UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, ALASKA, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, VIRGINIA, WASHINGTON and the DISTRICT OF COLUMBIA *ex rel.* JOHN ERICKSON and DAVID BARRY,

Plaintiffs,

v.

AMAZON.COM, INC. and AMAZON PILLPACK f/k/a PILLPACK, LLC,

Defendants.

UNITED STATES OF AMERICA,

Plaintiff-Intervenor,

v.

PILLPACK LLC,

Defendant.

STIPULATION OF SETTLEMENT

WHEREAS, this Stipulation of Settlement ("Stipulation") is entered into by and among plaintiff the United States of America (the "United States" or the "Government"), by its attorney, Damian Williams, United States Attorney for the Southern

District of New York; the relators John Erickson and David Barry ("Relators"), by their authorized representatives; and defendant PillPack LLC ("PillPack" or "Defendant", and together with the Government and Relators, the "Parties"), by its authorized representatives;

WHEREAS, PillPack is an online retail pharmacy headquartered in Manchester, New Hampshire, that is licensed to dispense prescription drugs to patients in all 50 states and the District of Columbia;

WHEREAS, PillPack is a wholly-owned subsidiary of Amazon.com, Inc. ("Amazon"), the online retailer headquartered in Seattle, Washington. In September 2018, Amazon acquired the corporate predecessor of PillPack, PillPack, Inc., which was founded in 2013 and began serving customers in 2014;

WHEREAS, on or about July 18, 2019, Relators filed a complaint ("Relator Complaint") under the *qui tam* provisions of the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*, and comparable state false claims and insurance fraud laws, against Amazon, and Amazon PillPack f/k/a PillPack, LLC alleging, among other things, that they engaged in a pattern of submitting false claims to Medicare and Medicaid seeking reimbursement for insulin pens dispensed to patients that exceeded the amounts prescribed by the patients' physicians for the time periods specified in the claims;

WHEREAS, the Government alleges that from April 2014 through November 2019 (the "Covered Period"), PillPack violated the FCA by submitting to Government Healthcare Programs, including Medicare, Medicaid, TRICARE, and the Federal Employees Health Benefits Program ("FEHBP," and collectively, "GHPs"), reimbursement claims for insulin pens¹ that falsely underreported the days-of-supply (*i.e.*, the number of days that insulin pens should last if the patient used insulin according to the prescribers' directions for use) and were dispensed substantially

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¹ A list of the types of insulin pens relevant to this Stipulation, by brand names and by national drug codes, is attached as Exhibit A herein.

earlier than the patients actually needed insulin pen refills according to the prescribers' instructions; and that, due to this practice, the GHPs reimbursed Defendant for more insulin than certain patients needed. The conduct described in this Paragraph is the "Covered Conduct" for purposes of this Stipulation;

WHEREAS, on or about April 21, 2022, the Government filed a Notice of Election to Intervene and Complaint-In-Intervention in the above-referenced *qui tam* action (the "Government Complaint"), in which it asserts claims against Defendant under the FCA for the Covered Conduct;

WHEREAS, in February 2020, the U.S. Attorney's Office for the Southern District of New York ("SDNY") contacted Defendant about SDNY's ongoing investigation of the Covered Conduct. Subsequently, counsel for PillPack informed SDNY that PillPack weeks before had started to prepare a submission to the U.S. Department of Health and Human Services Office of the Inspector General ("OIG") related to the Covered Conduct in order to request acceptance into OIG's Healthcare Fraud Self-Disclosure Protocol (the "Request"). On or about May 8, 2020, PillPack submitted the Request to OIG. OIG subsequently denied the Request;

WHEREAS, Defendant intends to enter into separate settlement agreements with a number of States and the District of Columbia named as plaintiffs in this Action (collectively, the "States") to resolve claims asserted by the States under state false claims laws for the Covered Conduct (the "State Settlements"), and has agreed to pay a total of \$175,522.55 to the States pursuant to the State Settlements;

WHEREAS, the Relators' claim to a share of the proceeds from the settlement of claims arising from the Relators' Complaint is the subject of a separate agreement between the Relators and the United States;

WHEREAS, the Parties have, through this Stipulation, reached a mutually agreeable resolution addressing the claims asserted against Defendant in the Government Complaint and the Relator Complaint, for the Covered Conduct;

NOW, THEREFORE, IT IS HEREBY AGREED THAT:

TERMS AND CONDITIONS

- 1. The Parties agree that this Court has subject matter jurisdiction over this action and consent to this Court's exercise of personal jurisdiction over each of them.
- 2. Defendant admits, acknowledges, and accepts responsibility for the following conduct (the "Admitted Conduct"):
 - a. Insulin "pens" are a common way for diabetic patients, including GHP beneficiaries, to self-administer insulin. Manufacturers distribute the insulin pens relevant here in tamper-evident cartons containing between two and five pens and with labeling approved by the U.S. Food and Drug Administration ("FDA")². Insulin pens are most frequently marketed in carton sizes containing five 100 unit/mL pens. In the five-pen boxes, each pen consists of a syringe, which contains 300 units (3 mL) of insulin solution, inside a hard plastic case. A box of five pens contains 1500 (15 mL) units of insulin solution.
 - b. FDA classifies the insulin pens relevant here as prescription drug products. Pharmacies can dispense such pens to patients only with valid prescriptions from licensed prescribers. Valid insulin prescriptions must set forth the "directions for use," which typically designate both how much insulin to administer (*e.g.*, 10 units) and the frequency and/or timing of when to administer it (*e.g.*, once a day at bedtime).
 - c. At all relevant times, when PillPack sought reimbursement for insulin pens from GHPs, it was required to report, among other data fields, the quantity dispensed and the days-of-supply. In pharmacy billing, "quantity dispensed" specifies the amount of medication being dispensed to a patient when they fill their prescription, and "days-of-supply" refers to the number of days that the quantity of medication dispensed should last if the patient uses the medication according to the directions for use. Typically, to calculate days-of-supply, a pharmacist divides the total quantity of medication being dispensed to a particular patient by that patient's "daily dose," *i.e.*, the amount of medication that the prescriber directs the patient to use each day.
 - d. GHPs, or pharmacy benefit managers ("PBMs") working on their behalf, typically establish procedures to calculate the date on which a prescription refill would be needed (the "refill due date") based on the date when a patient last filled a prescription and the days-of-supply reported by the pharmacy for that prior fill.

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² In November 2019, the FDA approved revisions to the labeling for insulin pens to emphasize the agency's recommendation for dispensing insulin pens to a single patient in their original sealed carton. The FDA strongly encouraged the manufacturers of insulin pens to consider developing smaller carton sizes to better accommodate variable insulin doses and needs. The FDA also suggested that organizations facing challenges with large carton sizes (multiple-pen cartons) contact the manufacturers to express the need for smaller (and single-pen) carton sizes. The FDA approved the first single-pen carton size for an insulin product on June 11, 2020.

- GHPs, and the PBMs working on their behalf, also typically establish automated processes to deny claims for reimbursement for refills that are submitted too far in advance of the refill due dates. The reliability of these procedures and processes depends on the accuracy of the days-of-supply reported by pharmacies.
- e. PillPack was aware that GHPs and payors working on their behalf had established dispensing limits for prescription drug products in terms of quantity and days-of-supply and that such GHPs and payors would deny a claim if the reported days-of-supply exceeded those days-of-supply limits, unless PillPack obtained an override from the GHP or payor authorizing PillPack to dispense the quantity of medication exceeding the days-of-supply limit.
- f. During the Covered Period, PillPack's insulin pen dispensing practice was to supply patients with a full carton of insulin pens. In many instances, this resulted in exceeding the GHP's applicable days-of-supply limit. Instead of accurately reporting the days-of-supply and contacting the GHP or its agent to attain the requisite override, in many instances PillPack would dispense and bill for the full carton, and reduce the days-of-supply reported to the GHP to conform to the GHP's days-of-supply limit. As a result, for those claims, PillPack reported days-of-supply data to GHPs that were different from, and lower than, the days-of-supply that should have been reported had PillPack calculated days-of-supply according to the typical pharmacy billing formula of dividing the quantity of insulin dispensed by the daily dose.
- g. PillPack utilizes prescription management and dispensing software, including a technology called the Refill Logic, to determine refill due dates for medications. The Refill Logic program is designed to prevent PillPack pharmacists from prematurely dispensing refills to patients, and to ensure that refills are not dispensed before patients should have taken approximately 80% of the medication dispensed through the last fill. Prior to April 2019, PillPack's Refill Logic program determined refill dates based on the reported days-of-supply. Thus, during this time period, when PillPack pharmacists reported inaccurate lower days-of-supply data to GHPs and payors working on their behalf, the Refill Logic program used this inaccurate data to generate premature refill due dates, causing PillPack pharmacists to dispense insulin pen refills to patients days or weeks before the patients actually needed them according to their prescriptions.
- h. During the Covered Period, PillPack received audit reports from PBMs, acting on behalf of GHPs, requesting that PillPack repay the overpayments it had received for insulin pen prescription claims due to inaccurate days-of-supply reporting.
- i. GHPs and payors working on their behalf approved and paid claims submitted by PillPack for insulin pen refills that they would not have approved if PillPack had accurately reported the days-of-supply for previous fills according to the typical pharmacy billing formula of dividing the quantity dispensed by the daily dose. Specifically, PillPack's practice of dispensing and submitting reimbursement claims for insulin pen refills using inaccurate lower days-of-supply data prevented GHPs and payors working on their behalf from reliably calculating refill due dates and confirming that refills had not been prematurely dispensed before approving PillPack's claims for reimbursement.

- j. In certain instances, over time, patients accumulated multiple extra insulin pens that they did not need according to their prescriptions.
- 3. Defendant shall pay to the Government within fourteen (14) business days of the Effective Date (defined below in Paragraph 30) the sum of \$5,616,136.85 plus interest which shall be compounded annually at a rate of 1.5% accruing from January 21, 2022, to the date of the payment (the "Settlement Amount") in accordance with instructions to be provided by the Financial Litigation Unit of the SDNY. Of the Settlement Amount, \$2,808,068.43 plus applicable interest constitutes restitution to the United States.
- 4. Defendant agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Stipulation. Upon reasonable notice, Defendant shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Defendant further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.
- 5. Subject to the exceptions in Paragraph 9 (concerning reserved claims) below and subject to Paragraph 10 (concerning default) and Paragraph 15 (concerning bankruptcy proceedings) below, and conditioned on Defendant's full compliance with the terms of this Stipulation, including full payment of the Settlement Amount to the United States pursuant to Paragraph 3 above, the United States releases Defendant, including its parents, subsidiaries and corporate predecessors, successors and assigns, from any civil or administrative monetary claim that the United States has for the Covered Conduct under

the FCA, the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, the Program Fraud Civil Remedies Act, 31 U.S.C. § 3801-3812, and the common law theories of fraud, payment by mistake, and unjust enrichment. For avoidance of doubt, this Stipulation does not release any current or former officer, director, employee, or agent of Defendant from liability of any kind.

- 6. Defendant fully and finally releases the United States, its agencies, officers, employees, servants, and agents from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Defendant has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, employees, servants, or agents related to the Covered Conduct or the United States' investigation, prosecution and settlement thereof.
- 7. Subject to Defendant's full payment of the Settlement Amount to the United States pursuant to Paragraph 3 above, Relators, for themselves and their heirs, successors, attorneys, agents, and assigns, release Defendant, including its parents, subsidiaries and corporate predecessors, successors and assigns, as well as all of its current and former officers, directors, employees, attorneys, and other agents, from any and all manner of claims, proceedings, liens, and causes of action of any kind or description that Relators have against Defendant up to and through the Effective Date of this Stipulation; provided, however, that nothing in this Stipulation shall preclude Relators from seeking to recover their reasonable expenses and attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d).
- 8. In consideration of the execution of this Stipulation by Relators and the Relators' release as set forth in Paragraph 7 above, Defendant, including its subsidiaries, predecessors, and corporate successors and assigns, as well as all of its current and former officers, directors, employees, attorneys, and other agents, release Relators and their heirs, successors, attorneys, agents, and assigns, from any and all manner of claims, proceedings,

liens, and causes of action of any kind or description that Defendant has against Relators up to and through the Effective Date of this Stipulation.

- 9. Notwithstanding the releases given in Paragraph 5 above, or any other term of this Stipulation, the following claims of the Government are specifically reserved and are not released by this Stipulation:
 - a. any liability arising under Title 26, United States Code (Internal Revenue Code);
 - b. any criminal liability;
 - c. except as explicitly stated in this Stipulation, any administrative liability or enforcement right, including but not limited to the mandatory or permissive exclusion from Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) or 42 U.S.C. § 1320a-7(b) (permissive exclusion);
 - d. any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
 - e. any liability based upon obligations created by this Stipulation; and
 - f. any liability of individuals.
- 10. Defendant shall be in default of this Stipulation if Defendant fails to make the required payment set forth in Paragraph 3 above on or before the due date for such payment, or if it fails to comply materially with any other term of this Stipulation that applies to it ("Default"). The Government will provide a written Notice of Default to Defendant of any Default in the manner set forth in Paragraph 29 below. Defendant shall then have an opportunity to cure the Default within seven (7) calendar days from the date of receipt of the Notice of Default by making the payment due and paying any additional interest accruing under the Stipulation up to the date of payment. If Defendant fails to cure the Default within seven (7) calendar days of receiving the Notice of Default ("Uncured Default"), interest on the remaining unpaid balance shall thereafter accrue at the rate of 12% per annum, compounded daily from the date of Default, on the remaining unpaid total

(principal and interest balance). In the event of an Uncured Default, Defendant shall agree to the entry of a consent judgment in favor of the United States against Defendant in the amount of the Settlement Amount as attached hereto as Exhibit B. Defendant also agrees that the United States, at its sole discretion, may (i) retain any payments previously made, rescind this Stipulation, and reinstate the claims asserted against Defendant in the Government Complaint, or bring any civil and/or administrative claim, action, or proceeding against Defendant for the claims that would otherwise be covered by the releases provided in Paragraph 5 above with any recovery reduced by the amount of any payments previously made by Defendant to the United States under this Stipulation; (ii) take any action to enforce this Stipulation in a new action or by reinstating the Government Complaint; (iii) offset the remaining unpaid balance from any amounts due and owing to Defendant and/or affiliated companies by any department, agency, or agent of the United States at the time of Default or subsequently; and/or (iv) exercise any other right granted by law, or under the terms of this Stipulation, or recognizable at common law or in equity. The United States shall be entitled to any other rights granted by law or in equity by reason of Default, including referral of this matter for private collection. In the event the United States pursues a collection action, Defendant agrees immediately to pay the United States the greater of (i) a ten-percent (10%) surcharge of the amount collected, as allowed by 28 U.S.C. § 3011(a), or (ii) the United States' reasonable attorneys' fees and expenses incurred in such an action. In the event that the United States opts to rescind this Stipulation pursuant to this paragraph, Defendant waives and agrees not to plead, argue, or otherwise raise any defenses of statute of limitations, laches, estoppel or similar theories, to any civil or administrative claims that (i) are filed by the United States against Defendant within 120 days of written notification that this Stipulation has been rescinded, and (ii) relate to the Covered Conduct, except to the extent these defenses were available on July 18, 2019.

Defendant agrees not to contest any offset, recoupment, and/or collection action undertaken by the United States pursuant to this paragraph, either administratively or in any state or federal court, except on the grounds of actual payment to the United States.

11. Defendant, having truthfully admitted to the Admitted Conduct set forth in Paragraph 2 hereof, agrees it shall not, through its attorneys, agents, officers, or employees, make any public statement, including but not limited to, any statement in a press release, social media forum, or website, that contradicts or is inconsistent with the Admitted Conduct or suggests that the Admitted Conduct is not wrongful (a "Contradictory Statement"). Any Contradictory Statement by Defendant, its attorneys agents, officers, or employees, shall constitute a violation of this Stipulation, thereby authorizing the Government to pursue any of the remedies set forth in Paragraph 10 hereof, or seek other appropriate relief from the Court. Before pursuing any remedy, the Government shall notify Defendant that it has determined that Defendant has made a Contradictory Statement. Upon receiving notice from the Government, Defendant may cure the violation by repudiating the Contradictory Statement in a press release or other public statement within four business days. If Defendant learns of a potential Contradictory Statement by its attorneys, agents, officers, or employees, Defendant must notify the Government of the statement within 24 hours. The decision as to whether any statement constitutes a Contradictory Statement or will be imputed to Defendant for the purpose of this Stipulation, or whether Defendant adequately repudiated a Contradictory Statement to cure a violation of this Stipulation, shall be within the sole discretion of the Government. Consistent with this provision, Defendant may raise defenses and/or assert affirmative claims or defenses in any proceeding brought by private and/or public parties, so long as doing so would not contradict or be inconsistent with the Admitted Conduct.

- 12. Relators and their heirs, successors, attorneys, agents, and assigns shall not object to this Stipulation; Relators agree and confirm that the terms of this Stipulation are fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B).
- 13. Defendant agrees that it waives and shall not seek payment for any of the health care billings covered by this Stipulation from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.
- 14. Defendant waives and shall not assert any defenses Defendant may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Stipulation bars a remedy sought in such criminal prosecution or administrative action.
- 15. In exchange for valuable consideration provided in this Stipulation, Defendant acknowledges the following:
 - a. Defendant has reviewed its financial situation and warrants that it is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I) and shall remain solvent following payment to the United States of the Settlement Amount.
 - b. In evaluating whether to execute this Agreement, the Parties intend that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to Defendant, within the meaning of 11 U.S.C. § 547(c)(1), and the Parties conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange.
 - c. The mutual promises, covenants, and obligations set forth herein are intended by the Parties to, and do in fact, constitute a reasonably equivalent exchange of value.
 - d. The Parties do not intend to hinder, delay, or defraud any entity to which Defendant was or became indebted on or after the date of any transfer contemplated in this Stipulation, within the meaning of 11 U.S.C. § 548(a)(1).

- e. If Defendant's obligations under this Stipulation are avoided for any reason (including but not limited to through the exercise of a trustee's avoidance powers under the Bankruptcy Code) or if, before the Settlement Amount is paid in full, Defendant or a third party commences a case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors seeking any order for relief of Defendant's debts, or to adjudicate Defendant as bankrupt or insolvent, or seeking appointment of a receiver, trustee, custodian, or other similar official for Defendant or for all or any substantial part of Defendant's assets:
 - (1) the United States may rescind the releases in this Stipulation and bring any civil and/or administrative claim, action, or proceeding against Defendant for the claims that would otherwise be covered by the releases provided in Paragraph 5 above;
 - (2) the United States has an undisputed, noncontingent, and liquidated allowed claim against Defendant in the amount of \$5,616,136.85 less any payments received pursuant to the Stipulation, provided, however, that such payments are not otherwise avoided and recovered from the United States by Defendant, a receiver, trustee, custodian, or other similar official for Defendant; and
 - if any payments are avoided and recovered by Defendant, a receiver, trustee, custodian, or similar official for Defendant, Relators shall, within thirty days of written notice from the United States to the undersigned Relators' counsel, return any portions of such payments already paid by the United States to Relators.
- f. Defendant agrees that any civil and/or administrative claim, action, or proceeding brought by the United States under Paragraph 15(e) above is not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) because it would be an exercise of the United States' police and regulatory power. Defendant shall not argue or otherwise contend that the United States' claim, action, or proceeding is subject to an automatic stay and, to the extent necessary, consents to relief from the automatic stay for cause under 11 U.S.C. § 362(d)(1). Defendant waives and shall 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 claim, action, or proceeding brought by the United States within 120 days of written notification to Defendant that the releases have been rescinded pursuant to this paragraph, except to the extent such defenses were available on July 18, 2019.
- 16. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare, Medicaid, TRICARE, or FEHBP contractor (*e.g.*, Medicare, Medicaid, TRICARE, or FEHBP Administrative Contractor, fiscal intermediary, carrier) or any state payor related to the Covered Conduct; and Defendant agrees not to resubmit to any Medicare, Medicaid, TRICARE, or FEHBP

contractor or any state payor any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

- 17. Defendant agrees to the following:
 - a. Unallowable Costs Defined: All 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. §§ 1395-1395III and 1396-1396w-6; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Defendant, including its present or former officers, directors, employees, and agents in connection with:

- (1) the matters covered by this Stipulation;
- (2) the United States' and States' audit(s) and civil investigation(s) of matters covered by this Stipulation;
- (3) Defendant's investigation, defense, and corrective actions undertaken in response to the United States' and States' audit(s) and civil investigation(s) in connection with matters covered by this Stipulation and the State Settlement (including attorneys' fees);
- (4) the negotiation and performance of this Stipulation and the State Settlement; and
- (5) any payment Defendant makes to the United States pursuant to this Stipulation, any payment Defendant makes to the States pursuant to the State Settlement, and any payment Defendant may make to Relators, including expenses, costs and attorneys' fees; are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and FEHBP (hereinafter referred to as "Unallowable Costs").
- b. <u>Future Treatment of Unallowable Costs</u>: Unallowable Costs shall be separately determined and accounted for by Defendant, and Defendant shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Defendant or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.
- c. <u>Treatment of Unallowable Costs Previously Submitted for Payment</u>: Within 90 days of the Effective Date of this Stipulation, Defendant shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this paragraph) included in payments previously sought from the United States, or any

State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Defendant or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Defendant agrees that the United States, at a minimum, shall be entitled to recoup from Defendant any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previouslysubmitted cost reports, information reports, cost statements, or requests for payment. Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States, including the Department of Justice and/or the affected agencies, reserves their rights to disagree with any calculation submitted by Defendant or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on Defendant or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

- d. Nothing in this Stipulation shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Defendant's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.
- 18. This Stipulation is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity except as otherwise provided herein.
- 19. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Stipulation; provided, however, nothing in this Stipulation shall preclude Relators from seeking to recover their expenses or attorneys' fees and costs from Defendant, pursuant to 31 U.S.C. § 3730(d).
- 20. Any failure by the Government to insist upon the full or material performance of any of the provisions of this Stipulation shall not be deemed a waiver of any of the provisions hereof, and the Government, notwithstanding that failure, shall have the right thereafter to insist upon the full or material performance of any and all of the provisions of this Stipulation.
- 21. This Stipulation is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Stipulation is the United States

District Court for the Southern District of New York.

- 22. The Parties agree that the Court shall retain jurisdiction over any disputes related to this Stipulation, including any action to enforce the terms of this Stipulation and any claim by Relators against Defendant for expenses, costs, or attorneys' fees pursuant to 31 U.S.C. § 3730(d).
- 23. For purposes of construing this Stipulation, this Stipulation shall be deemed to have been drafted by all Parties to this Stipulation and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.
- 24. This Stipulation constitutes the complete agreement between the Parties with respect to the subject matter hereof. This Stipulation may not be amended except by written consent of the Parties. No prior agreements, oral representations or statements shall be considered part of this Stipulation.
- 25. The undersigned counsel and other signatories represent and warrant that they are fully authorized to execute this Stipulation on behalf of the persons and the entities indicated below.
- 26. This Stipulation is binding on Defendant's successors, transferees, heirs, and assigns.
- 27. This Stipulation is binding on Relators' successors, transferees, heirs, and assigns.
- 28. This Stipulation may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Stipulation. E-mails that attach signatures in PDF form or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Stipulation.
- 29. Any notice pursuant to this Stipulation shall be in writing and shall, unless expressly provided otherwise herein, be delivered by hand, express courier, or e-mail transmission followed by postage-prepaid mail, and shall be addressed as follows:

TO THE UNITED STATES:

Danielle J. Levine Pierre G. Armand Assistant United States **Attorneys United States** Attorney's Office Southern District of New York 86 Chambers Street, Third Floor New York, New York 10007

Tel: (212) 637-2800

Email: danielle.levine@usdoj.gov pierre.armand@usdoj.gov

TO DEFENDANT:

Mylan Denerstein Jonathan M. Phillips Gibson, Dunn & Crutcher LLP 200 Park Avenue New York, New York 10166 Tel: (212) 351-4000 Email: mdenerstein@gibsondunn.com jphillips@gibsondunn.com

Amazon.com Legal Department

Attn: Litigation P.O. Box 81226 Seattle, WA 98108

Email: Contracts-legal@amazon.com

TO RELATORS:

Renee Brooker Eva Gunasekera Tycko & Zavareei LLP 1828 L Street, NW, Suite 1000 Washington, DC 20036 Tel: (202) 273-0900 Email: reneebrooker@tzlegal.com

eva@tzlegal.com

30. The effective date of this Stipulation is the date upon which the Stipulation is executed by the Parties (the "Effective Date").

Agreed to by:

THE UNITED STATES OF AMERICA

Dated: New York, New York

DAMIAN WILLIAMS United States Attorney for the Southern District of New York

By:

DANIELLE J. LEVINE PIERRE G. ARMAND

Assistant United States Attorneys 86 Chambers Street, Third Floor

New York, New York 10007

Tel.: (212) 637-2800

Email: danielle.levine@usdoj.gov pierre.armand@usdoj.gov

Attorney for the United States of America

RELATORS

Dated: 4/29/2022		By:	TYCKO & ZAVAREEI LLP Docusigned by: RUME BYFFFE BBS9AE639A4004C3 RENEE BROOKER EVA GUNASEKERA 1828 L Street, NW, Suite 1000 Washington, DC 20036 Telephone: (202) 973-0900 Email: reneebrooker@tzlegal.com eva@tzlegal.com Attorneys for the Relators
Dated: 4/29/2022	_, 2022		John Erickson JOHN ERICKSON Relator
Dated: 4/29/2022	_, 2022		Docusigned by: David J. Barry DAVID BARRY Relator

DEFENDANT

Dated: New York, New York

GIBSON, DUNN & CRUTCHER LLP

MYLAN DENERSTEIN

JONATHAN M. PHILLIPS

200 Park Avenue

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Attorneys for Defendant PillPack LLC



Exhibit A

NDC	Drug Name
00024592505	ADMELOG
00088250205	APIDRA
00002771559	BASAGLAR
00169320415	FIASP
00002751659	HUMALOG
00002771459	HUMALOG
00002771227	HUMALOG
00002879959	HUMALOG
00002879859	HUMALOG
00002879759	HUMALOG
00002880359	HUMULIN
00002880559	HUMULIN N
00002882427	HUMULIN R
66733082259	INSULIN LISPRO
00088221905	LANTUS
00169643910	LEVEMIR
00169643810	LEVEMIR
00169300715	NOVOLIN
00169633910	NOVOLOG
00169369619	NOVOLOG
00169330312	NOVOLOG
00024576105	SOLIQUA
00024587102	TOUJEO MAX
00024586903	TOUJEO
00169255013	TRESIBA
00169266015	TRESIBA
00169291115	XULTOPHY



Exhibit B

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, ALASKA, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, VIRGINIA, WASHINGTON and the DISTRICT OF COLUMBIA *ex rel.* JOHN ERICKSON and DAVID BARRY,

No. 19 Civ. 6717 (GHW)

Plaintiffs-Relators,

v.

AMAZON.COM, INC. and AMAZON PILLPACK f/k/a PILLPACK, LLC,

Defendants.

UNITED STATES OF AMERICA,

Plaintiff-Intervenor,

v.

PILLPACK LLC,

Defendant.

JUDGMENT

Upon the consent of plaintiff the United States of America and defendant PillPack LLC ("PillPack"), it is hereby

ORDERED, ADJUDGED and DECREED: that plaintiff the United States of America is awarded judgment in the amount of \$5,616,136.85 against PillPack as well as post-judgment interest at the rate of 12% per annum compounded daily.

Dated: New York, New York	
, 2022	DAMIAN WILLIAMS United States Attorney for the Southern District of New York
By:	DANIELLE J. LEVINE PIERRE G. ARMAND Assistant United States Attorneys 86 Chambers Street, Third Floor New York, New York 10007 Tel.: (212) 637- 2800 Email: danielle.levine@usdoj.gov pierre.armand@usdoj.gov
Dated: New York New York	Attorney for the United States of America GIBSON, DUNN & CRUTCHER LLP
Ву:	
	Attorneys for Defendant PillPack LLC
SO ORDERED:	
HON. GREGORY H. WOODS UNITED STATES DISTRICT JUDGE	
Dated:	