern District of Illinois

Dated: \_\_\_\_\_

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John W. Vaudreuil  
U.S. Attorney  
Western District of Wisconsin

Dated: \_\_\_\_\_

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Barbara L. McQuade  
U.S. Attorney  
Eastern District of Michigan

Dated: \_\_\_\_\_


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Kerry B. Harvey  
U.S. Attorney  
Eastern District of Kentucky

THE UNITED STATES OF AMERICA

Dated: \_\_\_\_\_

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Zachary T. Fardon  
U.S. Attorney  
Northern District of Illinois

Dated: 1/5/2017

  
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John W. Vaudreuil  
U.S. Attorney  
Western District of Wisconsin

Dated: \_\_\_\_\_

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Northern District of Illinois

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Western District of Wisconsin

Dated: 01-05-17

  
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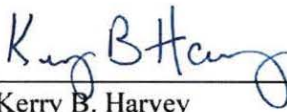
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John W. Vaudreuil  
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Western District of Wisconsin

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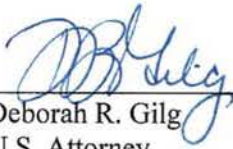
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Barbara L. McQuade  
U.S. Attorney  
Eastern District of Michigan

Dated: 1-6-17

  
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Kerry B. Harvey  
U.S. Attorney  
Eastern District of Kentucky

**THE UNITED STATES OF AMERICA**

Dated: 1/4/17

  
\_\_\_\_\_  
Deborah R. Gilg  
U.S. Attorney  
District of Nebraska

Dated: \_\_\_\_\_

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Phillip A. Talbert  
U.S. Attorney  
Eastern District of California

Dated: \_\_\_\_\_

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Carmen M. Ortiz  
U.S. Attorney  
District of Massachusetts

Dated: \_\_\_\_\_


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Paul J. Fishman  
U.S. Attorney  
District of New Jersey

**THE UNITED STATES OF AMERICA**

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District of Nebraska

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U.S. Attorney  
District of New Jersey

THE UNITED STATES OF AMERICA

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U.S. Attorney  
District of Nebraska

Dated: \_\_\_\_\_

\_\_\_\_\_  
Phillip A. Talbert  
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Eastern District of California

Dated: 1/6/17

Carmen M. Ortiz  
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U.S. Attorney  
District of Massachusetts

Dated: \_\_\_\_\_

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Paul J. Fishman  
U.S. Attorney  
District of New Jersey

THE UNITED STATES OF AMERICA

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U.S. Attorney  
District of Nebraska

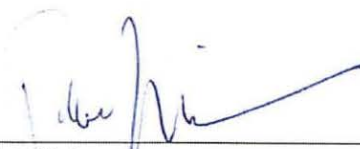
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Phillip A. Talbert  
U.S. Attorney  
Eastern District of California

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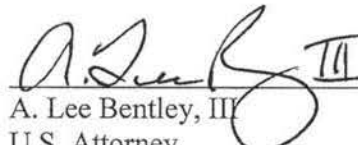
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Carmen M. Ortiz  
U.S. Attorney  
District of Massachusetts

Dated: 1/4/17

  
\_\_\_\_\_  
Paul J. Fishman  
U.S. Attorney  
District of New Jersey

THE UNITED STATES OF AMERICA

Dated: 1-3-17

  
A. Lee Bentley, III  
U.S. Attorney  
Middle District of Florida

Dated: \_\_\_\_\_

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Eileen M. Decker  
U.S. Attorney  
Central District of California

Dated: \_\_\_\_\_

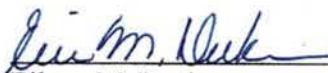
\_\_\_\_\_  
Wendy H. Goggin  
Chief Counsel  
U.S. Drug Enforcement Administration

**THE UNITED STATES OF AMERICA**

Dated: \_\_\_\_\_

\_\_\_\_\_  
A. Lee Bentley, III  
U.S. Attorney  
Middle District of Florida

Dated: 1/5/17

  
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Eileen M. Decker  
U.S. Attorney  
Central District of California

Dated: \_\_\_\_\_

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U.S. Attorney  
Central District of California


Dated: 1/5/17

  
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Wendy H. Goggin  
Chief Counsel  
U.S. Drug Enforcement Administration



**McKESSON CORPORATION**

Dated: 1/5/17

  
Lori A. Schechter  
Executive Vice President, General Counsel and  
Chief Compliance Officer for  
McKesson Corporation

Dated: 1/5/17

  
Geoffrey E. Hobart  
Covington & Burling LLP  
Counsel for McKesson Corporation