

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA *ex rel.* J. DOE,
STATE OF NEW YORK *ex rel.* J. DOE, STATE
of CALIFORNIA *ex rel.* J. DOE, STATE OF
TEXAS *ex rel.* J. DOE, STATE OF MICHIGAN
ex rel. J. DOE,

Plaintiffs,

v.

PROGENITY, INC.,

Defendant.

16 Civ. 9051 (LAP)

UNITED STATES OF AMERICA,

Plaintiff-Intervenor,

v.

PROGENITY, INC.,

Defendant.

STIPULATION AND ORDER OF SETTLEMENT AND DISMISSAL

WHEREAS, this Stipulation and Order of Settlement and Dismissal (“Stipulation”) is entered into by and among Plaintiff the United States of America (the “United States” or “Government”), by its attorney, Audrey Strauss, Acting United States Attorney for the Southern District of New York, and on behalf of the Office of Inspector General of the Department of Health and Human Services (“OIG-HHS”) and the Defense Health Agency (“DHA”), acting on

behalf of the TRICARE Program (“TRICARE”); Relator Demetria Katsanos (the “Relator”), by her authorized representative; and Defendant Progenity, Inc. (“Progenity”) (together with the Government and the Relator, the “Parties”), by its authorized representatives;

WHEREAS, Progenity is a company headquartered in California that provides molecular laboratory testing services to patients, through their healthcare providers, focusing on prenatal testing for genetic and chromosomal abnormalities;

WHEREAS, prior to August 2013, Progenity operated under the name Ascendant MDx, Inc.;

WHEREAS, throughout the period referenced in this Stipulation, Progenity provided services that were reimbursed by Federal healthcare programs, including Medicaid, TRICARE, the Federal Employee Health Benefit Program (“FEHBP”), and the United States Department of Veterans Affairs healthcare program (“VA”);

WHEREAS, on or about November 21, 2016, the Relator filed a complaint in the United States District Court for the Southern District of New York pursuant to the *qui tam* provisions of the False Claims Act (“FCA”), 31 U.S.C. § 3729 *et seq.* (the “Relator Complaint”), alleging, *inter alia*, that Progenity engaged in illegal kickback schemes to induce physicians to order Progenity tests;

WHEREAS, prior to the filing of the Relator Complaint, the United States Attorney’s Office for the Southern District of California (“USAO SDCA”) and its law enforcement partners were investigating Progenity’s use of Current Procedural Terminology (“CPT”) code 88271 in the submission of claims to TRICARE and the FEHBP seeking reimbursement for certain cell-free DNA sequencing-based non-invasive prenatal tests (“NIPTs”) that can screen for chromosomal aneuploidies and subchromosomal microdeletions to determine the risk that a fetus

will be born with certain genetic disorders or abnormalities through analysis of fetal DNA present in the woman's blood;

WHEREAS, contemporaneously herewith, the USAO SDCA has entered into a non-prosecution agreement as well as a separate civil settlement agreement with Progenity to resolve claims relating to the submission of false claims to TRICARE and the FEHBP seeking reimbursement for NIPTs, under which Progenity has agreed to pay a sum of \$16,400,000;

WHEREAS, in addition to investigating the allegations in the Relator Complaint, the United States Attorney's Office for the Southern District of New York also initiated an investigation into Progenity's use of CPT code 88271 in the submission of claims to Medicaid and the VA seeking reimbursement for NIPTs;

WHEREAS, the Government alleges that from March 2014 through April 2016, in violation of the FCA, Progenity knowingly and willfully submitted false claims to Medicaid and the VA by fraudulently using CPT code 88271 to seek reimbursement for NIPTs when this code misrepresented the services Progenity actually provided, and, as a result, Progenity received payments for non-reimbursable tests, or received substantially higher payments than it was entitled to receive for the genetic testing services provided ("Miscoding Covered Conduct");

WHEREAS, the Government further alleges that, in violation of the Anti-Kickback Statute (the "AKS"), 42 U.S.C. §§ 13320a-7b(b), Progenity knowingly and willfully induced physicians to order Progenity tests for Federal healthcare program beneficiaries by: (1) from January 2012 through March 2016, offering and providing remuneration in the form of above fair market value payments, or "draw fees," to physicians or physician offices for blood specimens collected for Progenity tests; (2) from January 2012 through December 2018, offering and providing remuneration in the form of meals and happy hours for physicians and their

employees; and (3) from January 2012 through April 2018, routinely offering to reduce or waive, and routinely reducing or waiving, coinsurance and deductible payments that Federal healthcare program beneficiaries were required to pay without making individualized determinations of financial need or reasonable collection efforts. As a result of the foregoing, Progenity submitted false claims for payment to Federal healthcare programs. The conduct described in this paragraph is referred to as the “Kickback Covered Conduct”;

WHEREAS, contemporaneous with the filing of this Stipulation, the Government, through the Office of the United States Attorney for the Southern District of New York, is filing a Notice of Election to Partially Intervene and a Complaint-In-Intervention in the above-referenced *qui tam* action (“Government Complaint”), in which it is asserting claims under the FCA against Progenity for the Miscoding Covered Conduct and the Kickback Covered Conduct;

WHEREAS, Progenity intends on entering into separate settlement agreements (“State Settlements”) with various states that participate in Medicaid (“States”) to resolve claims related to the Miscoding Covered Conduct and the Kickback Covered Conduct and has agreed to pay a total of \$13,150,684 to the States pursuant to the State Settlements;

WHEREAS, in connection with settlement discussions and in order to allow the Government to assess Progenity’s ability to make payments to resolve this matter, Progenity has submitted information concerning its financial condition to the Government, including but not limited to information relating to its assets, liabilities, expenses, revenues, profits, and financial projections (the “Progenity Financial Information”);

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

WHEREAS, the Relator's claim to a share of the proceeds from the settlement of claims arising from the Relator Complaint will be the subject of a separate agreement between the Relator and the United States, and the Relator acknowledges that this claim is limited to a share of the proceeds for the settlement of claims related to the Kickback Covered Conduct;

NOW, THEREFORE, upon the Parties' agreement, IT IS HEREBY ORDERED 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. Progenity admits, acknowledges, and accepts responsibility for the following conduct:

Miscoding:

- a. CPT codes are part of a numerical coding system that physicians and laboratories must use on claim forms to bill payors for healthcare services and to receive payments. The CPT code affects the rate that the payor will reimburse the provider. When there is no existing CPT code that accurately describes a specific service or test, an unlisted or miscellaneous CPT code should be used for a provider to seek reimbursement.
- b. From March 2014 through April 2016, Progenity knowingly submitted false claims for payment to Medicaid and the VA by using CPT code 88271 to obtain reimbursement for NIPTs.
- c. Progenity improperly used CPT code 88271, which applies to fluorescence in situ hybridization ("FISH") procedures, knowing that its genetic tests were cell-free DNA sequencing-based NIPTs that are not FISH procedures and that CPT code 88271 did not accurately represent the tests performed.
- d. Until January 2015, there was no CPT code specific to NIPTs. In the absence of a designated code prior to January 2015, Progenity used CPT code 88271 when

seeking reimbursement for certain NIPTs, instead of the miscellaneous CPT code 81479. The Medicaid reimbursement rate for CPT code 88271 during the relevant period was substantially more than the reimbursement rate for the miscellaneous CPT code 81479.

- e. On January 2, 2015, a new CPT code, 81420 (Genomic Sequencing Procedures and Other Molecular Multianalyte Assays), became active. Upon its implementation, CPT code 81420 became the correct code that Progenity should have used to bill for its NIPTs. However, Progenity knew that it would receive significantly higher reimbursement amounts by using CPT code 88271, and continued to knowingly submit false claims to Medicaid and the VA using the incorrect CPT code 88271.
- f. In addition, Progenity knew that the Medicaid programs for some states, such as Texas, Kansas, and New York, explicitly excluded reimbursement for certain NIPTs, such as those that tested for microdeletions, and allowed reimbursement for other NIPTs only if the patient had one or more high-risk factors, such as being over the age of 35 or having an ultrasound result showing an increased risk of aneuploidy. Progenity submitted claims seeking reimbursement for tests provided to Medicaid beneficiaries in these states even though it was aware that the tests were not eligible for coverage.
- g. As a result of fraudulently using CPT code 88721 and misrepresenting the type of test performed when submitting claims for payment to Medicaid and the VA for NIPTs, Progenity received payments for non-reimbursable tests, or received substantially higher payments than it was entitled to receive for the genetic testing services provided.

Draw Fee Payments:

- h. From January 2012 through March 2016, Progenity knowingly made “draw fee” payments to physicians or physicians’ offices for the collection of blood specimens for Progenity tests performed on Federal healthcare program beneficiaries. In total, Progenity paid over \$1.7 million in draw fees during this period.
- i. Progenity entered into agreements with physicians that specified the amount it would receive for each specimen collected for Progenity tests, and then paid the physician or physician’s office for those draws at the agreed-upon amount.
- j. The draw fees paid by Progenity exceeded the fair market value of the services performed when collecting blood specimens. Progenity frequently paid physicians \$20 or more for each blood draw. Progenity paid dozens of physicians and physician offices thousands of dollars in above fair market draw fee payments during the relevant time period.

Meals and Happy Hours:

- k. From 2012 through 2018, Progenity knowingly provided meals and happy hours to physicians who ordered Progenity tests for Federal healthcare program beneficiaries, as well to individuals who worked in physicians' offices. The value of these meals and happy hours exceeded Stark Law limits. In total, Progenity expended millions of dollars on food and drinks for physicians and their staff during this period.
- l. Progenity's sales management directed sales representatives to make frequent contact with physicians' practices, and sales representatives were permitted to provide meals and happy hours in order to facilitate these contacts. Sales staff purchased food and drinks for physicians and their staff at gatherings that often involved little or no educational or informational content. These gatherings included happy hours at bars and other establishments.
- m. During the vast majority of the relevant period, Progenity did not have effective systems in place to ensure that the company's expenses for meals and happy hours for physicians and their employees complied with the Stark Law and the AKS. For example, Progenity did not (i) reliably track the amount it spent on meals and happy hours for physicians or their staff; (ii) maintain accurate sign-in sheets reflecting attendance at Progenity-sponsored gatherings; (iii) keep records of materials or topics that were discussed during Progenity-sponsored gatherings; and (iv) implement and enforce limits on the total nonmonetary compensation that could be provided to physicians.

Waiver of Patient Coinsurance and Deductible Payments:

- n. From January 2012 through April 2018, Progenity knowingly routinely reduced or waived Federal healthcare program beneficiaries' coinsurance and deductible payments without making the required individualized determinations of financial need or reasonable collection efforts. Progenity offered to reduce or waive coinsurance and deductible payments as part of its sales efforts.
- o. Some of the Progenity tests were costly and required significant patient payments. To market its costly tests, sales representatives informed physicians and their staff, as well as patients, that Progenity would waive coinsurance and deductibles, or limit the patient's payment to a certain maximum out-of-pocket amount regardless of the actual coinsurance or deductible amount. Progenity often referred to this practice as the "Peace of Mind" program. Progenity used the Peace of Mind program to induce physicians to prescribe, and patients to consent to, Progenity tests.

3. Progenity shall pay to the United States the sum of \$19,449,316 plus applicable interest (the "Settlement Amount") to be paid in six installments according to the schedule set

forth below. Progenity shall make the below-referenced payments in accordance with instructions to be provided by the Financial Litigation Unit of the United States Attorney's Office for the Southern District of New York. Of the Settlement Amount, \$9,724,658 plus applicable interest constitutes restitution to the United States. The sum of \$9,664,998 plus applicable interest is being paid to resolve claims for the Miscoding Covered Conduct, and the sum of \$9,784,318 plus applicable interest is being paid to resolve claims for the Kickback Covered Conduct. The Government will allocate each installment payment proportionally between the amount being paid to resolve claims for the Miscoding Covered Conduct and the amount being paid to resolve claims for the Kickback Covered Conduct.

- a. Within fourteen (14) business days of the Effective Date (defined below in Paragraph 34), Progenity shall pay the United States the sum of \$9,073,361.77.
- b. On or before December 31, 2020, Progenity shall pay the United States the sum of \$1,587,699.27, plus interest which shall be compounded annually at a rate of 1.25% accruing from the Effective Date.
- c. On or before December 31, 2021, Progenity shall pay the United States the sum of \$1,984,624.08, plus interest which shall be compounded annually at a rate of 1.25% accruing from the Effective Date.
- d. On or before December 31, 2022, Progenity shall pay the United States the sum of \$2,778,473.71, plus interest which shall be compounded annually at a rate of 1.25% accruing from the Effective Date.
- e. On or before December 31, 2023, Progenity shall pay the United States the sum of \$3,175,398.53, plus interest which shall be compounded annually at a rate of 1.25% accruing from the Effective Date.

f. On or before December 31, 2024, Progenity shall pay the United States the sum of \$849,758.64, plus interest which shall be compounded annually at a rate of 1.25% accruing from the Effective Date.

4. In the event that, during any calendar year from 2020 through 2023, Progenity receives any civil settlements, damages awards, or tax refunds which exceed the aggregate value of \$5,000,000 in a calendar year (referred to herein as a “Windfall Event”), Progenity shall pay to the United States 26% of the value of the Windfall Event. This payment shall be made within 15 days of the occurrence of the Windfall Event, and Progenity shall promptly notify the United States of the Windfall Event and its value prior to making the payment. Each payment made pursuant to this provision will proportionately reduce the amount due in the last remaining installment payment set forth in Paragraph 3 above. (For example, if Progenity were to receive \$10,000,000 from a future Windfall Event that occurred in calendar year 2020, Progenity would be required to pay \$2,600,000 to the United States within 15 days of the occurrence of the Windfall Event, and this payment would proportionately reduce future installment payments so that Progenity would no longer need to make the payment required in Paragraph 3(f) above, and the payment required in Paragraph 3(e) would be reduced to \$1,425,157.17.) The aggregate amount of accelerated payments made pursuant to this Paragraph for the life of this Stipulation shall not exceed \$4,200,000. This provision shall no longer be operative after the Settlement Amount due under Paragraph 3 has been fully paid (\$19,449,316 plus applicable interest).

5. Harry G. Stylli, the Chief Executive Officer of Progenity, has executed a guaranty agreement with the United States personally guarantying up to \$2,000,000 of the Settlement Amount owed to the United States by Progenity, a copy of which is attached hereto as Exhibit A.

6. Progenity shall execute and agree to the entry of a consent judgment in favor of the Government and against Progenity in the amount of \$19,449,316, a copy of which is attached hereto as Exhibit B (the "Progenity Consent Judgment"). The Government may use the Progenity Consent Judgment to obtain a security interest in any asset or property of Progenity, but shall not engage in other collection activity with respect to the Progenity Consent Judgment so long as Progenity fully complies with the terms of this Stipulation. Should Progenity comply fully with the payment schedule set forth above as well as the other terms of this Stipulation, the Progenity Consent Judgment shall be deemed to be satisfied in full. Within thirty (30) calendar days after Progenity makes the final payment under the payment schedule, and upon Progenity's request, the Government shall file with the Clerk of the Court and deliver to Progenity a Full Satisfaction of Judgment. In the event that Progenity fully pays the Settlement Amount faster than as provided in the payment schedule set forth above, and fully complies with all other terms of the Stipulation, the Progenity Consent Judgment shall be deemed to be satisfied in full and, upon Progenity's request, the Government shall file with the Clerk of the Court and deliver to Progenity a Full Satisfaction of Judgment. Should Progenity fail to comply fully with the payment schedule set forth above or any other term of this Stipulation, Progenity shall be in default of this Stipulation, in which case the Government may take any of the actions set forth in Paragraph 16 below.

7. Progenity agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Stipulation. Upon reasonable notice, Progenity shall encourage, and agrees not to impair, the cooperation of Progenity's 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. Progenity 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 Miscoding Covered Conduct and Kickback Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

8. Subject to the exceptions in Paragraphs 14 and 21 below (concerning excluded claims and bankruptcy proceedings), and conditioned upon Progenity's full compliance with the terms of this Stipulation, including full payment of the Settlement Amount to the United States pursuant to Paragraphs 3 and 4 above, the United States releases Progenity, including Progenity's subsidiaries and corporate predecessors, successors, and assigns, including Molecular Diagnostic Health Sciences, LLC, Progenity Holding Company, Inc., SPX3, Inc., Avero Laboratory Holdings LLC, Progenity UK Limited, and Progenity Pty Ltd, from any civil or administrative monetary claim that the United States has for the Miscoding Covered Conduct and the Kickback 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, the civil monetary provisions of the Stark Law, 42 U.S.C. §§ 1395nn(g)(3) and (4), 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 Progenity from liability of any kind.

9. In consideration of Progenity's obligations in this Settlement Stipulation and the Corporate Integrity Agreement ("CIA") entered into between OIG-HHS and Progenity, and conditioned upon Progenity's full payment of the Settlement Amount, and except as expressly reserved in this Paragraph and in Paragraph 14 (concerning excluded claims), the OIG-HHS

agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal healthcare programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Progenity under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Miscoding Covered Conduct and the Kickback Covered Conduct. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Progenity from Medicare, Medicaid, and other Federal healthcare programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Miscoding Covered Conduct and the Kickback Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 14 below.

10. In consideration of the obligations of Progenity set forth in this Settlement Stipulation, and conditioned upon Progenity's full payment of the Settlement Amount, and except as expressly reserved in this Paragraph and in Paragraph 14 (concerning excluded claims), DHA agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from TRICARE against Progenity under 32 C.F.R. § 199.9 for the Kickback Covered Conduct. DHA expressly reserves authority to exclude Progenity from TRICARE under 32 C.F.R. §§ 199.9 (f)(1)(i)(A), (f)(1)(i)(B), and (f)(1)(iii) (mandatory exclusion), based upon the Kickback Covered Conduct. Nothing in this Paragraph precludes DHA or TRICARE from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 14 below.

11. Progenity fully and finally releases the United States and its agencies, officers, employees, servants, and agents from any claims (including attorneys' fees, costs, and expenses

of every kind and however denominated) that Progenity has asserted, could have asserted, or may assert in the future against the United States and its agencies, officers, employees, servants, or agents related to the Miscoding Covered Conduct and Kickback Covered Conduct and the United States' investigation, prosecution and settlement thereof.

12. Conditioned on Progenity's timely payment of the full Settlement Amount pursuant to Paragraphs 3 and 4 above, the Relator, for herself and her heirs, successors, attorneys, agents, and assigns, releases Progenity, including its subsidiaries and corporate predecessors, successors and assigns, as well as all of their 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 the Relator has against Progenity; provided, however, that nothing in this Stipulation shall preclude the Relator from seeking to recover her reasonable expenses and attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d). Defendant's payment to the Relator for expenses, attorney's fees, and costs pursuant to 31 U.S.C. § 3730(d) shall be addressed by separate agreement.

13. In consideration of the execution of this Stipulation by the Relator and the Relator's release as set forth in Paragraph 12 above, Progenity, including Progenity's subsidiaries, predecessors, and corporate successors and assigns, as well as all of their current and former officers, directors, employees, attorneys, and other agents release the Relator and her successors, heirs, assigns, attorneys, and other agents, from any and all manner of claims, proceedings, liens, and causes of action of any kind or description that Progenity has against the Relator related to or arising from the Relator Complaint.

14. Notwithstanding the release given in Paragraph 8, 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, including mandatory exclusion from Federal healthcare programs;
- d. any liability to the United States (or its agencies) for any conduct other than the Miscoding Covered Conduct and the Kickback Covered Conduct;
- e. any liability based upon obligations created by this Stipulation; and
- f. any liability of individuals.

15. Progenity has provided the Progenity Financial Information to the United States, and the United States has relied on the accuracy and completeness of that information in reaching this Stipulation. Progenity warrants that the Progenity Financial Information is complete, truthful, and accurate. If the United States learns of any misrepresentation or inaccuracy in the Progenity Financial Information, or of assets in which Progenity had an interest at the time of this Stipulation that were not disclosed in the Progenity Financial Information, and if such nondisclosure or misrepresentation changes either the estimated net worth, annual net income, or assets set forth in the Progenity Financial Information by 5% or more, the United States may at its option: (i) rescind this Stipulation and reinstate the claims asserted against Progenity in the Government Complaint, or (ii) let the Stipulation stand and collect the full Settlement Amount plus one hundred percent (100%) of the value of the net worth, net income or

assets that were previously not disclosed. Progenity agrees not to contest any collection action undertaken by the United States pursuant to this provision, and immediately to pay the United States all reasonable costs incurred in such an action, including attorneys' fees and expenses.

16. Progenity shall be in default of this Stipulation if it fails to make the required payments set forth in Paragraphs 3 and 4 above on or before the due date for such payments, or if it fails to comply materially with any other term of this Stipulation ("Default"). The Government shall provide written notice to Progenity of any Default in the manner set forth in Paragraph 33 below. Progenity shall then have an opportunity to cure the Default within ten (10) calendar days from the date of delivery of the notice of Default. In the event that a Default is not fully cured within ten (10) calendar days of the delivery of the notice of Default ("Uncured Default"), interest shall accrue at the rate of 12% per annum compounded daily on the remaining unpaid principal balance of the settlement amount set forth in Paragraph 3 above, beginning ten (10) calendar days after mailing of the notice of Default. The United States may also, at its option, (a) rescind this Stipulation and reinstate the claims asserted against Progenity in the Government Complaint; (b) seek specific performance of this Stipulation; (c) offset the remaining unpaid balance of the Settlement Amount set forth in Paragraph 3 above from any amounts due and owing Progenity by any department, agency, or agent of the United States; or (d) exercise any other rights granted by law, or under the terms of this Stipulation, or recognizable at common law or in equity. Progenity shall not contest any offset imposed or any collection undertaken by the Government pursuant to this Paragraph, either administratively or in any Federal or State court. In addition, Progenity shall pay the Government all reasonable costs of collection and enforcement under this Paragraph, including attorneys' fees and expenses. In the event that the United States opts to rescind this Stipulation pursuant to this Paragraph, Progenity shall not

plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that relate to the Miscoding Covered Conduct or Kickback Covered Conduct.

17. The Relator and her heirs, successors, attorneys, agents, and assigns shall not object to this Stipulation; the Relator agrees and confirms 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).

18. Progenity waives and shall not assert any defenses it may have to any criminal prosecution or administrative action relating to the Miscoding Covered Conduct or the Kickback 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.

19. Progenity, having truthfully admitted to the conduct set forth in Paragraph 2 above (the “Admitted Conduct”), agrees that 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 Progenity or 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 16 above, or seek other appropriate relief from the Court. Before pursuing any remedy, the Government shall notify Progenity that it has determined that Progenity has made a Contradictory Statement. Upon receiving such notice from the

Government, Progenity may cure the violation by repudiating the Contradictory Statement in a press release or other public statement within four business days. If Progenity learns of a potential Contradictory Statement by its attorneys, agents, officers, or employees, Progenity 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 Progenity for the purpose of this Stipulation, or whether Progenity 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, Progenity may raise defenses and/or assert affirmative claims or defenses in any proceedings brought by private and/or public parties, so long as doing so would not contradict the Admitted Conduct.

20. Progenity represents and warrants that it has reviewed its financial situation, that it is currently not insolvent as such term is defined in 11 U.S.C. § 101(32), and that it reasonably believes it shall remain solvent following payment to the Government of the Settlement Amount referenced in Paragraph 3 above. Further, the Parties warrant that, in evaluating whether to execute this Stipulation, they (a) have intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to Progenity, within the meaning of 11 U.S.C. § 547(c)(1); and (b) have concluded that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, 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 that is not intended to hinder, delay, or defraud any entity to which Progenity was or became indebted to on or after the date of this Stipulation, within the meaning of 11 U.S.C. § 548(a)(1).

21. If within 91 days of the Effective Date of this Stipulation or any payment made under this Stipulation, Progenity commences any case, action, or other proceeding under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors, or a third party commences any case, action, or other proceeding under any law related to bankruptcy, insolvency, reorganization, or relief of debtors (a) seeking an order for relief of Progenity's debts, or seeking to adjudicate Progenity as bankrupt or insolvent; or (b) seeking appointment of a receiver, trustee, custodian, or other similar official for Progenity or for all or part of Progenity's assets, Progenity agrees as follows:

- a. Progenity's obligations under this Stipulation may not be avoided pursuant to 11 U.S.C. § 547, and Progenity shall not argue or otherwise take the position in any such case, action, or proceeding that (i) Progenity's obligations under this Stipulation may be avoided under 11 U.S.C. § 547; (ii) Progenity is insolvent at the time this Stipulation was entered into; or (iii) the mutual promises, covenants, and obligations set forth in this Stipulation do not constitute a contemporaneous exchange for new value given to Progenity.
- b. If any of Progenity'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, the Government, at its option, may rescind the release in this Stipulation and bring any civil and/or administrative claim, action, or proceeding against Progenity for the claims that would otherwise be covered by the release in Paragraph 8 above. Progenity agrees that (i) any such claim, action, or proceeding brought by the Government would not be subject to an "automatic stay" pursuant to

11 U.S.C. § 362(a) as a result of the case, action, or proceeding described in the first sentence of this Paragraph, and Progenity shall not argue or otherwise contend that the Government's claim, action, or proceeding is subject to an automatic stay; (ii) Progenity shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any claim, action, or proceeding that is brought by the Government within 60 calendar days of written notification to Progenity that the release has been rescinded pursuant to this Paragraph, except to the extent such defenses were available on the date the Relator Complaint was filed; and (iii) the Government has an undisputed, noncontingent, and liquidated allowed claim against Progenity in the amount of the Settlement Amount set forth in Paragraph 3 above and the Government may pursue its claim in the case, action, or proceeding described in the first sentence of this Paragraph, as well as in any other case, action, or proceeding, and shall be allowed to offset the remaining unpaid balance of its claim from any amounts due and owing Progenity by any department, agency, or agent of the United States without seeking further authorization from any court under 11 U.S.C. § 362(a)(7).

- c. Progenity acknowledges that the agreements in this Paragraph are provided in exchange for valuable consideration provided in this Stipulation.

22. Progenity 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. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Progenity, including Progenity's present or former officers, directors, employees, and agents in connection with:

- (1) the matters covered by this Stipulation;
- (2) the United States' audit(s) and civil investigation(s) of matters covered by this Stipulation;
- (3) Progenity's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with matters covered by this Stipulation (including attorneys' fees);
- (4) the negotiation and performance of this Stipulation;
- (5) any payment Progenity makes to the United States pursuant to this Stipulation and any payment Progenity may make to the Relator, including expenses, costs, and attorneys' fees; and
- (6) the negotiation of, and obligations undertaken pursuant to the CIA to:
 - (i) retain an independent review organization to perform annual reviews as described in the CIA; and (ii) prepare and submit reports to the OIG-HHS, are unallowable costs for government contracting purposes (hereinafter referred to as "Unallowable Costs").

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Progenity, and Progenity shall not

charge such Unallowable Costs directly or indirectly to any contracts with the United States.

- c. Treatment of Unallowable Costs Previously Submitted for Payment: Within 90 days of the Effective Date of this Stipulation, Progenity shall identify and repay by adjustment to future claims for payment or otherwise any Unallowable Costs (as defined in this Paragraph) included in payments previously sought by Progenity from the United States. Progenity agrees that the United States, at a minimum, shall be entitled to recoup from Progenity any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted requests for payment. Any payments due 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 its right to audit, examine, or re-examine Progenity's books and records and to disagree with any calculation submitted by Progenity or any of Progenity's subsidiaries or affiliates regarding any Unallowable Costs included in payments previously sought by Progenity, or the effect of any such Unallowable Costs on the amounts of such payments.
- d. Nothing in this Stipulation shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Progenity's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

23. 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.

24. Progenity agrees that it waives and shall not seek payment for any of the health care billings covered by this Stipulation from any healthcare beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Miscoding Covered Conduct and Kickback Covered Conduct.

25. 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 the Relator from seeking to recover her expenses or attorneys' fees and costs from Progenity pursuant to 31 U.S.C. § 3730(d). Defendant's payment to the Relator for expenses, attorney's fees, and costs pursuant to 31 U.S.C. § 3730(d) shall be addressed by separate agreement.

26. 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.

27. 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. 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.

28. 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.

29. 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.

30. This Stipulation is binding on Progenity's successors, transferees, heirs, and assigns.

31. This Stipulation is binding on the Relator's successors, transferees, heirs, and assigns.

32. 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.

33. 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:
Jeffrey K. Powell, Esq.
Kirti Vaidya Reddy, Esq.
Assistant United States Attorneys
United States Attorney's Office
Southern District of New York
86 Chambers Street, Third Floor
New York, New York 10007
Telephone: (212) 637-2706/2751
Email: Jeffrey.Powell@usdoj.gov
Kirti.Reddy@usdoj.gov

TO DEFENDANT PROGENITY, INC.:

M. Kendall Day, Esq.

Jonathan M. Phillips, Esq.

Gibson, Dunn & Crutcher LLP

1050 Connecticut Avenue, N.W.

Washington, D.C. 20036-5306

Telephone: 202-955-8589

Email: kday@gibsondunn.com

TO RELATOR:

Robert W. Sadowski, Esq.

800 Third Avenue, 28th Floor

New York, NY 10022

Telephone Phone: 646-503-5341

Email: rsadowski@robertwsadowski.com

34. The effective date of this Stipulation is the date upon which the Stipulation is approved by the Court (the "Effective Date").

Agreed to by:

THE UNITED STATES OF AMERICA

Dated: July 21, 2020

AUDREY STRAUSS
Acting United States Attorney for the
Southern District of New York

By: Kirti Vaidya Reddy
Jeffrey K. Powell
Kirti Vaidya Reddy
Assistant United States Attorneys
86 Chambers Street, Third Floor
New York, New York 10007
Telephone: (212) 637-2706/2751
Email: Jeffrey.Powell@usdoj.gov
Kirti.Reddy@usdoj.gov

Dated: July _____, 2020

Office of the Inspector General, the U.S.
Department of Health and Human Services

By: _____
Lisa M. Re
Assistant Inspector General
for Legal Affairs

Agreed to by:

THE UNITED STATES OF AMERICA

Dated: July ____, 2020

AUDREY STRAUSS
Acting United States Attorney for the
Southern District of New York

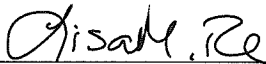
By:

Jeffrey K. Powell
Kirti Vaidya Reddy
Assistant United States Attorneys
86 Chambers Street, Third Floor
New York, New York 10007
Telephone: (212) 637-2706/2751
Email: Jeffrey.Powell@usdoj.gov
Kirti.Reddy@usdoj.gov

Dated: July 20, 2020

Office of the Inspector General, the U.S.
Department of Health and Human Services

By:



Lisa M. Re
Assistant Inspector General
for Legal Affairs

DEFENDANT

Dated: July 21, 2020

DEFENDANT PROGENITY, INC.

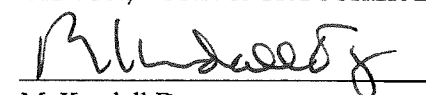
By:



Clarke Neumann
General Counsel

GIBSON, DUNN & CRUTCHER LLP

By:



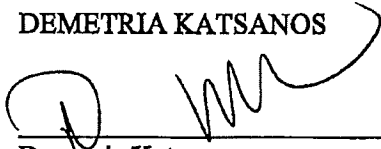
M. Kendall Day
Jonathan M. Phillips
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036-5306
Phone: 202-955-8220
Email: kday@gibsondunn.com
Attorneys for Progenity, Inc.

RELATOR

Dated: July 15, 2020

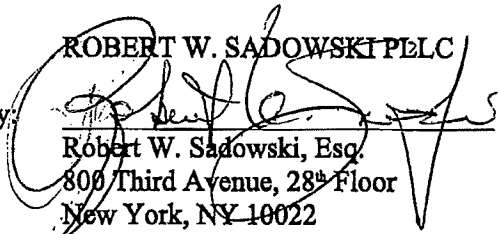
DEMETRIA KATSANOS

By:


Demetria Katsanos

ROBERT W. SADOWSKI PLLC

By:


Robert W. Sadowski, Esq.
800 Third Avenue, 28th Floor
New York, NY 10022
Phone: 646-503-5341
Email: rsadowski@robertsadowski.com
Attorney for Relator

SO ORDERED:

HON. LORETTA A. PRESKA
UNITED STATES DISTRICT JUDGE

Dated: July 23, 2020
New York, New York

EXHIBIT A

GUARANTY AGREEMENT

This Guaranty Agreement is entered into by and among Harry G. Stylli (“Guarantor”), the Chief Executive Officer of Progenity, Inc. (“Progenity”), acting in his personal capacity, and the United States of America (“United States”) (collectively the "Parties").

WHEREAS, the Government, through the Office of the United States Attorney for the Southern District of New York, is filing a Notice of Election to Partially Intervene and a Complaint-In-Intervention in a pending *qui tam* action in the United States District Court for the Southern District of New York, *United States ex. rel. J. Doe v. Progenity, Inc.*, Civ. No. 16 Civ. 9051 (LAP), which alleges, *inter alia*, that Progenity engaged in illegal kickback schemes to induce physicians to order Progenity tests;

WHEREAS, the United States, Progenity, and the relator in the *qui tam* action wish to settle claims related to the allegations of kickbacks and the miscoding of tests billed by Progenity through the execution of a Stipulation and Order of Settlement and Dismissal (the “Stipulation”) dated July 21, 2020, and the Exhibits thereto, including this Guaranty Agreement;

WHEREAS, the specific claims being resolved are set forth in the Stipulation;

WHEREAS, Progenity has executed the Stipulation, incorporated by reference herein, wherein Progenity promises to pay the United States \$19,449,316 plus applicable interest (the “Settlement Amount”) as set forth in Paragraphs 3 and 4 of the Stipulation;

WHEREAS, the Guarantor is not a party to the Stipulation;

IT IS HEREBY AGREED that, in exchange for adequate consideration, the Parties shall undertake the following obligations:

TERMS AND CONDITIONS

1. Statement of Guaranty. Guarantor unconditionally and personally guarantees the prompt payment of the full Settlement Amount by Progenity as set forth in Paragraphs 3 and 4 of the Stipulation, up to the total amount of \$2,000,000 (two million dollars). For the avoidance of doubt, under no circumstance will Guarantor’s liability exceed \$2,000,000 (two million dollars) under this Agreement.
2. Nature of Guaranty. The Guaranty set forth in Paragraph 1 of this Agreement constitutes a personal guaranty of payment of the full Settlement Amount by Progenity as set forth in Paragraphs 3 and 4 of the Stipulation, up to the total amount of \$2,000,000 (two million dollars), and shall not be affected by any event, occurrence or circumstance which might otherwise constitute a legal or equitable discharge or defense of a guarantor or surety (other than full and complete payment of the Settlement Amount). In the event that any payment by Progenity pursuant to the Stipulation is rescinded or must otherwise be returned by virtue of any action by any bankruptcy court, Guarantor shall remain personally liable hereunder with respect to such Settlement Amount as if payment had

not been made. Guarantor agrees that the United States may resort to Guarantor for payment of any unpaid portion of the Settlement Amount, up to \$2,000,000 (two million dollars), without regard to whether the United States shall have proceeded against any other person or entity primarily or secondarily obligated with respect to any of the Settlement Amount.

3. Acceleration. Guarantor agrees that, within ten days of receipt of written notice from the United States that Progenity (i) has failed to make any payment required by the Stipulation, and (ii) has not cured its Default as provided for under Paragraph 16 of the Stipulation, Guarantor will be obligated to pay in full the amount then due under the Stipulation, up to the total amount of \$2,000,000 (two million dollars). Guarantor understands that the failure to adhere fully to the terms of this paragraph would be a material breach of this Guaranty Agreement.
4. No Waiver; Cumulative Rights. No failure on the part of the United States to exercise, and no delay in exercising, any right, remedy or power hereunder shall operate as a waiver thereof, nor shall any single or partial exercise by the United States of any right, remedy or power hereunder preclude any other or future exercise of any right, remedy or power. Each and every right, remedy and power hereby granted to the United States or allowed by law or other agreement shall be cumulative and not exclusive of any other, and may be exercised by the United States from time to time.
5. Effective Date. This Guaranty Agreement shall become effective on the Effective Date, as defined in Paragraph 34 of the Stipulation.
6. Subrogation. Guarantor shall not exercise any subrogation rights it may acquire against Progenity as a result of this Guaranty Agreement until all of the Settlement Amount owed to the United States has been paid in full.
7. Waiver of Notice. Guarantor waives notice of the acceptance of this Guaranty, presentment, demand, notice of dishonor, protest, and all other notices whatsoever.
8. Duration. This Guaranty shall continue in full force and effect until all of the Settlement Amount has been paid in full.
9. Entire Agreement. Each Party hereto represents and warrants that this Agreement constitutes a valid and binding agreement enforceable against each Party in accordance with its terms. This Agreement embodies the entire guaranty agreement between the Parties. There are no promises, terms, conditions or obligations other than those contained in this Agreement. This Agreement supersedes all previous communications, representations or agreements either verbal or written between Guarantor and the United States.
10. Severability. Should any one or more provisions of this Agreement be determined to be illegal, unenforceable, void or voidable, all other provisions shall remain in effect.

11. Assignment. No Party hereto may assign its rights, interest or obligations hereunder to any other person or entity without prior written consent of the other Party. The provisions of this Agreement shall be binding on the Parties hereto and their successors and assigns. This Agreement is to continue in full force and effect notwithstanding a change in the composition, ownership or corporate structure of Progenity.
12. Miscellaneous. This Agreement shall not be amended except in a writing signed by all Parties. Each signatory hereto represents and warrants that he or she is authorized to execute and deliver this Agreement on behalf of the Party for whom he or she is purporting to act. 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.
13. Governing Law; Consent to Jurisdiction. This Agreement shall be governed by and construed in accordance with federal common law. The Parties consent to the jurisdiction of the United States District Court for Southern District of New York in any action to enforce any term of this Agreement.

GUARANTOR

Dated: July 17, 2020


HARRY G. STYLLI

THE UNITED STATES OF AMERICA

Dated: July __, 2020

AUDREY STRAUSS
Acting United States Attorney for the
Southern District of New York

By: _____

Jeffrey K. Powell
Kirti Vaidya Reddy
Assistant United States Attorneys
86 Chambers Street, Third Floor
New York, New York 10007
Telephone: (212) 637-2706/2751
Email: Jeffrey.Powell@usdoj.gov
Kirti.Reddy@usdoj.gov

GUARANTOR

Dated: July ___, 2020

HENRY G. STYLLI

THE UNITED STATES OF AMERICA

Dated: July 21, 2020

AUDREY STRAUSS
Acting United States Attorney for the
Southern District of New York

By: *Kirti Vaidya Reddy*
Jeffrey K. Powell
Kirti Vaidya Reddy
Assistant United States Attorneys
86 Chambers Street, Third Floor
New York, New York 10007
Telephone: (212) 637-2706/2751
Email: Jeffrey.Powell@usdoj.gov
Kirti.Reddy@usdoj.gov

EXHIBIT B

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA *ex rel.* J. DOE,
STATE OF NEW YORK *ex rel.* J. DOE, STATE
of CALIFORNIA *ex rel.* J. DOE, STATE OF
TEXAS *ex rel.* J. DOE, STATE OF MICHIGAN
ex rel. J. DOE,

Plaintiffs,

v.

PROGENITY, INC.,

Defendant.

16 Civ. 9051 (LAP)

UNITED STATES OF AMERICA,

Plaintiff-Intervenor,

v.

PROGENITY, INC.,

Defendant.

CONSENT JUDGMENT

Upon the consent of Plaintiff the United States of America and defendant Progenity, Inc.,
it is hereby

ORDERED, ADJUDGED and DECREED: that plaintiff the United States of America is
awarded judgment in the amount of \$19,449,316 against Progenity, Inc.

Agreed to by:

Dated: July ___, 2020


AUDREY STRAUSS
Acting United States Attorney for the
Southern District of New York

By:

Jeffrey K. Powell, Esq.
Kirti Vaidya Reddy, Esq.
Assistant United States Attorneys
86 Chambers Street, Third Floor
New York, New York 10007
Telephone: (212) 637-2706/2751
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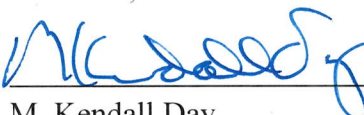
Dated: July 21, 2020

DEFENDANT PROGENITY, INC.

By: 

44E8420F12204B3
Clarke Neumann
General Counsel

GIBSON, DUNN & CRUTCHER LLP

By: 

M. Kendall Day
Jonathan M. Phillips
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036-5306
Telephone: 202-955-8220
Email: kday@gibsondunn.com
Attorneys for Progenity, Inc.

Dated: June 21, 2020

GEOFFREY S. BERMAN
United States Attorney for the
Southern District of New York

By: Kirti Vaidya Reddy
Jeffrey K. Powell, Esq.
Kirti Vaidya Reddy, Esq.
Assistant United States Attorneys
86 Chambers Street, Third Floor
New York, New York 10007
Telephone: (212) 637-2706/2751
Email: Jeffrey.Powell@usdoj.gov
Kirti.Reddy@usdoj.gov

Dated: June _____, 2020

DEFENDANT PROGENITY, INC.

By: _____
Clarke Neumann
General Counsel

GIBSON DUNN LLP

By: _____
Kendall Day
Jonathan M. Phillips
1050 Conn. Avenue, N.W.
Washington, D.C. 20036-5306
Telephone: 202-955-8589
Email: kday@gibsondunn.com
Attorneys for Progenity, Inc.

SO ORDERED:

HON. LORETTA A. PRESKA
UNITED STATES DISTRICT JUDGE

Dated: July 23, 2020
New York, New York