U.S. Department of Justice

Joshua S. Levy
Acting United States Attorney
District of Massachusetts

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1 Courthouse Way
Suite 9200
Boston, Massachusetts 02210

May 20, 2024

Adam J. Hollingsworth, Esq.
Jones Day
901 Lakeside Avenue
Cleveland, OH 44114

24cr10146

Re: United States v. Magellan Diagnostics, Inc.

Dear Adam:

The Acting United States Attorney for the District of Massachusetts (the "U.S. Attorney") and your client, Magellan Diagnostics, Inc. ("Magellan" or "Defendant"), agree as follows, pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C):

1. Change of Plea

At the earliest practicable date, Defendant shall waive indictment and plead guilty to the Information attached to this Plea Agreement (Exhibit A) charging it with two misdemeanor violations of the Food, Drug, and Cosmetic Act, 21 U.S.C. §§331(a), 333(a)(1). Defendant admits that Defendant committed the crimes specified in these counts and is in fact guilty of each one.

2. Penalties

Defendant faces the following maximum penalties on each count of the Information:

a. A fine of $200,000, or twice the gross gain/loss, whichever is greater. The gross gain resulting from the offenses is $10,900,000. Thus, the maximum fine is $21,800,000;

b. A term of probation of not more than five years;

c. A mandatory special assessment of $125;

d. Restitution to any victims of the offense; and

e. Forfeiture to the extent charged in the Information.

3. Rule 11(c)(1)(C) Plea

In accordance with Rule 11(c)(1)(C), if the Court accepts this Plea Agreement, the Court must include the agreed disposition in the judgment. If the Court rejects any part of this Plea Agreement, the U.S. Attorney may void the agreement and/or Defendant may withdraw from it. Defendant may not withdraw Defendant's plea for any other reason.

Should the U.S. Attorney void the agreement and/or Defendant moves to withdraw Defendant's guilty plea, Defendant agrees to waive any defenses based upon statute of limitations, the constitutional protection against pre-indictment delay, and the Speedy Trial Act for all charges that could have been brought as of the date of this Plea Agreement.

Defendant may seek sentencing by the Court immediately following the Rule 11 plea hearing. The United States does not object to the Court proceeding to sentence Defendant immediately following the Rule 11 plea hearing or in the absence of a Presentence Report in this case. Defendant understands that the decision whether to proceed immediately with the sentencing proceeding following the plea hearing, and to do so without a Presentence Report, is exclusively that of the Court.

4. Sentencing Guidelines

The parties agree jointly to take the following positions at sentencing under the United States Sentencing Guidelines ("USSG" or "Guidelines"). The parties also agree that while the fine provisions of the Guidelines do not apply to organizational defendants for misdemeanor violations of the Food, Drug, and Cosmetic Act, *see* USSG § 8C2.1, the following is consonant with the Guidelines and takes into account Magellan's conduct under 18 U.S.C. §§3553 and 3572 and USSG §8C2.10, as follows:

a. The base fine is $10,900,000, because this is the reasonably estimated pecuniary gain to the Defendant from the offenses. *See* USSG §8C2.4(a)(2);

b. Under USSC §8C2.5(a), the culpability score is five, determined as follows:

1. Two points are added because the organization had 50 or more employees and an individual within substantial authority personnel participated in, condoned, or was willfully ignorant of the offense, under USSG §8C2.5(b)(4); and

2. Two points are deducted because the organization fully cooperated in the investigation and clearly demonstrated recognition and affirmative acceptance of responsibility for its criminal conduct, under USSG §8C2.5(g)(2).

c. Under USSG §8C2.6, the appropriate multiplier range associated with a culpability score of five is 1.0 to 2.0;

d. Thus, under USSG §8C2.7, the Guidelines fine range is $10,900,000 to 21,800,000; and

e. Disgorgement under USSG §8C2.9 is not necessary.

Defendant understands that the Court is not required to follow this calculation. Defendant also understands that the government will object to any reduction in Defendant's sentence based on acceptance of responsibility, and may be released from the parties' agreed-upon disposition in Paragraph 5 if: (a) at sentencing, Defendant (directly or through counsel) indicates that Defendant does not fully accept responsibility for having engaged in the conduct underlying each of the elements of the crimes to which Defendant is pleading guilty; or (b) by the time of sentencing, Defendant has committed a new federal or state offense, or has in any way obstructed justice.

Nothing in this Plea Agreement affects the U.S. Attorney's obligation to provide the Court and the U.S. Probation Office with accurate and complete information regarding this case.

5. Agreed Disposition

The parties agree on the following sentence:

a. A criminal fine in the amount of $21,800,000, paid in eight quarterly installments over two years, with the first quarterly payment to occur within 90 calendar days of the date of sentencing and the remaining payments due every 90 days thereafter. Defendant shall pay interest on any unpaid portion of the criminal fine, and the interest shall be computed pursuant to 18 U.S.C. §3612(f).[1]

[1] Pursuant to §3612(f)(1), the defendant shall pay interest on any fine amount that is not paid in full before the fifteenth day after the date of the judgment. Pursuant to §3612(f)(2), the interest on the fine shall be computed daily from the first day on which the defendant is liable for interest and the rate of interest shall be equal to the weekly average 1-year constant maturity Treasury yield, as published by the Board of Governors of the Federal Reserve System, for the calendar week preceding the first day on which the defendant is liable for interest.

b. A mandatory special assessment of $250, which Defendant must pay to the Clerk of the Court by the date of sentencing;

c. Forfeiture in the amount of $10,900,000 to be paid within 15 days of the date of sentencing; and

d. In light of Magellan's commitment to enter into the attached two-year Deferred Prosecution Agreement (Exhibit B) with the United States concerning additional criminal liability and its agreement to retain a Compliance Monitor (Exhibit C), Magellan will not be placed on probation.

In light of Magellan's commitments under the Deferred Prosecution Agreement concerning victim identification and establishing a Victim Compensation Program (Exhibit D), the parties agree that no additional restitution shall be awarded in this criminal case.

If Defendant fails to make a quarterly payment of the criminal fine due pursuant to this Plea Agreement and fails to cure such default upon 30 days' written notice from the U.S. Attorney, the United States may enforce the criminal fine judgment against any interest of the Defendant as permitted by law.

If Defendant fails to timely pay the full amount of forfeiture within 15 days of sentencing, the United States shall be entitled to forfeit as "substitute assets" any other assets of Defendant up to the value of $10,900,00, and Defendant agrees to consent to the forfeiture of any such "substitute asset."

If the Defendant fails to make a quarterly payment of the criminal fine that is not timely cured and/or fails to timely pay the full amount of the forfeiture within 15 days of sentencing, if the U.S. Attorney requests: (a) Defendant shall deliver to the U.S. Attorney within 30 days of such request a sworn financial statement disclosing all assets in which Defendant currently has any interest and all assets over which Defendant has exercised control, or has had any legal or beneficial interest; and (b) Defendant agrees to be deposed with respect to Defendant's assets.

Defendant agrees that in the event Defendant fails to make a quarterly payment of the criminal fine that is not timely cured and/or fails to timely pay the full amount of forfeiture within 15 days of sentencing all criminal monetary penalties, including special assessment, forfeiture, and/or fine imposed shall be due and payable immediately, and further agrees that any Court-ordered repayment schedule does not preclude further enforcement or collection by the United States pursuant to the terms of this Plea Agreement.

6. Waiver of Appellate Rights and Challenges to Conviction or Sentence

Defendant has the right to challenge Defendant's conviction and sentence on "direct appeal." This means that Defendant has the right to ask a higher court (the "appeals court") to look at what happened in this case and, if the appeals court finds that the trial court or the parties made certain mistakes, overturn Defendant's conviction or sentence. Also, in some instances, Defendant

has the right to file a separate civil lawsuit claiming that serious mistakes were made in this case and that Defendant's conviction or sentence should be overturned.

Defendant understands that Defendant has these rights, but now agrees to give them up. Specifically, Defendant agrees that:

a. Defendant will not challenge Defendant's conviction on direct appeal or in any other proceeding, including in a separate civil lawsuit; and

b. Defendant will not challenge Defendant's sentence, including any court orders related to forfeiture, restitution, fines or supervised release, on direct appeal or in any other proceeding, including in a separate civil lawsuit.

The U.S. Attorney agrees not to appeal the imposition of the sentence agreed to by the parties in Paragraph 5.

Defendant understands that, by agreeing to the above, Defendant is agreeing that Defendant's conviction and sentence will be final when the Court issues a written judgment after the sentencing hearing in this case. That is, after the Court issues a written judgment, Defendant will lose the right to appeal or otherwise challenge Defendant's conviction and sentence regardless of whether Defendant later changes Defendant's mind or finds new information that would have led Defendant not to agree to give up these rights in the first place.

Defendant is agreeing to give up these rights in exchange for concessions the U.S. Attorney is making in this Agreement.

The parties agree that, despite giving up these rights, Defendant keeps the right to later claim that Defendant's lawyer rendered ineffective assistance of counsel, or that the prosecutor or a member of law enforcement involved in the case engaged in misconduct serious enough to entitle Defendant to have Defendant's conviction or sentence overturned.

7. Forfeiture

Defendant understands that the Court will, upon acceptance of Defendant's guilty plea, enter an order of forfeiture as part of Defendant's sentence, and that the order of forfeiture may include assets directly traceable to Defendant's offense, assets used to facilitate Defendant's offense, substitute assets and/or a money judgment equal to the value of the property derived from, or otherwise involved in, the offense.

The assets to be forfeited specifically include, without limitation, the following:

a. $10,900,000 in United States currency, to be entered in the form of an Order of Forfeiture (Money Judgment).

Defendant admits that $10,900,000 is subject to forfeiture on the grounds that it constitutes, or is derived from, gross proceeds traceable to the commission of Counts One and Two of the Information.

Defendant acknowledges and agrees that the amount of the forfeiture money judgment represents proceeds the Defendant obtained (directly or indirectly), and/or facilitating property and/or property involved in, the crimes to which Defendant is pleading guilty and that, due at least in part to the acts or omissions of Defendant, the proceeds or property have been transferred to, or deposited with, a third party, spent, cannot be located upon exercise of due diligence, placed beyond the jurisdiction of the Court, substantially diminished in value, or commingled with other property which cannot be divided without difficulty. Accordingly, Defendant agrees that the United States is entitled to forfeit as "substitute assets" any other assets of Defendant up to the value of the now missing directly forfeitable assets.

Defendant agrees to consent to the entry of an order of forfeiture for such property and waives the requirements of Federal Rules of Criminal Procedure 11(b)(1)(J), 32.2, and 43(a) regarding notice of the forfeiture in the charging instrument, advice regarding the forfeiture at the change-of-plea hearing, announcement of the forfeiture at sentencing, and incorporation of the forfeiture in the judgment. Defendant understands and agrees that forfeiture shall not satisfy or affect any fine, lien, penalty, restitution, cost of imprisonment, tax liability, or any other debt owed to the United States.

Defendant also agrees to waive all constitutional, legal, and equitable challenges (including direct appeal, habeas corpus, or any other means) to any forfeiture carried out in accordance with this Plea Agreement.

Defendant hereby waives and releases any claims Defendant may have to any vehicles, currency, or other personal property seized by the United States, or seized by any state or local law enforcement agency and turned over to the United States, during the investigation and prosecution of this case, and consents to the forfeiture of all such assets.

8. Civil Liability

This Plea Agreement does not affect any civil liability, including any tax liability, Defendant has incurred or may later incur due to Defendant's criminal conduct and guilty plea to the charges specified in Paragraph 1 of this Agreement.

9. Breach of Plea Agreement

Defendant understands that if Defendant breaches any provision of this Agreement, violates any condition of Defendant's pre-trial release, or commits any crime following Defendant's execution of this Plea Agreement, Defendant cannot rely upon such conduct to withdraw Defendant's guilty plea. Defendant's conduct, however, would give the U.S. Attorney the right to be released from the U.S. Attorney's commitments under this Agreement, to pursue any charges that were, or are to be, dismissed under this Agreement, and to use against Defendant any of Defendant's statements, and any information or materials Defendant provided to the government during investigation or prosecution of Defendant's case—even if the parties had entered any earlier written or oral agreements or understandings about this issue.

Defendant also understands that if Defendant breaches any provision of this Agreement or engages in any of the aforementioned conduct, Defendant thereby waives any defenses based on the statute of limitations, constitutional protections against pre-indictment delay, and the Speedy Trial Act, that Defendant otherwise may have had to any charges based on conduct occurring before the date of this Agreement.

10. Who is Bound by Plea Agreement

This Agreement is only between Defendant and the U.S. Attorney for the District of Massachusetts. It does not bind the Attorney General of the United States or any other federal, state, or local prosecuting authorities.

11. Modifications to Plea Agreement

This Agreement can be modified or supplemented only in a written memorandum signed by both parties, or through proceedings in open court.

If this letter accurately reflects the agreement between the U.S. Attorney and Defendant, please have Defendant sign the Acknowledgment of Plea Agreement below. Please also sign below as Witness. Return the original of this letter to Assistant U.S. Attorney Kelly Lawrence.

Sincerely,

JOSHUA S. LEVY
Acting United States Attorney

By: _____
AMANDA P.M. STRACHAN
WILLIAM F. ABELY
Criminal Division Chiefs

_____
KELLY BEGG LAWRENCE
Chief, Health Care Fraud Unit
PATRICK M. CALLAHAN
Deputy Chief, Health Care Fraud Unit

JAMES D. HERBERT
ELYSA Q. WAN
LESLIE A. WRIGHT
Assistant U.S. Attorneys

Acknowledgement on behalf of Magellan Diagnostics, Inc.

I, Emerson C. Moser, Senior Vice President and General Counsel, the duly authorized representative of Magellan Diagnostics, Inc. ("Magellan"), hereby expressly acknowledge the following: (1) that I have read this entire Agreement as well as the other documents filed herewith in conjunction with this Agreement, including the Information and Statement of Facts; (2) that Magellan has had an opportunity to discuss this Agreement fully and freely with its counsel; (3) that Magellan fully and completely understands each and every one of the terms of this Agreement; (4) that Magellan is fully satisfied with the advice and representation provided to it by its counsel; (5) that I am authorized on behalf of Magellan to enter into this Agreement and to take all such actions as may be necessary to effectual this Agreement; and (6) that Magellan has signed this Agreement knowingly and voluntarily.

Date: 5/21/24

EMERSON C. MOSER
Magellan Diagnostics, Inc.
Senior Vice President and General Counsel

Acknowledgement by Counsel of Magellan Diagnostics, Inc.

I, Adam J. Hollingsworth the attorney representing Magellan Diagnostics, Inc., hereby expressly acknowledge the following: (1) that I have reviewed and discussed this Agreement with my client; (2) that I have explained fully each one of the terms of the Agreement to my client; (3) that I have answered fully each and every question put to me by my client regarding the Agreement; and (4) that I believe my client fully and completely understands all of the Agreement's terms.

Date: 5/21/2024

ADAM J. HOLLINGSWORTH
Jones Day
Attorney for Defendant Magellan Diagnostics, Inc.

EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA v. MAGELLAN DIAGNOSTICS, INC., Defendant	)	Criminal No. Counts One and Two: Introduction of Misbranded Medical Devices into Interstate Commerce (21 U.S.C. §§ 331(a), 333(a)(1)) Forfeiture Allegation: (18 U.S.C. § 982(a)(7))

INFORMATION

The Acting United States Attorney (the "United States Attorney") alleges that, at all times relevant to this Information:

General Allegations

1. MAGELLAN DIAGNOSTICS, INC., headquartered in Billerica, MA, was a medical device company that sold products for detecting lead levels in the blood of children and adults.

2. MAGELLAN did not timely notify the FDA about a malfunction that tended to cause its lead-testing devices to produce inaccurate blood lead level results or about MAGELLAN's subsequent corrective change in the devices' instructions for use.

MAGELLAN's Lead-Testing Devices

3. MAGELLAN produced a family of instruments for blood lead analysis using a method called anodic stripping voltammetry. Those devices included, but were not limited to, LeadCare II and LeadCare Ultra (collectively the "LeadCare Devices").

4. LeadCare II was released in 2006 and was the only point-of-care lead testing device, which means it was cleared by the United States Food and Drug Administration (FDA) for use in non-laboratory settings such as doctors' offices and clinics. The LeadCare II device could be used to test blood samples drawn from a vein ("venous" samples) and samples drawn from a fingerstick. Most LeadCare II tests were conducted on fingerstick samples; MAGELLAN estimated that approximately 5–8% of LeadCare II users conducted testing with venous blood samples. In 2017, MAGELLAN estimated that LeadCare II devices were used to conduct 2.5 million blood lead tests per year—accounting for more than half of all lead tests conducted in the United States.

5. LeadCare Ultra was released in 2013 and was designed for use at medium and large hospitals and reference labs. LeadCare Ultra could be used to test both fingerstick blood samples and venous blood samples but was predominantly used for venous blood samples. In 2017, MAGELLAN estimated that LeadCare Ultra devices were used to conduct 420,000 blood lead tests per year.

6. MAGELLAN sold its LeadCare Devices to customers located throughout the United States and in foreign countries.

FDA and FDCA

7. FDA was responsible for protecting the health and safety of the American public by ensuring, among other things, that medical devices—including diagnostic testing devices—were safe and effective. Under its statutory mandate, FDA regulated the manufacture, processing, packing, labeling, and shipment in interstate commerce of medical devices.

8. The federal Food, Drug, and Cosmetic Act (FDCA), among other things, governed the manufacture and interstate distribution of medical devices for human use, as codified at 21 U.S.C. §§ 301 et seq.

9. The FDCA and its implementing regulations required device manufacturers to submit pre-market notifications to the FDA at least 90 days before medical devices were introduced into interstate commerce for commercial distribution. Pre-market notifications were required when a device that was already on the market was about to be significantly changed or modified in design or intended use, and the change could significantly affect the safety or effectiveness of the product. 21 C.F.R. § 807.81. A device was deemed to be "misbranded" under 21 U.S.C. § 352(o) if a device manufacturer failed to submit necessary pre-market notification.

10. The FDCA and its implementing regulations provided a mechanism that allowed FDA, and others, to identify and monitor adverse events and malfunctions involving medical devices. Medical device reports (MDRs) were one of the post-market surveillance tools that FDA used to monitor device performance and detect potential device-related safety issues.

11. Medical device manufacturers were required to submit MDRs within 30 calendar days after becoming aware of a device malfunction pursuant to 21 U.S.C. § 360i(a) and 21 CFR Part 803 if the malfunction was likely to cause or contribute to serious injury or death if it recurred. Device malfunctions were defined as a failure of the device to perform as intended or meet its performance specifications, including all claims made in the device labeling under 21 CFR § 803.3.

12. The FDCA and its implementing regulations required device manufacturers to notify FDA about device corrections—which included modifications, adjustments, and

relabeling—within 10 working days of initiating the device correction if the correction was initiated to reduce a risk to health posed by the device. 21 CFR § 806.10.

13. A device was deemed to be "misbranded" under 21 U.S.C. § 352(t)(2) if the manufacturer failed or refused to file any material or information required by or under 21 U.S.C. § 360i, including an MDR or a device correction.

14. The FDCA prohibited the introduction, or causing the introduction, of misbranded medical devices into interstate commerce, pursuant to 21 U.S.C. § 331(a).

LeadCare Ultra Application for FDA Clearance

15. In or around November 2012, MAGELLAN sought clearance from FDA to introduce into the market its newly developed LeadCare Ultra device. MAGELLAN submitted a Traditional 510(k) application to FDA (the "LeadCare Ultra 510(k) application"), which claimed that the LeadCare Ultra was substantially equivalent to the already-cleared LeadCare II device. In its application, MAGELLAN described LeadCare Ultra as "an *in vitro* diagnostic device that relies on electrochemistry . . . and a unique sensor to detect lead in whole blood . . . When a sample of whole blood is mixed with Treatment Reagent (a diluted solution of hydrochloric acid), [lead is separated from the red blood cells] and lead becomes available for detection."

16. MAGELLAN's LeadCare Ultra 510(k) application contained performance testing comparing LeadCare Ultra's performance to a reference method for testing blood lead concentrations using standardized blood samples, donor blood, and human and animal blood spiked to certain lead concentrations. The reference method was called graphite furnace atomic absorption spectrometry (GFAAS). MAGELLAN's performance testing also included a clinical study in which 394 blood samples were collected. Of the 394 blood samples collected, 148 samples were within range (1.9-65 µg/dL). MAGELLAN represented to FDA that the clinical data "met

the acceptance criteria, defined as average bias within the range of ±2 µg/dL in the concentration range of 1.9 to 10 µg/dL and ±10% for concentrations above 10 µg/dL."

17. On or about January 14, 2013, FDA issued a Hold Memo for MAGELLAN's LeadCare Ultra 510(k) application, which noted several deficiencies and requested additional studies and documentation concerning, among other things, the operation of LeadCare Ultra within various temperature and humidity ranges.

Discovery of LeadCare Malfunction

18. While conducting the temperature and humidity studies requested by FDA in the Hold Memo, MAGELLAN discovered a malfunction affecting the LeadCare Ultra device (the "Malfunction").

19. The Malfunction tended to result in lower blood lead values when the blood sample was tested shortly after it was mixed with treatment reagent (sometimes referred to as "T0" for 0 minutes of incubation) and higher blood lead values if the blood-treatment reagent mixture were allowed to sit, or "incubate," for several hours or days before testing (sometimes referred to as "T[amount of incubation time]," such as "T4" for four hours of incubation time or "T24" for 24 hours of incubation time). When the Malfunction occurred, the lower blood lead value was often below that of the GFAAS device for the same sample. With incubation, the higher blood lead value was often closer to that of GFAAS but could be higher than GFAAS.

20. The Malfunction was first observed in or around June 27, 2013, when a MAGELLAN employee performed the temperature and humidity studies requested by FDA. This employee forwarded the results of this study to other MAGELLAN employees who expressed concerns over the findings.

21. At least as early as June 28, 2013, MAGELLAN's senior executive team was aware of the Malfunction affecting LeadCare Ultra.

22. MAGELLAN did not notify FDA about the results of its temperature and humidity studies that showed the Malfunction.

FDA Clearance of LeadCare Ultra

23. FDA—unaware of the Malfunction—cleared the LeadCare Ultra device for marketing and distribution on or about August 20, 2013. In its clearance letter, FDA emphasized, "We remind you, however, that the device labeling must be truthful and not misleading."

24. The label for the FDA-cleared Ultra device made accuracy claims based on its method comparison study, as shown below:

ACCURACY:
The accuracy of the LeadCare Ultra Blood Lead Testing System was determined by a Method Comparison study at two hospital laboratory sites. Three hundred ninety-four (394) results, from a combination of spiked and unspiked blood samples, were generated. One hundred forty-eight results were within the claimed analytical range of 1.9 – 65.0 µg/dL. The LeadCare Ultra results were plotted versus the results obtained by the Reference Method, GFAAS. The LeadCare Ultra average bias from GFAAS and the scatter plot of LeadCare Ultra vs. GFAAS results, with the linear regression, are provided in Table 2 and Graph 1, respectively.

Table 2: LeadCare Ultra Average Bias from GFAAS

GFAAS (µg/dL)	Predicted LeadCare Ultra (µg/dL)	Avg. Bias (µg/dL)	Bias (%)
1.90	1.95	0.05	2.4%
5.00	5.01	0.01	0.2%
10.00	9.96	-0.04	-0.4%
20.00	19.85	-0.15	-0.7%
30.00	29.74	-0.26	-0.9%
40.00	39.64	-0.36	-0.9%
50.00	49.53	-0.47	-0.9%
60.00	59.42	-0.58	-1.0%
65.00	64.37	-0.63	-1.0%

25. MAGELLAN's method comparison study, however, did not control for the amount of time that the blood-treatment reagent incubated before testing, which is to say that the laboratories participating in the method comparison study were free to run the tests at any time after mixing the blood sample and treatment reagent as permitted by the LeadCare Ultra label. The

LeadCare Ultra label's instructions for use stated in part: "After mixing the blood with the Treatment Reagent, analyze it in less than 48 hours if stored at room temperature. If stored refrigerated, analyze within 7 days." Thus, if the normal workflow of these laboratories included sufficient incubation time after mixing, the study was unlikely to show the effects of the Malfunction.

26. The label for the FDA-cleared LeadCare Ultra device also stated:

> Childhood lead poisoning is a major, preventable problem in the United States. Numerous studies have shown that exposure to lead can result in damage to the nervous, hematopoietic, endocrine, renal, and reproductive systems causing lifelong physical and mental health problems. Children are particularly susceptible to the effects of lead as their nervous systems are still developing.
>
> In 2012, based on the increased body of evidence demonstrating there is no safe level of lead in the blood, experts established a new reference value to identify children who have elevated blood lead levels (BLL). According to the Centers for Disease Control (CDC) website (www.cdc.gov/nceh/lead), this level is based on the U.S. population of children ages 1-5 years who are in the top 2.5% of children when tested for lead in their blood (when compared to children who are exposed to more lead than most children). Currently this reference value is 5 μg/dL.

Confirmation of the Malfunction and Delayed Release of LeadCare Ultra

27. MAGELLAN did not release LeadCare Ultra to the market shortly after FDA clearance because of concerns about the Malfunction. From in or around August 2013 until in or around December 2013, MAGELLAN designed and conducted multiple studies comparing LeadCare Ultra test results measured (a) immediately after blood samples were mixed with treatment reagent and (b) after allowing the blood-treatment reagent to incubate for various time periods ("the 2013 Malfunction Studies"). While the Malfunction did not appear in every experiment, the 2013 Malfunction Studies repeatedly showed that the Malfunction occurred when

testing various types of blood samples, at various lead concentrations, and using various sensors and treatment reagents.

28. MAGELLAN knew that the Malfunction was likely to cause or contribute to serious injury or death if it recurred.

29. MAGELLAN released LeadCare Ultra for sale to customers in or around December 2013. MAGELLAN did not notify customers or FDA in 2013 that the Malfunction could cause false lows and false highs, especially if testing was conducted immediately after mixing blood samples with treatment reagent.

Discovery and Confirmation of the Malfunction in LeadCare II

30. During the 2013 Malfunction Studies, MAGELLAN conducted studies to determine whether the Malfunction affected LeadCare II sensors and treatment reagent as well as LeadCare Ultra. Those studies confirmed that the Malfunction was not an isolated problem with LeadCare Ultra but was "a general phenomenon" that also affected LeadCare II when it was used to test venous samples.

31. Prior to November 2016, MAGELLAN did not inform customers and FDA that the Malfunction was likely to cause inaccurate test results when LeadCare II was tested using venous samples.

LeadCare Ultra Customer Letter

32. Beginning in or around August 2014 and continuing through in or about October 2014, certain LeadCare Ultra customers independently discovered the Malfunction after they observed inaccurate and changing lead test results. These customers reported to MAGELLAN that they had received unexpectedly low test results when samples were tested immediately after being

mixed with treatment reagent, as the label allowed, and had found that the lead test result was higher if the sample was tested an hour after the sample was mixed with treatment reagent.

33. On or about November 24, 2014, MAGELLAN sent LeadCare Ultra customers a letter about the Malfunction (the "LeadCare Ultra Customer Letter").

34. The LeadCare Ultra Customer Letter advised customers to allow the blood-treatment reagent mixture to sit for a minimum of 24 hours before testing. This advice contradicted the LeadCare Ultra label, which permitted users to analyze the sample immediately after mixing the blood sample and treatment reagent and permitted users to analyze the mixture within 48 hours if the mixture was kept at room temperature or within seven days if the mixture was refrigerated.

Overdue Filing of the LeadCare Ultra MDR

35. Prior to April 2015, MAGELLAN did not notify FDA about (a) MAGELLAN's discovery of the Malfunction and (b) MAGELLAN's change to the LeadCare Ultra user instructions, communicated directly to customers via the LeadCare Ultra Customer Letter.

36. On or about April 2, 2015, MAGELLAN submitted an MDR about the Malfunction (the "LeadCare Ultra MDR"). MAGELLAN did not receive a response from FDA following its submission of the LeadCare Ultra MDR.

37. In or around August 2015, MAGELLAN approved an engineering change order (ECO) that changed the LeadCare Ultra label, user guide, and website to incorporate the 24-hour incubation instruction.

38. MAGELLAN did not notify FDA of the change to the device and product insert, nor did FDA clear the significantly changed device.

Overdue Notification to FDA about LeadCare II Malfunction

39. In or around November 2016, MAGELLAN submitted an amendment to the LeadCare Ultra MDR disclosing that the Malfunction also affected LeadCare II (the "LeadCare II MDR").

40. The LeadCare II MDR was submitted by MAGELLAN on or around November 7, 2016. However, the LeadCare II MDR was not properly filed and was not received by FDA until in or around 2017.

The 2017 Recall

41. In or around 2017, FDA contacted MAGELLAN with questions about the Malfunction and ultimately found that MAGELLAN's data showed that LeadCare Devices could not accurately test venous samples, regardless of the recommended incubation times.

42. In or around May 2017, FDA recommended a recall of all LeadCare Devices using venous samples.

COUNT ONE

Introduction of Misbranded Devices into Interstate Commerce
(Failure to Timely File Medical Device Reports)
(21 U.S.C. §§ 331(a), 333(a)(1))

43. The United States Attorney re-alleges and incorporates by reference paragraphs 1-42 of this Information.

44. From in or around December 2013 through in or around May 2017, within the District of Massachusetts and elsewhere, the defendant,

MAGELLAN DIAGNOSTICS, INC.,

caused to be introduced into interstate commerce misbranded medical devices, to wit, the LeadCare Ultra and LeadCare II products, which were distributed to customers outside Massachusetts even though necessary medical device reports pursuant to 21 U.S.C. § 360i(a) and 21 CFR Part 803 reporting product malfunctions had not been filed.

All in violation of Title 21, United States Code, Sections 331(a) and 333(a)(1).

COUNT TWO

Introduction of Misbranded Devices into Interstate Commerce
(Failure to Provide Pre-Market Notification and Timely File Reports of Correction)
(21 U.S.C. §§ 331(a), 333(a)(1))

45. The United States Attorney re-alleges and incorporates by reference paragraphs 1-42 of this Information.

46. From in or around November 2014 through in or around May 2017, within the District of Massachusetts and elsewhere, the defendant,

MAGELLAN DIAGNOSTICS, INC.,

caused to be introduced into interstate commerce misbranded medical devices, to wit, the LeadCare Ultra, which were distributed to customers outside Massachusetts with instructions to incubate the blood-treatment reagent samples for 24 hours, even though (i) the defendant failed to provide the FDA pre-market notification at least 90 days before distributing a significantly changed device pursuant to 21 C.F.R. Part 807, and (ii) the defendant did not file the necessary reports of device correction initiated to reduce a risk to health posed by the device pursuant to 21 U.S.C. § 360i(g) and 21 CFR Part 806.

All in violation of Title 21, United States Code, Sections 331(a) and 333(a)(1).

FORFEITURE ALLEGATION

(18 U.S.C. § 982(a)(7))

The United States Attorney further alleges that:

47. Upon conviction of one or more of the offenses in violation of Title 21, United States Code, Section 331(a), set forth in Counts One and Two of this Information, the defendant,

MAGELLAN DIAGNOSTICS, INC.,

shall forfeit to the United States, pursuant to Title 18, United States Code, Section 982(a)(7), any property, real or personal, that constitutes or is derived, directly or indirectly, from proceeds traceable to the offenses.

48. If any of the property described in Paragraph 47, above, as being forfeitable pursuant to Title 18, United States Code, Section 982(a)(7), as a result of any act or omission of the defendant —

a. cannot be located upon the exercise of due diligence;

b. has been transferred or sold to, or deposited with, a third party;

c. has been placed beyond the jurisdiction of the Court;

d. has been substantially diminished in value; or

e. has been commingled with other property which cannot be divided without difficulty;

it is the intention of the United States, pursuant to Title 21, United States Code, Section 853(p), incorporating Title 18, United States Code, Section 982(b)(1), to seek forfeiture of any other property of the defendants up to the value of the property described in Paragraph 47 above.

All pursuant to Title 18, United States Code, Section 982(a)(7).

Respectfully submitted,

JOSHUA S. LEVY
ACTING UNITED STATES ATTORNEY

By: */s/ Kelly Begg Lawrence*
JAMES D. HERBERT
KELLY BEGG LAWRENCE
ELYSA Q. WAN
LESLIE A. WRIGHT
Assistant U.S. Attorneys

EXHIBIT B

UNITED STATES DISTRICT COURT
FOR THE MASSACHUSETTS

UNITED STATES OF AMERICA	)	
	)	**Criminal No. 23-cr-_____**
v.	)	
	)	
MAGELLAN DIAGNOSTICS, INC.	)	
	)	
Defendant.	)	
	)	
	)	

DEFERRED PROSECUTION AGREEMENT

The United States Attorney's Office, by its attorney, Joshua S. Levy, Acting United States Attorney for the District of Massachusetts (the "Office") and defendant Magellan Diagnostics, Inc. ("Magellan" or "the Company") hereby enter into this Deferred Prosecution Agreement (the "Agreement"). The terms and conditions of this Agreement are as follows:

Criminal Information and Acceptance of Responsibility

1. The Company acknowledges and agrees that the Office will file the attached criminal Information in the United States District Court for the District of Massachusetts charging the Company with (1) conspiracy to commit wire fraud in violation of Title 18, United States Code, Section 1349; and (2) conspiracy to defraud the United States in violation of Title 18, United States Code, Section 371 (hereinafter, "the Felony Information"). In so doing, the Company: (a) knowingly waives any right it may have to indictment on these charges, as well as all rights to a speedy trial pursuant to the Sixth Amendment to the United States Constitution, Title 18, United States Code, Section 3161, and Federal Rule of Criminal Procedure 48(b); (b) agrees to venue of the case in the District of Massachusetts and knowingly waives any objection with respect to venue to any charges by the United States arising out of the conduct described in the Statement of Facts attached hereto as Attachment A ("Statement of Facts"); (c) knowingly waives any applicable

statute of limitations and any legal or procedural defects in the Felony Information; and (d) consents to the filing of the Felony Information, as provided under the terms of this Agreement, in the United States District Court for the District of Massachusetts. The Office agrees to defer prosecution of the Company pursuant to the terms and conditions described below.

2. The Company admits, accepts, and acknowledges that it is responsible under United States law for the acts of its officers, directors, employees, and agents as charged in the Felony Information, and as set forth in the Statement of Facts, and that the allegations described in the Felony Information and the facts described in the Statement of Facts are true and accurate. The Company agrees that, as of the Effective Date (as defined herein), in any prosecution that is referenced by this Agreement, it will not dispute the Statement of Facts set forth in this Agreement, and, in any such prosecution, the Statement of Facts shall be admissible as: (a) substantive evidence offered by the government in its case-in-chief and rebuttal case; (b) impeachment evidence offered by the government on cross-examination; and (c) evidence at any sentencing hearing or other hearing. In addition, in connection therewith, the Company agrees not to assert any claim under the United States Constitution, Rule 410 of the Federal Rules of Evidence, Rule 11(f) of the Federal Rules of Criminal Procedure, Section 1B1.1(a) of the United States Sentencing Guidelines, or any other federal rule that the Statement of Facts should be suppressed or is otherwise inadmissible as evidence in any form.

Term of the Agreement

3. This Agreement is effective for a period beginning on the date on which the Information is filed (the "Effective Date") and ending twenty-four (24) months from the later of the Effective Date or the date on which the independent compliance monitor (the "Monitor") is retained by the Company, as described in Paragraphs 14–17 below (the "Term"). The Company

agrees, however, that, in the event the Office determines, in its sole discretion, that the Company has knowingly violated any provision of this Agreement or has failed to completely perform or fulfill each of the Company's obligations under this Agreement, an extension or extensions of the Term may be imposed by the Office, in its sole discretion, for up to a total additional time period of one year, without prejudice to the Office's right to proceed as provided in Paragraphs 20–23 below. Any extension of the Agreement extends all terms of this Agreement, including the terms of the reporting requirements and monitorship in Attachment D, for an equivalent period. Conversely, in the event the Office finds, in its sole discretion, independently or after a request by the Company, that there exists a change in circumstances sufficient to eliminate the need for the reporting requirements and monitorship in Attachment D, and that the other provisions of this Agreement have been satisfied, the Agreement may be terminated early. If the Court refuses to grant exclusion of time under the Speedy Trial Act, Title 18, United States Code, Section 3161(h)(2), the Term shall be deemed to have not begun, and all provisions of this Agreement shall be deemed null and void, except: (a) the provisions contained within Paragraph 2 of this Agreement; and (b) the statute of limitations for any prosecution relating to the conduct described in the Statement of Facts shall be tolled from the Effective Date of this Agreement until the date the Court refuses to grant the exclusion of time plus six months.

Relevant Considerations

4. The Office enters into this Agreement based on the individual facts and circumstances presented by this case and the Company, including:

a. The Company's acknowledgement of its conduct and acceptance of responsibility for that conduct;

b. The Company's cooperation in the investigation of this matter and the Company's commitment to continue cooperation with the government's investigation and prosecution of violations of federal law by individuals associated with Magellan;

c. The Company's commitment to enhanced compliance measures;

d. Remedial measures undertaken by the Company and its parent company and the Company's commitment to undertake additional remediation as identified herein;

e. The Company's guilty plea to two misdemeanor violations of the Food, Drug, and Cosmetic Act ("FDCA"), Title 21, United States Code, Sections 331 and 333 as charged in an information ("FDCA Information") filed by the Office in this matter, and payment of $32,700,000 in criminal fines and forfeiture in connection with the FDCA Information; and

f. The Company's commitment to fulfill all of the terms of this Agreement;

g. Accordingly, after considering (a) though (f) above, the Office believes that the appropriate resolution in this case is a deferred prosecution agreement with the Company, payment of victim compensation of at least $9,300,000 as detailed herein and in attachments to this Agreement; and the Company's agreement to report to the Office as set forth in the Compliance Reporting Requirements and to engage an independent compliance Monitor.

Future Cooperation and Disclosure Requirements

5. The Company shall cooperate fully with the Office in any and all matters relating to the facts and conduct described in this Agreement and the Statement of Facts until all investigations and prosecutions arising out of such conduct are concluded. At the request of the Office, the Company shall also cooperate fully with other domestic or foreign law enforcement and regulatory authorities and agencies in any investigation of the Company, its parent company or subsidiaries, or any of its present or former officers, directors, employees, agents, and

consultants, or any other party, in any and all matters relating to the facts and conduct described in this Agreement and the Statement of Facts. The Company's cooperation pursuant to this Paragraph is subject to applicable law and regulations, as well as valid claims of attorney-client privilege or attorney work product doctrine; however, the Company must provide to the Office a description of any information or cooperation that is not provided based on an assertion of law, regulation, or privilege, and the Company bears the burden of establishing the validity of any such an assertion. The Company agrees that its cooperation pursuant to this paragraph shall include, but not be limited to, the following:

a. The Company shall truthfully disclose all factual information with respect to its activities, those of its parent company and subsidiaries, and those of its present and former directors, officers, employees, agents, and consultants, including any evidence or allegations and internal or external investigations, about which the Company has any knowledge or about which the Office may inquire. This obligation of truthful disclosure includes, but is not limited to, the obligation of the Company to provide to the Office, upon request, any non-privileged document, record, or other tangible evidence about which the Office may inquire of the Company.

b. Upon request of the Office, the Company shall designate knowledgeable employees, agents, or attorneys to provide to the Office the information and materials described in Paragraph 5(a) above on behalf of the Company. The Company agrees that it must at all times provide complete, truthful, and accurate information to the Office.

c. As requested by the Office, the Company shall make available for interviews or testimony any present officers, directors, employees, agents, and consultants of the Company, its parent company and subsidiaries. This obligation includes, but is not limited to, sworn testimony as well as interviews with domestic or foreign law enforcement and regulatory

authorities. Cooperation under this Paragraph shall include identification of witnesses who, to the knowledge of the Company, may have material information regarding the matters under investigation.

d. With respect to any information, testimony, documents, records, or other tangible evidence provided to the Office pursuant to this Agreement, the Company consents to any and all disclosures to other governmental authorities, including United States authorities and those of a foreign government, of such materials as the Office, in its sole discretion, shall deem appropriate.

Victim Compensation

6. The Company agrees to establish a Victim Compensation Fund of at least $9,300,000 to compensate patients and/or minor patients' legal guardians who were harmed by the conduct described in the Statement of Facts between June 27, 2013 and May 31, 2017. The Company shall establish a dedicated bank account for the Victim Compensation Fund and make deposits to the account according to the following schedule: $3,000,000 shall be deposited no later than 15 days after the Effective Date of this Agreement; $3,000,000 shall be deposited no later than one year after the Effective Date of this Agreement; and $3,300,000 shall be deposited no later than two years after the Effective Date of this Agreement.

7. The parties agree that the Monitor shall, according to the processes and standards described in Attachments D and F, (i) oversee the Company's efforts to identify and notify potential victims; (ii) review and evaluate victim compensation claims; (iii) oversee the Company's payment of victim compensation claims that the Monitor determines shall be paid; and (iv) resolve any disputes between a victim and the Company concerning the victim's entitlement to compensation. The Company agrees to fully compensate victims the Monitor determines to be

entitled to victim compensation, even if the total compensation requires the Company to add funds to the dedicated bank account.

8. The Company agrees to pay for all costs, fees, and expenses incurred in connection with the dedicated bank account, the Monitor's oversight and administration of the victim compensation process, and any victim outreach efforts.

9. The parties agree that any portion of the Victim Compensation Fund that (a) has not been paid out to victims at the conclusion of the Victim Payment Period (as that term is defined in Attachment F) and (b) is not subject to a pending claim submitted to the Monitor (as specified in Attachment F) shall instead be paid to qualified Childhood Lead Poisoning Prevention Programs ("CLPPPs"). CLPPPs are state and local programs dedicated to reducing childhood lead poisoning as a public health problem through strengthening blood testing, reporting, and surveillance, linking exposed children to recommended services, and targeted population-based interventions. The parties agree that the Monitor shall, according to the processes and standards described in Attachments D and F, determine—subject to approval by the Office—which CLPPPs are qualified to receive payments and the amount each CLPPP shall receive.

Conditional Release from Liability

10. Subject to Paragraphs 20–23, the Office agrees, except as provided in this Agreement and the Company's plea agreement concerning the FDCA Information, that it will not bring any criminal or civil case against the Company relating to any of the conduct described in the Statement of Facts, the Felony Information, or the FDCA Information filed pursuant to this Agreement. The Office, however, may use any information related to the conduct described in the Statement of Facts against the Company: (a) in a prosecution for perjury or obstruction of justice; (b) in a prosecution for making a false statement; (c) in a prosecution or other proceeding relating

to any crime of violence; or (d) in a prosecution or other proceeding relating to a violation of any provision of Title 26 of the United States Code.

a. This Agreement does not provide any protection against prosecution for any future conduct by the Company.

b. In addition, this Agreement does not provide any protection against prosecution of any individuals, regardless of their affiliation with the Company.

Corporate Compliance Program

11. The Company has implemented and will continue to implement a compliance and ethics program designed to prevent and detect violations of the FDCA and its associated regulations throughout its operations, including those of its subsidiaries, agents, and joint ventures, and those of its contractors and subcontractors whose responsibilities relate to the Company's interactions with domestic government agencies (including the Food and Drug Administration ("FDA")) and the Company's communications with customers about FDA-regulated products, including, but not limited to, the elements set forth in Attachment C.

12. In order to address any deficiencies in its internal controls, policies, and procedures, the Company represents that it has undertaken, and will continue to undertake in the future, in a manner consistent with all of its obligations under this Agreement, a review of its existing internal controls, policies, and procedures regarding compliance with the FDCA, focusing on the Company's interactions with domestic government agencies (including the FDA) and the Company's handling of complaints or malfunction reports concerning FDA-regulated products. Where necessary and appropriate, the Company agrees to adopt a new compliance program, or to modify its existing one, including internal controls, compliance policies, and procedures in order to ensure that it maintains an effective compliance program, including a system of internal

controls, designed to effectively detect and deter violations of the FDCA and its associated regulations. The compliance program, including the internal controls system, will include, but not be limited to, the elements set forth in Attachment C.

Corporate Compliance Reporting

13. The Company agrees that it will report to the Office during the Term regarding remediation and implementation of the compliance measures described in Attachment C. These reports will be prepared in accordance with, and at the frequency defined in, Attachment D.

Independent Compliance Monitor

14. Promptly after the Office's selection of a Monitor pursuant to Paragraph 16, the Company agrees to retain the Monitor for the term specified in Paragraph 17. The Monitor's duties and authority, and the obligations of the Company with respect to the Monitor and the Office, are set forth in Attachment D. Within 15 business days after the Effective Date of this Agreement, the Company shall submit a written proposal identifying three Monitor candidates, and, at a minimum, providing the following:

a. a description of each candidate's qualifications and credentials in support of the evaluative considerations and factors listed below;

b. a written certification by the Company that it will not employ or be affiliated with the Monitor for a period of not less than two years from the date of the termination of the monitorship;

c. a written certification by each of the candidates that the candidate is not a current or recent (i.e., within the prior two years) employee, agent, or representative of the Company and holds no interest in, and has no relationship with, the Company, its parent company, subsidiaries, or related entities, or its employees, officers, or directors;

d. a written certification by each of the candidates that the candidate has notified any clients that the candidate represents in a matter involving the Office (or any other Department of Justice component handling the Monitor selection process), and that the candidate has either obtained a waiver from those clients or has withdrawn as counsel in the other matter(s); and

e. A statement identifying the Monitor candidate that is the Company's first, second, and third choice to serve as the Monitor.

15. The Monitor candidates or their team members shall have, at a minimum, the following qualifications:

a. experience and expertise with respect to designing and/or reviewing corporate compliance policies, procedures, and internal controls, including those specific to maintaining compliance with the FDCA and its associated regulations and other applicable laws concerning in vitro diagnostic testing devices;

b. experience and expertise with mass tort litigation, product liability, and/or personal injury;

c. the ability to access and deploy resources as necessary to discharge the Monitor's duties as described in this Agreement; and

d. sufficient independence from the Company to ensure effective and impartial performance of the Monitor's duties as described in this Agreement.

16. The Office retains the right, in its sole discretion, to choose the Monitor from among the candidates proposed by the Company consistent with DOJ policy concerning the selection of corporate monitors. Any submission or selection of a Monitor candidate by either the Company or the Office shall be made without unlawful discrimination against any person or class

of persons. If the Office determines, in its sole discretion, that any or all of the three candidates lack the requisite qualifications, the Office shall notify the Company and request that the Company propose another candidate or candidates within 20 business days. This process shall continue until a Monitor acceptable to both parties is chosen. The Office and the Company will use their best efforts to complete the selection process within 60 calendar days of the Effective Date of this Agreement. The Office retains the right to determine that the Monitor should be removed if, in the Office's sole discretion, the Monitor fails to conduct the monitorship effectively, fails to comply with this Agreement, or no longer meets the qualifications outlined in Paragraph 15. If the Monitor resigns, is removed, or is otherwise unable to fulfill the Monitor's obligations as set out herein and in Attachment D, the Company shall within 20 business days recommend a pool of three qualified Monitor candidates from which the Office will choose a replacement, following the process outlined above.

17. The Monitor's term shall be 24 months from the date on which the Monitor is retained by the Company, subject to extension or early termination as described in Paragraph 3. Notwithstanding the foregoing, the Company agrees that the Monitor's role as claims administrator shall continue for a 36-month period as set forth in Attachment F. The Monitor's powers, duties, and responsibilities, as well as additional circumstances that may support an extension of the Monitor's term, are set forth in Attachment D. The Company agrees that it will not employ or be affiliated with the Monitor or the Monitor's firm for a period of not less than two years from the date on which the Monitor's term expires, nor will the Company discuss with the Monitor or the Monitor's firm the possibility of further employment or affiliation during the Monitor's term. Upon agreement by the parties, this prohibition will not apply to other monitorship responsibilities

that the Monitor or the Monitor's firm may undertake in connection with resolutions with foreign or other domestic authorities.

Deferred Prosecution

18. In consideration of the undertakings agreed to by the Company herein, the Office agrees that any prosecution of the Company for the conduct set forth in the Statement of Facts (other than the FDCA Information, as described in Paragraph 4(e)) be and hereby is deferred for the Term. To the extent there is conduct disclosed by the Company that is not set forth in the Statement of Facts, such conduct will not be exempt from further prosecution and is not within the scope of or relevant to this Agreement.

19. The Office shall, if the Company is in full compliance with all of its obligations under this Agreement, within three months after the expiration of the Term of this Agreement set forth above in Paragraph 3, or earlier at the discretion of the Office, seek dismissal with prejudice of the Felony Information filed against the Company pursuant to Paragraph 1, and this Agreement shall expire and be of no further force and effect. The Office further agrees not to file charges in the future against the Company based on conduct described in this Agreement, the Felony Information, the FDCA Information, or the Statement of Facts. If, however, the Office determines during this three-month period that the Company breached the Agreement during the Term, as described in Paragraph 20, the Office's ability to extend the Term, as described in Paragraph 3, or to pursue other remedies, including those described in Paragraphs 20–23, remains in full effect.

Breach of the Agreement

20. If, during the Term, the Company (a) commits any felony under U.S. federal law; (b) provides in connection with this Agreement deliberately false, incomplete, or misleading information, including in connection with its disclosure of information about individual

culpability; (c) fails to abide by its plea agreement concerning the FDCA Information; (d) fails to cooperate as set forth in Paragraph 5 of this Agreement; (e) fails to implement a compliance program as set forth in Paragraphs 11–12 of this Agreement and Attachment C; (f) fails to make any reports as set forth in Paragraph 13 of this Agreement and Attachment D; or (g) otherwise fails to completely perform or fulfill each of the Company's obligations under the Agreement and its duties to the Monitor, regardless of whether the Office becomes aware of such a breach after the Term is complete, the Company shall thereafter be subject to prosecution for any federal criminal violation of which the Office has knowledge, including, but not limited to, the charges in the Felony Information described in Paragraph 1, which may be pursued by the Office in the U.S. District Court for the District of Massachusetts or any other appropriate venue. Determination of whether the Company has breached the Agreement and whether to pursue prosecution of the Company shall be in the Office's sole discretion. Any such prosecution may be premised on information provided by the Company or its personnel. Any such prosecution relating to the conduct described in the Statement of Facts or relating to conduct known to the Office prior to the Effective Date of this Agreement that is not time-barred by the applicable statute of limitations on the Effective Date of this Agreement may be commenced against the Company, notwithstanding the expiration of the statute of limitations, between the Effective Date and the expiration of the Term plus one year. By signing this Agreement, the Company agrees that the statute of limitations with respect to any such prosecution that is not time-barred on the Effective Date of this Agreement shall be tolled for the Term plus one year. In addition, the Company agrees that the statute of limitations as to any violation of U.S. federal law that occurs during the Term will be tolled from the date upon which the violation occurs until the earlier of the date upon which the Office is made

aware of the violation or the duration of the Term plus five years, and that this period shall be excluded from any calculation of time for purposes of the application of the statute of limitations.

21. In the event the Office determines that the Company has breached this Agreement, the Office agrees to provide the Company with written notice of such alleged breach prior to instituting any prosecution resulting from such breach. Within 15 calendar days of receipt of such notice, unless the government agrees to a different period, the Company shall have the opportunity to respond to the Office in writing to explain the nature and circumstances of such alleged breach, as well as the actions the Company has taken to address and remediate the situation, which explanation the Office shall consider in determining whether to pursue prosecution of the Company. The parties expressly understand and agree that if the Company fails to make the above-noted presentation within such period, it shall be presumed that the Company is in willful and material breach of this Agreement. The parties further understand and agree that the Office's exercise of discretion under this paragraph is not subject to review in any court or tribunal outside the Department of Justice and the Office.

22. In the event that the Office determines that the Company has breached this Agreement: (a) all statements made by or on behalf of the Company to the Office or to the Court and any testimony given by the Company before a grand jury, a court, or any tribunal, or at any legislative hearings, whether prior or subsequent to this Agreement, and any leads derived from such statements or testimony, shall be admissible in evidence in any and all criminal proceedings brought by the Office against the Company; and (b) the Company shall not assert any claim under the United States Constitution, Rule 11(f) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules of Evidence, or any other federal rule that any such statements or testimony made by or on behalf of the Company prior or subsequent to this Agreement, or any leads derived

therefrom, should be suppressed or are otherwise inadmissible. The decision whether conduct or statements of any current director, officer, or employee, or any person acting on behalf of, or at the direction of, the Company, will be imputed to the Company for the purpose of determining whether the Company has violated any provision of this Agreement shall be in the sole discretion of the Office.

23. The Company acknowledges that the Office has made no representations, assurances, or promises concerning what sentence may be imposed by the Court if the Company breaches this Agreement and this matter proceeds to judgment. The Company further acknowledges that any such sentence is solely within the discretion of the Court and that nothing in this Agreement binds or restricts the Court in the exercise of such discretion.

Sale, Merger, or Other Change in Corporate Form of Company

24. Except as may otherwise be agreed by the parties in connection with a particular transaction, the Company agrees that in the event that, during the Term, it undertakes any change in corporate form, including if it sells, merges, or transfers business operations that are material to the Company's operations, or to the operations of any parent company or subsidiaries involved in the conduct described in the Statement of Facts, as they exist as of the Effective Date of this Agreement, whether such sale is structured as a sale, asset sale, merger, transfer, or other change in corporate form, it shall include in any contract for sale, merger, transfer, or other change in corporate form a provision binding the purchaser, or any successor in interest thereto, to the obligations described in this Agreement. The purchaser or successor in interest must also agree in writing that the Office's ability to determine a breach under this Agreement is applicable in full force to that entity. The Company agrees that the failure to include these provisions in the transaction will make any such transaction null and void. The Company shall provide notice to the

Office at least 30 business days prior to undertaking any such sale, merger, transfer, or other change in corporate form. The Office shall notify the Company prior to such transaction (or series of transactions) if the Office determines that the transaction(s) will have the effect of circumventing or frustrating the enforcement purposes of this Agreement. At any time during the Term the Company engages in a transaction(s) that has the effect of circumventing or frustrating the enforcement purposes of this Agreement, the Office may deem it a breach of this Agreement pursuant to Paragraph 20 of this Agreement. Nothing herein shall restrict the Company from indemnifying (or otherwise holding harmless) the purchaser or successor in interest for penalties or other costs arising from any conduct that may have occurred prior to the date of the transaction, so long as such indemnification does not have the effect of circumventing or frustrating the enforcement purposes of this Agreement, as determined by the Office.

Insolvency Proceedings

25. The Company agrees that in the event that, during the Term, the Company 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 the Company's debts, or to adjudicate the Company as bankrupt or insolvent; or seeking appointment of a receiver, trustee, custodian, or other similar official for the Company or for all or any substantial part of the Company's assets (collectively an "Insolvency Proceeding") or if the Company's obligations under this Agreement are avoided for any reason, including but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code in an Insolvency Proceeding or in any other case, proceeding or action:

a. The Office, at its sole option, may subject the Company to prosecution for any federal criminal violation of which the Office has knowledge, including, but not limited to,

the charges in the Felony Information described in Paragraph 1, pursuant to the terms further set forth in Paragraphs 20–23 of this Agreement.

b. The Company shall take such actions as may be reasonably necessary or appropriate in an Insolvency Proceeding to ensure the Company will be able to comply with its obligations under this Agreement, including, without limitation, assuming its obligations under this Agreement and any agreements required pursuant to Paragraphs 14–17, including any agreements with the Monitor.

c. The terms of Paragraph 24 of this Agreement shall apply to any sale, merger, or other change in corporate form effectuated through an Insolvency Proceeding, including a sale of all or substantially of the Company's assets.

d. Any Definitive Documents[1] related to an Insolvency Proceeding shall be consistent in all material respects with this Agreement and shall not in any manner, by their terms, contain any provisions that amend, modify, supplement, supersede, or conflict with any of the provisions of this Agreement. Any Definitive Documents related to an Insolvency Proceeding shall be in form and substance reasonably acceptable to the United States.

e. In any Insolvency Proceeding in which this Agreement is not assumed and the Company's criminal fine and forfeiture obligations under the plea agreement concerning the FDCA Information are not otherwise paid in full, the United States shall be entitled to an

[1] Definitive Documents means all material agreements, schedules, and judicial or regulatory orders related to an Insolvency Proceeding that are necessary to implement this Agreement or materially affect this Agreement, including without limitation any plan of reorganization or liquidation and any order confirming such plan, and any motion to sell the Company or to sell all or substantially all of the Company's assets and any order approving such sale.

undisputed, noncontingent, and liquidated claim that is not subject to reconsideration or subordination against the Company for the then-unpaid balance of the criminal fine and forfeiture.

f. The Company shall not argue or otherwise contend in an Insolvency Proceeding that the United States' claim, action, or proceeding with respect of the matters covered by this Agreement 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).

g. The Company shall not argue that the dedicated bank account described in Paragraph 6 of this Agreement is property of the estate or that any agreement with respect to such account is an executory contract. Further, the Company shall not argue or otherwise contend in an Insolvency Proceeding that distributions from the dedicated bank account pursuant to Paragraphs 14–17 of this Agreement are subject to the automatic stay and, to the extent necessary, consents to relief from the automatic stay for cause under 11 U.S.C. § 362(d)(1).

26. The Company's obligations under this Agreement may not be avoided pursuant to 11 U.S.C. § 547 or 11 U.S.C. § 548(a)(1), and the Company shall not argue or otherwise take the position in any Insolvency Proceeding or in any other case, proceeding, or action that: (i) the Company's obligations under this Agreement may be avoided under 11 U.S.C. § 547; (ii) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to the Company; or (iii) the mutual promises, covenants, and obligations set forth herein are not intended to and do not, in fact, represent a reasonably equivalent exchange of value or that such mutual promises, covenants, and obligations are intended to hinder, delay, or defraud any entity to which the Company was or became indebted to on or after the date of this Agreement, within the meaning of 11 U.S.C. § 548(a)(1).

27. In evaluating whether to execute this Agreement, the Company and the Office warrant that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to the Company, within the meaning of 11 U.S.C. § 547(c)(1), and the Company and the Office conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Company and the Office 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 the Company was or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).

28. The Company shall provide notice to the Office at least 30 business days prior to commencing an Insolvency Proceeding.

Public Statements by Company

29. The Company expressly agrees that it shall not, through present or future attorneys, officers, directors, employees, agents, or any other person authorized to speak for the Company make any public statement, in litigation or otherwise, contradicting the acceptance of responsibility by the Company set forth above or the facts described in the Statement of Facts. Any such contradictory statement shall, subject to cure rights of the Company described below, constitute a breach of this Agreement, and the Company thereafter shall be subject to prosecution as set forth in Paragraphs 20–23 of this Agreement. The decision whether any public statement by any such person contradicting a fact contained in the Statement of Facts will be imputed to the Company for the purpose of determining whether it has breached this Agreement shall be at the sole discretion of the Office. If the Office determines that a public statement by any such person contradicts in whole or in part a statement contained in the Statement of Facts, the Office shall so

notify the Company, and the Company may avoid a breach of this Agreement by publicly repudiating such statement(s) within five business days after notification. The Company shall be permitted to raise defenses and to assert affirmative claims in other proceedings relating to the matters set forth in the Statement of Facts provided that such defenses and claims do not contradict, in whole or in part, a statement contained in the Statement of Facts. This Paragraph does not apply to any statement made by the Company in litigation against its former employees, or made by any present or former officer, director, employee, or agent of the Company in the course of any criminal, regulatory, or civil case initiated against such individual, unless such individual is speaking on behalf of the Company.

30. The Company agrees that if it, its parent company, or any of its direct or indirect subsidiaries issues a press release or holds any press conference in connection with this Agreement, the Company shall first consult with the Office to determine (a) whether the text of the release or proposed statements at the press conference are true and accurate with respect to matters between the Office and the Company; and (b) whether the Office has any objection to the release.

31. The Office agrees, if requested, to bring to the attention of law enforcement and regulatory authorities the facts and circumstances relating to the nature of the conduct underlying this Agreement, including the nature and quality of the Company's cooperation and remediation. By agreeing to provide this information to such authorities, the Office is not agreeing to advocate on behalf of the Company, but rather is agreeing to provide facts to be evaluated independently by such authorities.

Publication

32. Within 10 business days of the Effective Date of this Agreement, the Company agrees to make the Information and this Agreement available to the public on its website in a

conspicuous location to the Office's reasonable satisfaction for 24 months after the Effective Date of this Agreement.

Limitations on Binding Effect of Agreement

33. This Agreement is binding on the Company and the Office but specifically does not bind any other component of the Department of Justice, other federal agencies, or any state, local, or foreign law enforcement or regulatory agencies, or any other authorities, although the Office will bring the cooperation of the Company and its compliance with its other obligations under this Agreement to the attention of such agencies and authorities if requested to do so by the Company.

Notice

34. Unless otherwise directed by the Office in writing, any notice to the Office under this Agreement shall be given by personal delivery by a recognized delivery service, or registered or certified mail, addressed to:

Chief, Health Care Fraud Unit
U.S. Attorney's Office for the District of Massachusetts
John Joseph Moakley Federal Courthouse
One Courthouse Way
Boston, MA 02210

35. Any notice to the Company under this Agreement shall be given by personal delivery, overnight delivery by a recognized delivery service, or registered or certified mail, addressed to:

Legal Department
Magellan Diagnostics, Inc.
101 Billerica Avenue
North Billerica, MA 01862

Adam J. Hollingsworth
Jones Day
901 Lakeside Avenue
Cleveland, OH 44114

Complete Agreement

36. This Agreement, including its attachments, sets forth all the terms of the agreement between the Company and the Office. No amendments, modifications, or additions to this Agreement shall be valid unless they are in writing and signed by the Office, the attorneys for the Company, and a duly authorized representative of the Company.

* * *

FOR THE UNITED STATES ATTORNEY'S OFFICE
FOR THE DISTRICT OF MASSACHUSETTS

Date: 5/21/24

JOSHUA S. LEVY
Acting United States Attorney

By: _____
JAMES D. HERBERT
KELLY BEGG LAWRENCE
ELYSA Q. WAN
LESLIE A. WRIGHT
Assistant U.S. Attorneys

FOR MAGELLAN DIAGNOSTICS, INC.

Date: 5/21/24

By: _____
EMERSON C. MOSER
Senior Vice President and General Counsel
Magellan Diagnostics, Inc.

Date: _____

By: _____
ADAM J. HOLLINGSWORTH
Counsel for Magellan Diagnostics, Inc.
Jones Day

COMPANY OFFICER'S CERTIFICATE

I have read this Agreement and carefully reviewed every part of it with outside counsel for Magellan Diagnostics, Inc. (the "Company"). I understand the terms of this Agreement and voluntarily agree, on behalf of the Company, to each of its terms. Before signing this Agreement, I consulted outside counsel for the Company. Counsel fully advised me of the rights of the Company, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into this Agreement.

I have carefully reviewed the terms of this Agreement with the Board of Directors of the Company. I have advised and caused outside counsel for the Company to advise the Board of Directors fully of the rights of the Company, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into this Agreement.

No promises or inducements have been made other than those described in this Agreement. Furthermore, no one has threatened or forced me, or to my knowledge any person authorizing this Agreement on behalf of the Company, in any way to enter into this Agreement. I am also satisfied with outside counsel's representation in this matter. I certify that I am the Senior Vice President and General Counsel for the Company and that I have been duly authorized by the Company to execute this Agreement on behalf of the Company.

MAGELLAN DIAGNOSTICS, INC.

Date: 5/21/24

By: _____

EMERSON C. MOSER
Senior Vice President and General Counsel
Magellan Diagnostics, Inc.

CERTIFICATE OF COUNSEL

I am counsel for Magellan Diagnostics, Inc. (the "Company") in the matter covered by this Agreement. In connection with such representation, I have examined relevant Company documents and have discussed the terms of this Agreement with the Company Board of Directors. Based on our review of the foregoing materials and discussions, it is my opinion that the representative of the Company signing this Agreement has been duly authorized to enter into this Agreement on behalf of the Company and that this Agreement has been duly and validly authorized, executed, and delivered on behalf of the Company and is a valid and binding obligation of the Company. Further, I have carefully reviewed the terms of this Agreement with the Board of Directors and the Senior Vice President and General Counsel of the Company. I have fully advised them of the rights of the Company, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into this Agreement. To my knowledge, the decision of the Company to enter into this Agreement, based on the authorization of the Board of Directors, is an informed and voluntary one.

Date: 5/21/2024

By: _____

ADAM J. HOLLINGSWORTH
Jones Day
Counsel for Magellan Diagnostics, Inc.

EXHIBIT C

ATTACHMENT C

CORPORATE COMPLIANCE PROGRAM

In order to address any deficiencies in its internal controls, compliance code, policies, and procedures regarding compliance with the Federal Food, Drug, and Cosmetic Act ("FDCA") and its associated regulations, Magellan Diagnostics, Inc. (the "Company"), on behalf of itself, its parent, and its subsidiaries, agrees to continue to conduct, in a manner consistent with all of its obligations under this Agreement, appropriate reviews of its existing internal controls, compliance code, policies, and procedures.

Where necessary and appropriate, the Company agrees to adopt a new or to modify its existing compliance program, including internal controls, compliance code, policies, and procedures, to ensure that it maintains an effective compliance program that is designed, implemented, and enforced to effectively deter and detect violations of the FDCA and its associated regulations. At a minimum, this should include, but not be limited to, the following elements to the extent they are not already part of the Company's existing internal controls, compliance code, policies, and procedures:

Commitment to Compliance

1. The Company will ensure that its directors and senior management provide strong, explicit, and visible support and commitment to its corporate policy against violations of the FDCA and its associated regulations and the Company's compliance codes and demonstrate rigorous adherence by example. The Company will also ensure that all managers, in turn, reinforce those standards and encourage employees to abide by them. The Company will create and foster a culture of ethics and compliance with the law in its day-to-day operations at all levels of the company.

Policies and Procedures

2. The Company will develop and promulgate a clearly articulated and visible corporate policy requiring adherence to the FDCA and its associated regulations, which policy shall be memorialized in a written compliance code or codes.

3. The Company will take appropriate measures to encourage and support the observance of ethics and compliance policies and procedures by personnel at all levels of the Company. These policies and procedures shall apply to all directors, officers, and employees and, where necessary and appropriate, outside parties acting on behalf of the Company, including, but not limited to, agents and intermediaries, consultants, representatives, distributors, teaming partners, contractors and suppliers, consortia, and joint venture partners (collectively, "agents and business partners"). The Company shall notify all employees that compliance with the policies and procedures is the duty of individuals at all levels of the Company.

4. The Company will ensure that it has a system of procedures, including a system of internal controls, reasonably designed to ensure the maintenance of (1) good manufacturing practices, (2) complaint handling, and (3) the additional quality assurance and regulatory affairs procedures instituted to date by the Company's parent, Meridian Bioscience Inc. This system shall be designed to provide reasonable assurances that, at a minimum:

a. All customer complaints are promptly evaluated for reportability under the FDCA and its associated regulations;

b. Instructions for use and any communications with the Company's customers that modify, amend, or otherwise revise instructions for use are promptly evaluated for compliance with the FDCA and its associated regulations; and

c. All Magellan studies or experiments showing inaccurate test results with any of the Company's products are promptly brought to the attention of senior compliance executives and the Monitor (see Attachment D).

Periodic Risk-Based Review

5. The Company shall review its compliance policies and procedures regarding the FDCA and its associated regulations no less than annually and update them as appropriate to ensure their continued effectiveness, taking into account relevant developments in the field, evolving industry standards, and the risk profile of the Company and its products.

Proper Oversight and Independence

6. The Company will assign responsibility to one or more senior corporate executives of the Company for the implementation and oversight of the Company's compliance code, policies, and procedures regarding the FDCA and its associated regulations. Such corporate official(s) shall have the authority to report directly to independent monitoring bodies, including the Company's Board of Directors, or any appropriate committee of the Board of Directors, and shall have an adequate level of stature and autonomy from management as well as sufficient resources and authority to maintain such autonomy.

Training and Guidance

7. The Company will implement mechanisms designed to ensure that its compliance code, policies, and procedures regarding the FDCA and its associated regulations are effectively communicated to all directors, officers, employees, and, where necessary and appropriate, agents and business partners. These mechanisms shall include: (a) periodic training for all directors and officers, all employees in positions of leadership or trust or in positions that require such training (e.g., regulatory, quality, manufacturing, research and development, sales, marketing, legal,

compliance), and, where necessary and appropriate, agents and business partners; and (b) corresponding certifications by all such directors, officers, employees, agents, and business partners, certifying compliance with the training requirements. The Company will conduct training in a manner tailored to the audience's size, sophistication, or subject matter expertise and, where appropriate, will discuss prior compliance incidents.

8. The Company will maintain, or where necessary establish, an effective system for providing guidance and advice to directors, officers, employees, and, where necessary and appropriate, agents and business partners, on complying with the Company's compliance code, policies, and procedures regarding the FDCA and its associated regulations, including when they need advice on an urgent basis.

Internal Reporting and Investigation

9. The Company will maintain, or where necessary establish, an effective system for internal and, where possible, confidential reporting by, and protection of, directors, officers, employees, and, where appropriate, agents and business partners concerning violations of the FDCA and its associated regulations or the Company's compliance code, policies, and procedures regarding the FDCA and its associated regulations.

10. The Company will maintain, or where necessary establish, an effective and reliable process with sufficient resources for responding to, investigating, and documenting allegations of violations of the FDCA and its associated regulations or the Company's compliance code, policies, and procedures regarding the FDCA and its associated regulations. The Company will handle the investigations of such complaints in an effective manner, including routing the complaints to proper personnel, conducting timely and thorough investigations, and following up with appropriate discipline where necessary.

Enforcement and Discipline

11. The Company will implement mechanisms designed to effectively enforce its compliance code, policies, and procedures, including appropriately incentivizing compliance and disciplining violations. At a minimum, these mechanisms will include policies that incorporate adherence to compliance as one portion of employee and officer evaluations, that impose financial penalties for compliance-related misconduct, and that provide affirmative incentives for compliance-promoting behavior.

12. The Company will institute appropriate disciplinary procedures to address, among other things, violations of the FDCA and its associated regulations and the Company's compliance code, policies, and procedures regarding the FDCA and its associated regulations by the Company's directors, officers, and employees. Such procedures should be applied consistently, fairly, and in a manner commensurate with the violation, regardless of the position held by, or perceived importance of, the director, officer, or employee. The Company shall implement procedures to ensure that where misconduct is discovered, reasonable steps are taken to remedy the harm resulting from such misconduct, and to ensure that appropriate steps are taken to prevent further similar misconduct, including assessing the internal controls, compliance code, policies, and procedures and making modifications necessary to ensure the overall compliance program is effective.

Mergers and Acquisitions

13. The Company will develop and implement policies and procedures for mergers and acquisitions requiring that the Company conduct appropriate risk-based due diligence on potential new business entities, including appropriate due diligence regarding the FDCA and its associated regulations by legal and compliance personnel.

14. The Company will ensure that the Company's compliance code, policies, and procedures regarding the FDCA and its associated regulations apply as quickly as is practicable to newly acquired businesses or entities merged with the Company and will promptly:

a. train the directors, officers, employees, consultants, agents, and business partners consistent with Paragraph 8 above on the FDCA and its associated regulations and the Company's compliance code, policies, and procedures regarding the FDCA and its associated regulations; and

b. conduct an audit of all newly acquired or merged businesses as quickly as practicable concerning compliance with the FDCA and its associated regulations.

Monitoring, Testing, and Remediation

15. In order to ensure that its compliance program does not become stale, the Company will conduct periodic reviews and testing of its compliance codes, policies, and procedures regarding the FDCA and its associated regulations designed to evaluate and improve their effectiveness in preventing and detecting violations of the FDCA and its associated regulations and the Company's compliance codes, policies, and procedures regarding the FDCA and its associated regulations, taking into account relevant developments in the field, evolving industry standards, and the risk profile of the Company and its products. The Company will ensure that compliance and control personnel have sufficient direct or indirect access to relevant sources of data to allow for timely and effective monitoring and/or testing. Based on such review and testing and its analysis of any prior misconduct, the Company will conduct a thoughtful root cause analysis and timely and appropriately remediate to address the root causes.

EXHIBIT D

ATTACHMENT F

VICTIM COMPENSATION PROGRAM

The duties and authority of the Independent Compliance Monitor (the "Monitor"), and the obligations of Magellan Diagnostics, Inc. ("Magellan" or "the Company") with respect to victim outreach, identification, and compensation are as described below. These processes and procedures shall govern the funding and administration of the Victim Compensation Fund, and such additional payments as may be required, as described in Paragraphs 6 through 9 of the Deferred Prosecution Agreement ("Agreement") with the United States Attorney's Office for the District of Massachusetts (the "Office").

General Principles

1. The Company agrees to pay victim compensation in connection with the Agreement and in lieu of court-ordered restitution in connection with its guilty plea to the FDCA Information (as defined in the Agreement).

Company's Payment Obligations

2. The Company agrees to establish a Victim Compensation Fund of at least $9,300,000 to compensate patients and/or minor patients' legal guardians who were harmed by the conduct described in the Statement of Facts between June 27, 2013 and May 31, 2017. The Company shall establish a dedicated bank account for the Victim Compensation Fund and make deposits to the account according to the following schedule: $3,000,000 shall be deposited no later than 15 days after the Effective Date of this Agreement; $3,000,000 shall be deposited no later than one year after the Effective Date of this Agreement; and $3,300,000 shall be deposited no later than two years after the Effective Date of this Agreement.

3. The Monitor shall evaluate victim compensation claims and shall make recommendations to the Office regarding the individuals who should receive payments from the Victim Compensation Fund and the compensation amounts that these individuals should receive. Only the Office shall be empowered to make final decisions regarding who should receive payments from the Victim Compensation Fund and the compensation amounts that these individuals should receive.

4. Should the Monitor recommend and the Office approve payment in excess of the amount in the dedicated bank account, the Company shall deposit additional funds into the dedicated bank account within 90 days of such determination in order to permit those claims to be paid.

5. The Company agrees to pay all costs, fees, and expenses incurred by the Monitor in connection with the claims administration process and any fees associated with the dedicated bank account. The Company may, with approval of the Monitor, use funds in the dedicated bank account to pay for reasonable costs associated with its notification obligations below, provided that any funds expended shall not diminish the Company's obligations pursuant to Paragraph 4.

Company's Victim Notification and Identification Obligations

6. Within 30 days of the Effective Date of the Agreement, the Company shall make a public notice on its website in a suitably prominent location, describing the Company's resolution with the Office and the availability of compensation for victims. The website shall include contact information for patients to seek additional information or to submit a claim. The Company shall coordinate with the Monitor on the manner of receiving and organizing claims or requests for information.

7. In addition, the Company will promptly initiate a patient identification program to affirmatively identify individuals who may have been harmed by the conduct described in the Statement of Facts. That program will include the following minimum elements:

a. The Company shall retain at least one fulltime employee ("FTE") whose responsibility will be to identify patients who may have been harmed by the conduct described in the Statement of Facts. The Company shall retain the FTE in this role for at least 24 months.

b. The FTE will review and analyze data and records of patients identified by the Office including but not limited to patients who (a) received venous blood lead test results from a LeadCare II, LeadCare Ultra, or LeadCare Plus device or (b) responded to FBI's victim identification survey in *United States v. Amy Winslow et al.*, Case No. 23-cr-10094-PBS.

c. The FTE will review and analyze information from the Company, including but not limited to customer complaints to identify patients who may have been harmed by the conduct described in the Statement of Facts.

d. The FTE will work directly with the Company's customers from the relevant period (*i.e.*, doctors, clinics, hospitals) and the 62 state and local Childhood Lead Poisoning Prevention Programs ("CLPPPs") to identify and contact potentially harmed individuals. If the Company customer or the CLPPP is not willing or able to identify the patients because of time or resource limitations, the Company will provide financial reimbursement and/or other assistance for patient identification purposes.

e. The Company will structure the FTE's compensation to incentivize timely completion of milestones designed, in consultation with the Monitor, to result in the

successful identification of patients who may have been harmed by the conduct described in the Statement of Facts.

f. The Company shall notify any patient who may have been harmed by the conduct described in the Statement of Facts and identified as a result of this program of the availability for victim compensation and the process for submitting claims. The Company shall also provide such patients with information about other forms of assistance or services that may be helpful under their individual circumstances.

8. The Company shall promptly and fully inform the Monitor of the steps the Company takes pursuant to Paragraphs 6–7. The Company shall implement the Monitor's reasonable recommendations concerning any modifications to the Company's notice and patient identification program designed to efficiently and effectively identify and notify patients who may have been harmed. Should the Company and the Monitor disagree as to any such recommendation, such parties shall attempt in good faith to reach an agreement within 30 days. In the event that the Company and the Monitor remain unable to agree as to such a recommendation at the conclusion of thirty days, the Company shall promptly consult with the Office. The Office may consider the Monitor's recommendation and the Company's reasons for not adopting the recommendation in determining whether the Company has fully complied with its obligations under the Agreement.

9. The Monitor shall provide quarterly updates to the Office regarding the status of the patient identification program.

Monitor's Role as Claims Administrator

10. The Monitor shall act as a claims administrator for the Victim Compensation Fund. In conjunction with the Company and the expert retained pursuant to Paragraph 13, the Monitor shall propose a compensation system—subject to approval by the Office—for patients who were

harmed by the conduct described in the Statement of Facts. The Monitor's proposed compensation system shall include all demonstrated pecuniary damages for harm suffered by patients or their legal guardian(s) as a result of delayed detection of lead poisoning or lead exposure.

11. The Monitor's proposed compensation system shall not include any non-pecuniary damages for harm suffered by patients or their legal guardian(s) as a result of delayed detection of lead poisoning or lead exposure.

12. The Monitor's proposed compensation system shall not include any purported attorney fees or other related legal costs incurred by any victim, and such fees/costs shall not be compensable from the Fund.

13. The Monitor shall retain a qualified expert on lead issues as a consultant to evaluate patient circumstances and compensation amounts to assist in evaluating claims.

14. Any individual (or individual's legal guardian) who believes he or she is entitled to compensation must submit a claim to the Monitor within two years of the Monitor being selected (the "Claims Period"). Only one claim may be submitted on behalf of a patient by the patient or any of his or her legal guardian(s).

15. The Monitor shall make recommendations to the Office regarding individuals who should receive payments from the Victim Compensation Fund and the compensation amounts that these individuals should receive. The Monitor shall make its recommendations to the Office within 90 days of the conclusion of the Claims Period and shall identify any pending claims that the Monitor has not yet resolved. The Office shall review the Monitor's recommendations and shall make final determinations of disbursements from the Victim Compensation Fund within 90 days of receiving the Monitor's recommendations. The Office shall notify the Company and the Monitor of its final determinations. The Company shall then have 90 days to make disbursements

to victims from the dedicated bank account (the "Victim Payment Period") or, to the extent the Company reasonably believes that a determination by the Office is inconsistent with the terms of the DPA or the compensation framework contemplated by Paragraph 10, seek review by the Judge to whom the matter is assigned.

16. Any individual who receives compensation under the Victim Compensation Fund shall agree, as a condition of receiving payment from the Victim Compensation Fund, that any future recovery, payment, settlement, or compensation received from the Company for the same harm addressed by the Victim Compensation Fund (e.g., from a Federal or State civil proceeding or other source) shall be reduced by the amount the individual received from the Victim Compensation Fund by executing the acknowledgement included as Attachment F-1.

Disposition of Unused Victim Compensation Funds

17. Any portion of the Victim Compensation Fund that (a) has not been paid out to victims at the conclusion of the Victim Payment Period and (b) is not subject to a pending claim submitted to the Monitor, shall be paid to CLPPPs. Any portion of the Victim Compensation Fund that is subject to a pending claim submitted to the Monitor shall remain in the dedicated bank account until the claim is fully resolved, after which the remaining funds, if any, shall be paid to CLPPPs. Under no circumstances shall any portion of the Victim Compensation Fund revert to the Company or its affiliates.

18. At the conclusion of the Victim Payment Period or resolution of all pending claims, whichever is later, the Monitor shall determine the amount, if any, of unused Victim Compensation Funds to be paid to CLPPPs. The Monitor shall determine—subject to approval by the Office—which CLPPPs are qualified to receive payments and the amount that each CLPPP should receive

from the remaining funds. The Company shall then have 90 days to disburse the remaining funds to CLPPPs as directed by the Monitor.