SETTLEMENT AGREEMENT

I. Recitals

1. Parties. The Parties to this Settlement Agreement (Agreement) are the United States Department of Health and Human Services (HHS), acting through the Office of Inspector General (OIG), and Sandoz Inc. (hereafter "Sandoz" or "Respondent").

2. Description of the Medicaid Drug Rebate Program and Civil Monetary Penalties. The Medicaid Drug Rebate Program, codified at 42 U.S.C. § 1396r-8, requires pharmaceutical drug manufacturers to enter into and have in effect a national rebate agreement with the Secretary of HHS in order for Medicaid payments to be available for a pharmaceutical manufacturer's covered drugs. Manufacturers with such agreements are required to submit certain drug pricing information to HHS, including quarterly Average Sales Price (ASP) and sales volume data. 42 U.S.C. § 1396r-8(b)(3)(A); 42 U.S.C. 1395w–3a; see 42 C.F.R. §§ 414.804, 414.806.

Under 42 U.S.C. § 1396r-8(b)(3)(C), the Secretary of HHS is authorized to impose a civil money penalty of $100,000 for each item of false information which is knowingly provided to HHS. Further, 42 U.S.C. § 1395w-3a(d)(4) provides for civil monetary penalties of $10,000 per day for a manufacturer that has made a misrepresentation in the reporting of the manufacturer's average sales price for a drug or biological.

3. Factual Background and Covered Conduct. The OIG contends that Sandoz failed to submit accurate ASP data to CMS for each quarter from January 2010 through March 2012. The submission of inaccurate ASP data described in this paragraph is hereinafter referred to as the "Covered Conduct." The OIG contends that the Covered Conduct violated 42 U.S.C. § 1396r-8(b)(3). OIG contends that, based on the Covered Conduct, the OIG may impose civil monetary penalties against Respondent under 42 U.S.C. §§ 1396r-8(b)(3)(C) and 1395w-3a(d)(4).

4. No Admission nor Concession. This Agreement is neither an admission of liability by Respondent nor a concession by the OIG that its claims are not well-founded.

5. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, the Parties agree to resolve this matter according to the Terms and Conditions below.

6. Effective Date. This Agreement shall become effective (i.e., final and binding) upon the date of signature by the last signatory and upon payment of the Settlement Amount as described in Paragraph 7 (Effective Date).

II. Terms and Conditions

7. Settlement Amount. Respondent agrees to pay the OIG $12,640,000 (Settlement Amount). This payment shall be made via wire transfer to the United States Department of Health and Human Services according to written instructions provided by OIG. Respondent shall make full payment no later than ten business days after Respondent signs the Agreement.

8. Certification. On or before the Effective Date of this Agreement, Sandoz shall provide the OIG with a certification (at Appendix A, which is incorporated by reference), regarding its Government Pricing Compliance Program.

9. Release by OIG. In consideration of the obligations of Respondent under this Agreement and the Certification in Appendix A, and conditioned upon Respondent's full and timely payment of the Settlement Amount as set forth in Paragraph 7, the OIG releases Respondent from any claims or causes of action it may have under 42 U.S.C. §§ 1396r-8(b)(3) and 1395w-3a(d)(4)for the Covered Conduct. The OIG and HHS do not waive any rights, obligations, or causes of action other than those specifically referred to in this Paragraph. This release is applicable only to the Respondent and any successors in interest to Respondent, and includes without limitation Sandoz and its parents, subsidiaries, and affiliates, and is not applicable in any manner to any other individual, partnership, corporation, or entity.

10. Agreement by Released Parties. Respondent shall not contest the Settlement Amount under this Agreement. Respondent waives all procedural rights granted under the Civil Monetary Penalties Law (42 U.S.C. § 1320a-7a) and related regulations (42 C.F.R. Part 1003), and HHS claims collection regulations (45 C.F.R. Part 30), including, but not limited to, notice, hearing, and appeal with respect to the Settlement Amount.

11. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including Respondent) are the following:

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

b. Any criminal liability;

c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs; and

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct.

12. Binding on Successors. This Agreement is binding on Respondent and its successors, heirs, transferees, and assigns.

13. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

14. No Additional Releases. This Agreement is intended to be for the benefit of the Parties only and by this instrument the Parties do not release any claims against any other person or entity.

15. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties relating to the Covered Conduct. All material representations, understandings, and promises of the Parties are contained solely in this Agreement. Any modification to this Agreement shall be set forth in writing and signed by all the Parties. Respondent represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. Respondent further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

16. Disclosure of Agreement. Respondent consents to OIG's disclosure of this Agreement and information about this Agreement to the public.

17. Execution in Counterparts. This Agreement may be executed in counterparts and by facsimile, each of which constitutes an original, and all of which shall constitute one and the same Agreement.

18. Authorizations. The individuals signing this Agreement on behalf of Respondent represent and warrant that they are authorized by Respondent to execute this Agreement. The individuals signing this Agreement on behalf of the OIG represent and warrant that they are signing this Agreement in their official capacities and that they are authorized to execute the Agreement.

ON BEHALF OF SANDOZ INC.

MARKUS HARTMANN
Vice President & North American General Counsel
Sandoz Inc.

3/9/2015
DATE

JONATHAN L. DIESENHAUS
Partner
Hogan Lovells US, LLP
Counsel for Sandoz Inc.

3/9/2015
DATE

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

Robert K. DeConti
ROBERT K. DECONTI
Assistant Inspector General for Legal Affairs
Office of Inspector General
United States Department of Health and Human Services

3/11/15
DATE

Geeta Kaveti by NC
GEETA W. KAVETI
Senior Counsel
Office of Counsel to the Inspector General

3/10/15
DATE

Nicole Caucci
NICOLE CAUCCI
Senior Counsel
Office of Counsel to the Inspector General

3/10/15
DATE

APPENDIX A

GOVERNMENT PRICING COMPLIANCE PROGRAM CERTIFICATION

I. PREAMBLE

Sandoz, Inc. has established a voluntary Government Pricing Compliance Program (GP Compliance Program). The GP Compliance Program includes a GP Compliance Director and GP Compliance Committee. The GP Compliance Program also includes a Code of Conduct and written policies requiring, among other thing, written GP methodologies, a GP-specific training program, a Disclosure Program that allows for confidential disclosure and investigation of potential compliance violations and disciplinary procedures, and an auditing and monitoring program.

The following definitions govern the scope of this Certification.

1. "Government Pricing Programs" refers to the Medicaid Drug Rebate Program (codified at 42 U.S.C. § 1396r-8), the Medicare Program (42 U.S.C. §§ 1395-1395hhh), state price reporting programs, and the 340B Drug Pricing Program, codified at 42 U.S.C. § 256b (the 340B Program).

2. "Government Pricing Functions" refers to the collection, calculation, verification, or reporting of information for purposes of the Government Pricing Programs. Persons engaged in these functions include individuals whose job responsibilities include the calculation and reporting of Average Sales Price (ASP), Average Manufacturer Price (AMP), Best Price (BP), the 340B Program ceiling price, Average Wholesale Price (AWP) (if applicable), non-Federal Average Manufacturer Price, and all other information calculated and reported by Sandoz and used in connection with Federal health care programs.

3. "Government Pricing Personnel" include any owners, managers, directors, employees, contractors, subcontractors or other persons who are engaged in or have responsibilities relating to the Government Pricing Functions described above.

II. CERTIFICATION

The certifier is currently the Vice President, Chief Ethics and Compliance Officer for Sandoz, Inc. and has personal knowledge of the facts stated herein. The following describes the Government Pricing compliance program (Program) at Sandoz, Inc. The Program includes:

1. A Government Pricing Compliance Director (Compliance Director) who is responsible for overseeing the Program which includes policies, procedures, and practices designed to ensure compliance with Government Pricing and Reporting requirements. The Compliance Director reports directly to the Chief Ethics and Compliance Officer of Sandoz, Inc. The Compliance Director makes periodic (monthly) reports regarding compliance matters to the Government Pricing Compliance Committee.

2. A Government Pricing Compliance Committee that is chaired by the Vice President, Head Pricing, Contracts and Business Analytics and that is made up of members of senior management necessary to support the Compliance Director in fulfilling his/her responsibilities under the Program (e.g., senior executives of departments with responsibilities related to the Government Pricing Functions, including the Vice Presidents and Heads or delegates of Compliance, Finance, Legal, Pricing and Market Analytics, Marketing and Sales, Supply Chain and Development).

3. Dedicated departmental liaisons knowledgeable in Government Pricing Policies for each relevant business function (including Launch, Marketing and Sales, Communication Operations, Regulatory, and Product Management). The departmental liaisons are responsible for ensuring their designated group's involvement and compliance with Government Pricing Policies. The departmental liaisons participate in governmental training and periodic meetings with the Compliance Director.

4. A Code of Conduct and US Supplement that includes: (a) Sandoz's commitment to comply with all Federal health care program and Government Pricing Program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements; (b) Sandoz's requirement that all of its personnel are expected to comply with all Federal health care program and Government Pricing Program requirements and with the Policies and written methodologies described in Paragraph 5 below; (c) the requirement that all of Sandoz's personnel are expected to report to the Compliance Director or other appropriate individual designated by Sandoz suspected violations of any Federal health care program and/or Government Pricing Program requirements or of Sandoz's own Policies and written methodologies; (d) the possible consequences of failure to comply with Federal health care program and Government Pricing Program requirements and with Sandoz's own Policies and Procedures and the failure to report such noncompliance; and (e) the right of Sandoz's

personnel to use the Disclosure Program described in Paragraph 8 below and Sandoz's commitment to non-retaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures. All Government Pricing Personnel are required to certify in writing that he or she has received, read, understood, and will abide by the Code of Conduct and US Supplement.

5. Government Pricing Policies regarding Sandoz's compliance with all GP requirements and Sandoz's commitment to appropriate compliance, resources, training, corrective and disciplinary actions. The Policies include specific federal pricing policies (AMP, BP, ASP, Federal Supply Schedule, non-FAMP) and relevant state policies. The Policies require that Sandoz draft, update and maintain written GP methodologies that include appropriate methodologies for all of the federal pricing requirements and include specific information regarding responsible parties, key controls, timely completion, and documented review. The Policies and written GP methodologies are and will be distributed to all relevant Sandoz Government Pricing personnel. At least annually (and more frequently, if appropriate), Sandoz reviews and updates as necessary its Policies and written GP methodologies and, if revisions are made, distributes the relevant portions of any revised Policies and written GP methodologies to Government Pricing Personnel whose job functions relate to the revised Policies and methodologies.

6. An annual training program that requires Government Pricing Personnel to attend annual compliance training that addresses Sandoz's Code of Conduct and the operation of the Program, including federal price points, bundling, and state reporting. Sandoz's annual training program also requires additional specific GP training on the following topics: (a) Class of Trade; (b) Product Master; (c) Returns and Transaction Types; (d) applicable reimbursement statutes, regulations, and program requirements and directives; and (e) 340B reporting. Sandoz maintains written or electronic records that identify the type of annual training provided, the date(s) of the training, and the attendees. Persons providing the training are knowledgeable about the subject area. Sandoz reviews the training content on an annual basis and, as appropriate, updates the training to reflect changes in GP requirements and/or any issues discovered during the internal audits described in Paragraph 7 below.

7. An audit program that will assess Sandoz's GP pricing for all four federal price types (AMP, BP, Non-FAMP, and ASP) and state reporting (Texas) compliance in three-year cycles. Years 1 and 2 of the cycle will use a sampling approach to randomly sample all attributes of the GP System including Class of Trade, Transaction Type, and Treatment (i.e., bundling, smoothing, inclusions/exclusions) and the testing includes at least 120 sales and price concession transactions and product master testing for at least 30 NDCs. In Year 3 of the audit cycle, Sandoz will perform a full assessment of the GP system including a full population parallel calculation, attribute profiling and analysis. Under the audit program description, each audit includes a Corrective Action Plan (CAP)

that is presented to the GP Compliance Committee and managed by the GP Compliance Director.

8. A Disclosure Program that includes a mechanism to enable individuals to disclose, to the Compliance Director or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Sandoz's policies, conduct, practices, or procedures with respect to a Federal health care program and/or a Government Pricing Program believed by the individual to be a potential violation of criminal, civil, or administrative law. Sandoz publicizes the existence of the disclosure mechanism to all personnel. The Disclosure Program emphasizes a nonretribution, nonretaliation policy and includes a reporting mechanism for anonymous communications for which appropriate confidentiality is maintained. Disclosures related to Government Pricing are reviewed by the Compliance Director, who either investigates the disclosure or refers the disclosure to the relevant department or manager for follow up and any appropriate corrective action. Sandoz maintains disclosure logs, which include a record and summary of each disclosure received (whether anonymous or not), the status of Sandoz's internal review of the allegations, and any corrective action taken in response to the internal review.

The undersigned signatory represents and warrants that he/she is authorized to execute this certification on behalf of Sandoz.

I certify under penalty of perjury that Sandoz has implemented the GP Compliance Program described in this Appendix A.

Executed on this 9 day of March - 2015.

Edward Stueck
Vice President,
Chief Ethics and Compliance Officer
Sandoz Inc.