SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement ("Agreement") is entered into between the United States of America, acting through the United States Department of Justice ("DOJ") and the United States Attorney's Office for the Western District of Tennessee, 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 6555 State Highway 161, Irving, TX 70539.

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 a distribution center located in Memphis, Tennessee.

C. At all times relevant to this Agreement, McKesson owned and operated a drug packaging business located at 4971 Southridge Blvd., Memphis, TN 38141 ("McKesson RxPak"), which maintained a DEA Distributor registration number (RM0539734) as well as a DEA Manufacturer registration number (RR0276837). McKesson RxPak is no longer in business after ceasing all operations on March 4, 2020.

D. At all times relevant to this Agreement, McKesson and McKesson RxPak 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.*

E. 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.

F. 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).

G. The CSA provides for a "closed system" of distribution of controlled substances in the United States by imposing registration requirements and recordkeeping obligations on DEA registrants. *See* 21 C.F.R. § 1304.03. Accurate recordkeeping by DEA registrants is essential to maintain integrity and accountability within the controlled-substances supply chain for legitimate medical and scientific uses. The CSA gives the DEA authority to inspect DEA registrants to verify recordkeeping and inventory controls. *See* 21 C.F.R. § 1316.

H. Recognizing the importance of accurate recordkeeping to prevent the threat of diversion, the CSA authorizes liability for recordkeeping violations. *See* 21 U.S.C. § 842(a)(5). Direct evidence of illicit uses of controlled substances resulting from recordkeeping violations is not required for a penalty to be assessed. Here, the United States' inspection and investigation uncovered no direct evidence of illicit uses of controlled substances at McKesson RxPak. However, as described below as Covered Conduct, the United States' investigation did reveal numerous record-keeping deficiencies.

III. COVERED CONDUCT

A. The "Covered Conduct" shall mean the following alleged conduct that occurred between January 1, 2018 and the Effective Date of this Settlement Agreement, with respect to McKesson RxPak's DEA registration numbers RM0539734 and RR0276837.

1. McKesson RxPak failed to maintain a complete and accurate record of each controlled substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of as required by 21 C.F.R. § 1304.21(a) and 21 U.S.C. § 827(a)(3), including failure to take an initial inventory of all stocks of controlled substances as required by 21 C.F.R. § 1304.11(b) and 21 U.S.C. § 827(a)(1). Thus, an accountability audit in December of 2018 revealed overages in eight controlled substances.

2. McKesson RxPak failed to maintain and execute DEA-222 forms for Schedule II controlled substances as required by the CSA and its regulations. Examples of the alleged deficiencies include:

    i. Failure to maintain an undetermined number of Copy 3 of DEA-222 forms for purchases of Schedule II controlled substances;

    ii. Failure to maintain at least one Copy 1 of DEA-222 form for a sale of Schedule II controlled substances;

    iii. Failure to correctly identify the supplier's DEA registration number on Copies 1 and 2 of DEA-222 forms on numerous occasions, including instances where the customer's DEA registration number was used in place of the supplier's DEA registration number;

    iv. Failure to timely submit Copy 2 DEA-222 forms to DEA on numerous occasions; and

    v. Failure to maintain complete and accurate DEA-222 forms on multiple occasions, resulting in inconsistencies between McKesson RxPak's records and the information reported in ARCOS, including discrepancies in ARCOS between McKesson RxPak's reported sales and customers' reported purchases of controlled substances.

3. McKesson RxPak failed to maintain separate records for each independent activity for which they were registered, as required by 21 C.F.R. § 1304.21(c) and 21 U.S.C. § 827(b)(2)(a). For instance, during the period August 7, 2018 through December 13, 2018, RxPak transferred 13,349 containers of Schedule II controlled substances for three different drugs without maintaining Copy 1 of DEA-222, and 36,313 containers of Schedule III-V controlled substances,

for five different drugs without maintaining invoices for same. An updated ARCOS report showed that there was a difference of 1,671,500 dosage units when comparing what RxPak reported as sales versus what customers reported purchasing. There was also a difference of 410,000 dosage units when comparing what RxPak reported as a purchase versus what suppliers reported as a sale to RxPak.

4. On numerous occasions, McKesson RxPak failed to completely and accurately report to ARCOS its sales and purchases of various controlled substances. Examples of the alleged deficiencies include:

   i. Failure to report to ARCOS sales of controlled substances to its customers on multiple occasions;

   ii. Failure to report to ARCOS purchases of controlled substances from its suppliers on multiple occasions;

   iii. Failure to accurately report to ARCOS the quantity and/or type of controlled substances sold on multiple occasions;

   iv. Failure to accurately report DEA-222 Order Form numbers in ARCOS on multiple occasions.

5. On one occasion, McKesson RxPak shipped controlled substances to a customer using a DEA registration number that was no longer valid, instead of using the customer's then-current DEA registration number.

6. Investigators noted at least 12 discrepancies between the date McKesson RxPak reported controlled substances were shipped, as reported into ARCOS, when compared to the corresponding physical DEA-222 forms.

B. At all times relevant to the Covered Conduct, the CSA (21 U.S.C. § 842(c)(1)) authorized the imposition of a civil penalty of up to $25,000 for each violation of the CSA, which is subject to an inflation adjustment up to $67,627 for penalties assessed after June 19, 2020; except that violations of 21 U.S.C. § 842(a)(5) (recordkeeping and reporting violations) are subject to a civil penalty of up to $10,000 for each violation, which is subject to an inflation adjustment up to $15,691 for penalties assessed after June 19, 2020.

C. The United States contends that it has or may have certain causes of action against McKesson for civil penalties under the CSA because of the Covered Conduct.

D. This Agreement shall not be construed as an admission of liability, wrongdoing, or guilt on the part of McKesson, or a concession by the United States that its claims are not well founded.

E. To avoid the delay, expense, inconvenience, and uncertainty of litigation of these claims, the Parties agree to settle, compromise, and resolve all existing or potential claims for civil penalties the United States may have against McKesson under 21 U.S.C. § 842 of the CSA based on the Covered Conduct described in Section III above, and as further described below.

IV. 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 to the United States One Million Dollars ($1,000,000.00) ("the Settlement Amount"), by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney's Office for the Western District of Tennessee, no later than fifteen (15) days after the Effective Date of this Agreement.

B. Subject to the exceptions set forth in Paragraph IV.D. below, and conditioned only upon timely receipt of the payment as described above in Paragraph IV.A. of this Agreement, the United States agrees to settle and fully and finally release McKesson and the McKesson RxPak facility, including McKesson subsidiary entities, affiliates, and its employees from all claims for civil penalties that the United States could have asserted, or may assert in the future, under 21 U.S.C. § 842 for possible violations of the CSA, and the regulations promulgated thereunder, based on the Covered Conduct.

C. McKesson fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind

and however denominated) which it has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents related to the investigation, prosecution, and settlement of this matter.

D. Notwithstanding any term of this Agreement, the following are specifically reserved and excluded from its scope and terms as to any entity or person:

1. Any potential criminal liability;

2. Any criminal, civil, or administrative claims arising under Title 26, U.S. Code (Internal Revenue Service);

3. Any administrative liability, including mandatory exclusion from any federal programs;

4. Any liability to the United States for any conduct other than that covered by the release in Paragraph IV.B; and

5. Any claims based on such obligations as are created by this Agreement.

E. McKesson agrees that any and all costs it has or will incur in connection with this matter—including payment of the Settlement Amount under this Agreement, attorney's fees, costs of investigation, negotiation, 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, including but not limited to Medicare, Medicaid, TriCare and FEHBP.

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

G. This Agreement is intended to be only for the benefit of the Parties. The Parties do not release any claims against any other person or entity not expressly released by this Agreement.

H. This Agreement shall be governed by the laws of the United States. If a dispute arises under this Agreement between the Parties, exclusive jurisdiction and venue shall lie in the United States District Court for the Western District of Tennessee.

I. This Agreement sets forth the entire agreement between the parties hereto, and fully supersedes any and all prior agreements between those parties pertaining to the subject matter hereof. No representations, warranties, or other statements or promises have been made by any party in connection with this Agreement.

J. This Agreement may be amended or modified only by written agreement, executed by the authorized representative of each party, and expressly stating the intent to modify the Agreement.

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

L. This Agreement shall be effective on the date of signing by all parties ("the Effective Date of this Agreement").

M. All parties acknowledge that the United States may disclose this Agreement, and information about this Agreement, to the public.

N. Each person who signs this 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 Agreement in their official capacities.

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

P. This Agreement is binding on McKesson's successors, transferees, heirs, and assigns.

Q. This Agreement may be executed in counterparts, each of which shall constitute an original and all of which shall constitute one and the same agreement. For the convenience of the Parties, faxed or emailed signatures will suffice for the purposes of binding all parties to this Agreement.

R. It is also agreed, by and among the Parties, that the Parties will each bear their own costs, fees, and expenses incurred in connection with the investigation, negotiation, and resolution of this matter, including the preparation and performance of this Agreement.

On behalf of McKesson Corporation:

Saralisa Brau,
McKesson Corporate Secretary

Dated: February 3, 2022

On behalf of the United States of America

DEA
J. Todd Scott Special Agent in Charge
Dated: 2.22.2022

Eileen Kuo
Assistant United States Attorney
United States Attorney's Office, WDTN
167 N. Main St. Suite 800
Memphis, TN 38103

Dated: 2.15.2022