

UNITED STATES DISTRICT COURT  
MIDDLE DISTRICT OF FLORIDA  
TAMPA DIVISION

UNITED STATES OF AMERICA

v.

Case No. 8:15-cr-

GENZYME CORPORATION

**DEFERRED PROSECUTION AGREEMENT**

Defendant Genzyme Corporation (“Genzyme”), a corporation organized under the laws of the Commonwealth of Massachusetts, by its undersigned representatives, pursuant to authority granted by its Board of Directors; and the United States Department of Justice, Consumer Protection Branch and the Office of the United States Attorney for the Middle District of Florida (collectively, “the Government”) enter into this deferred prosecution agreement (the “Agreement”). The terms and conditions of this Agreement are:

**Criminal Information and Acceptance of Responsibility**

1. Genzyme acknowledges and agrees that the Government will file the attached criminal Information in the United States District Court for the Middle District of Florida, charging (a) one misdemeanor count of causing a medical device to become adulterated while held for sale after shipment in interstate commerce in violation of the Federal Food, Drug, and Cosmetic Act (“FDCA”), Sections 331(k)

and 333(a)(1) of Title 21, United States Code, related to the alteration of Genzyme's Seprafilm® adhesion barrier into Seprafilm® slurry, a new medical device that lacked an approved application for pre-market approval with the United States Food and Drug Administration ("FDA") and (b) one misdemeanor count of causing a medical device to be misbranded while held for sale after shipment in interstate commerce in violation of the FDCA, Sections 331(k) and 333(a)(1) of Title 21, United States Code, related to a misleading claim used in a promotional brochure for Seprafilm®.

2. With regard to that Information, Genzyme knowingly and voluntarily waives all rights to a speedy trial pursuant to the Sixth Amendment to the United States Constitution, Section 3161 of Title 18, United States Code, Federal Rule of Criminal Procedure 48(b), and any applicable Rule of the United States District Court for the Middle District of Florida. In addition, Genzyme agrees that any statutes of limitations and any other legal, equitable, or constitutional basis for barring prosecution based on the passage of time applicable to the subject matter of the conduct as set forth in the Information and Statement of Facts shall be tolled as of the Effective Date of this Agreement in accordance with Paragraph 19 herein. Genzyme also knowingly waives any objection with respect to venue and consents to the filing of the Information, as provided under the terms of this Agreement, in the United States District Court for the Middle District of Florida.

3. Genzyme admits that it is responsible under the laws of the United States for the acts of its employees and agents as set forth in the Statement of Facts attached hereto as "Attachment A," and incorporated by reference into this

Agreement. Genzyme further admits that the facts described in the Statement of Facts are true and accurate, and constitute violations of the statute cited in paragraph 1. Should the Government pursue the prosecution that is deferred by this Agreement, Genzyme agrees that it will neither contest the admissibility of, nor contradict the Statement of Facts in any such proceeding, including any guilty plea or sentencing proceeding. Neither this Agreement nor the criminal Information is a final adjudication of the matters addressed in such documents.

#### **Term of the Agreement**

4. 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 that date (the "Term"). However, Genzyme agrees that, in the event that the Government determines, in its sole discretion, that Genzyme has knowingly violated any provision of this Agreement, an extension or extensions of the term of the Agreement may be imposed by the Government, in its sole discretion, for up to a total additional period of one year, without prejudice to the Government's right to proceed as provided in Paragraphs 18–23 below. Any extension of the Agreement extends all terms of this Agreement, including the terms of Enhanced Compliance Measures in Attachment B, for an equivalent period. In the event that the Government determines that an extension of the Term of this Agreement is or may be warranted, the Government shall notify Genzyme in writing of its determination no later than sixty (60) days prior to the expiration of the Term. Within thirty (30) days

of receipt of that notice, Genzyme shall have the opportunity to respond to that determination in writing, to explain the nature and circumstances of any alleged breach or deficiency, including whether Genzyme believes a breach has occurred, whether such breach was material, and whether such breach was knowingly or willfully committed, and to document the actions taken to address and remediate the situation. The Government agrees to consider such explanation in determining whether to extend the term of the Agreement.

### **Relevant Considerations**

5. The Government enters into this Agreement based on the specific facts and circumstances presented by this case and Genzyme. Among the facts considered were the following:

a. Prior to learning of the Government's investigation regarding Septrafilm® slurry, Genzyme made meaningful efforts to prevent and remediate the misconduct that was the subject of that investigation including: implementing more austere policies regarding promotional practices, reducing sales quotas to reduce incentives for unlawful promotional activities, and terminating the employment of individuals who committed the misconduct. Among those that Genzyme terminated was the sales representative who was consistently Genzyme's leading performer in terms of sales and revenue generated from Septrafilm®;

b. Days after learning of the Government's investigation of Genzyme regarding Seprafilm® slurry from a physician-customer who had been contacted by Government agents, Genzyme contacted the Government to offer its assistance in the Government's investigation. This assistance included early disclosure to the Government that Genzyme's own internal investigation had uncovered substantial evidence which demonstrated the misconduct under investigation described in the Statement of Facts. In addition, Genzyme's assistance included a voluntary disclosure of other evidence, unrelated to the subject of the investigation, some of which also is referenced in the Information and the Statement of Facts;

c. Genzyme has cooperated with the Government's investigation by voluntarily collecting and producing voluminous evidence and facilitating interviews of former Genzyme employees, as well as complying with various requests made by the Government during the course of the investigation;

d. Genzyme has instituted various compliance policies, procedures, and enhanced controls to detect employee misconduct and to comply with the legal requirements for promoting medical devices under the FDCA;

e. Genzyme has agreed to continue to cooperate with the Government in any ongoing investigation as set forth in Paragraph 6, below;

f. The entry of Sanofi US<sup>1</sup> into a corporate integrity agreement with the United States Department of Health and Human Services Office of Inspector General containing provisions designed in part to address the misconduct;

g. Genzyme's settlement of parallel civil actions brought by the United States and several individual states under the Federal False Claims Act and analogous state statutes related to this misconduct;

h. The agreement by Sanofi US to maintain robust compliance policies and procedures and to provide the Government with the written notifications and certifications as described in Attachment B to this Agreement;

i. The potential collateral consequences of proceeding with a prosecution, which may cause undue harm to innocent individuals including current Genzyme employees and shareholders and those of affiliated entities.

6. Genzyme shall continue to cooperate fully with the Government in any and all matters relating to the use, marketing, sale, and promotion of Seprafilm<sup>®</sup> slurry until the date upon which all investigations and prosecutions arising out of the conduct described in this Agreement are concluded, whether or not they are concluded during the Term of this Agreement. This cooperation shall include, but is not limited to the following:

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<sup>1</sup> In April 2011 (after the conduct described in the Information had ceased), Genzyme Corporation was acquired by the Sanofi Group. As a result of the acquisition, Genzyme became affiliated with Sanofi US Services, Inc. and Sanofi-Aventis LLC (collectively, "Sanofi US"). A business unit of Sanofi US is currently responsible for the sale and marketing of Seprafilm<sup>®</sup> within the United States.

a. Genzyme shall truthfully disclose all factual information not protected by a valid claim of attorney-client privilege or work product doctrine with respect to its activities and those of its present and former directors, officers, employees, agents, and consultants concerning all matters relating to the misbranding or adulteration of Seprafilm® about which the Government may inquire. This obligation of truthful disclosure includes Genzyme's obligation to provide to the Government, upon request, any document, record or other tangible evidence relating to such adulteration or misbranding about which the Government may inquire of Genzyme.

b. Upon the Government's request, with respect to any issue relevant to its investigation of adulteration or misbranding of Seprafilm®, Genzyme shall designate knowledgeable employees, agents or attorneys to provide to the Government the information and materials described in Paragraph 6(a) above on behalf of Genzyme. It is further understood that Genzyme must at all times provide complete, truthful, and accurate information.

c. With respect to any issue relevant to the Government's investigation of the misbranding or adulteration of Seprafilm®, Genzyme shall use its best efforts to make available for interviews or testimony, as requested by the Government, present or former officers, directors, employees, agents and consultants of Genzyme. This obligation includes, but is not limited to, sworn testimony before a federal grand jury or in federal trials, as well as interviews with federal law enforcement and regulatory authorities. Cooperation under

this Paragraph shall include identification of witnesses who, to the knowledge of Genzyme, 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 Government pursuant to this Agreement, Genzyme consents to any and all disclosures, subject to applicable law and regulations, to other governmental authorities, including United States authorities and those of a foreign government, of such materials as the Government, in its sole discretion, shall deem to be relevant and necessary to accomplish a legitimate governmental or regulatory purpose. Upon the termination of this Agreement, Genzyme may request that, subject to applicable law and regulations, the Government return or destroy documents provided by Genzyme pursuant to this Agreement that contain trade secret or other confidential research, development, or other commercial information. The decision whether to return, destroy, or retain any such document shall remain at the sole discretion of the Government.

#### **Payment of Monetary Penalty**

7. The Government and Genzyme agree that Genzyme will pay a monetary penalty in the amount of \$32,587,439.00 to the United States Treasury within ten (10) business days following the Effective Date of this Agreement. The amount of this penalty was informed by the application of Chapter 8 of the UNITED



STATES SENTENCING COMMISSION GUIDELINES MANUAL (2012) to the unlawful conduct described in Attachment A.

8. The Government and Genzyme agree that this penalty is appropriate given all the facts and circumstances of this case, including Genzyme's cooperation and remediation. This penalty is final and shall not be refunded. Furthermore, nothing in this Agreement shall be deemed an agreement by the Government that the agreed-upon monetary penalty provided in this Agreement is the maximum penalty that may be imposed in any future prosecution in the event of a breach of this Agreement, and the Government is not precluded from arguing or presenting evidence in any future prosecution that the Court should impose a higher fine. However, in the event of a future prosecution due to a breach of this Agreement, the Government agrees that it will recommend to the Court that any amount paid by Genzyme under this Agreement should be offset against any fine the Court might impose as part of a future judgment and conviction.

9. Genzyme acknowledges that no tax deduction may be sought in the United States in connection with the payment of any part of this monetary penalty.

#### **Conditional Release from Liability**

10. In return for Genzyme's full and truthful cooperation and its compliance with all other terms and conditions of this Agreement, the Government agrees, subject to Paragraphs 21 and 22 below, not to use any information related

to the conduct described in the attached Statement of Facts against Genzyme in any criminal case, except:

- a. In a prosecution for perjury or obstruction of justice;
- b. In a prosecution for making a false statement;
- c. In a prosecution relating to a violation of any provision of Title 26 of the United States Code.

In addition, the Government agrees it will not bring any criminal charges against Genzyme or any of its affiliated business entities regarding the conduct described in the attached Statement of Facts or relating to the information Genzyme disclosed to the Government prior to the Effective Date of this Agreement.

11. This conditional release of liability does not provide any protection against prosecution for conduct not disclosed by Genzyme to the Government prior to the Effective Date of this Agreement, nor does it provide protection against any prosecution for any future involvement by Genzyme in criminal activity, including violations of the FDCA.

12. This conditional release of liability does not provide any protection against prosecution against any present or former officer, director, employee, shareholder, or agent of Genzyme.

#### **Deferred Prosecution**

13. In consideration of Genzyme's past and future cooperation described above, Genzyme's payment of the monetary penalty as described in Paragraph 7,

and the implementation and maintenance of the compliance measures described below, the Government agrees that within five (5) business days of the Effective Date of this Agreement, the Government will recommend to the United States District Court for the Middle District of Florida that the prosecution of Genzyme on the Information be deferred for the duration of the Term of this Agreement. Except as otherwise provided under this Agreement, the Government agrees to defer prosecution of Genzyme for the conduct set forth in the attached Statement of Facts, and for conduct that Genzyme disclosed to the Government prior to the Effective Date of this Agreement.

14. In the event that the Court declines to defer prosecution for any reason, the Government agrees to move to dismiss all charges brought under the Information without prejudice, and this Agreement will become null and void.

15. The Government agrees that if Genzyme fully complies with all of its obligations under this Agreement, the Government will not continue the criminal prosecution against Genzyme described in Paragraph 1 and, at the conclusion of the Term, this Agreement shall expire. Within thirty (30) days following such expiration, the Government shall seek dismissal with prejudice of the criminal Information filed against Genzyme described in Paragraph 1.

#### **Publication**

16. Within ten (10) business days of the Effective Date of this Agreement, Genzyme will:

a. make the Information, this Agreement, and the Statement of Facts conspicuously available to the public on its website for the duration of this Agreement; and

b. communicate to all Genzyme employees located in the United States and responsible for the sale, marketing and promotion of its products in the United States and those Sanofi US employees currently responsible for the sale, marketing and promotion of Septrafilm® in the United States that Genzyme has entered into this Agreement and distribute the Information, this Agreement, and the Statement of Facts to all such employees.

### **Compliance Measures**

17. A business unit of Sanofi US is responsible for the sale and marketing of Septrafilm® in the United States. As a result, both Genzyme and Sanofi US have agreed through Attachment B to institute and maintain, at a minimum, the policies and procedures as described therein, which are intended to prevent future violations of the FDCA.

### **Breach of the Agreement**

18. Subject to Paragraph 20, Genzyme shall be subject to prosecution in the United States District Court for the Middle District of Florida for any federal criminal violation of which the Government has knowledge, including the charges in the Information described in Paragraph 1, if during the Term of this Agreement the Government determines, in its sole discretion, that Genzyme has:

a. Committed any criminal violation of 21 U.S.C. § 331 relating to the sale, marketing, or promotion of its products subsequent to the Effective Date of this Agreement;

b. Committed any felony under United States federal law subsequent to the Effective Date of this Agreement;

c. At any time in connection with this Agreement, provided deliberately false, incomplete, or misleading information;

d. Failed to perform any of the obligations set forth in Attachment B to this Agreement; or

e. Otherwise failed to perform or fulfill its obligations under this Agreement.

19. Any such prosecution may be premised on information provided by Genzyme. Any such prosecution that is not time-barred by the applicable statute of limitations on the Effective Date of this Agreement may be commenced against Genzyme notwithstanding the expiration of the statute of limitations between the Effective Date of this Agreement and the expiration of the Term of this Agreement, plus one year. Thus, by executing this Agreement, Genzyme 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 of the Agreement plus one year.

20. In the event that the Government determines that Genzyme has breached this Agreement, the Government agrees to provide Genzyme with written

notice of such breach prior to instituting any prosecution resulting from such breach. Genzyme shall, within thirty (30) days of receipt of such notice, have the opportunity to respond to the Government in writing to explain the nature and circumstances of such breach, as well as the actions Genzyme has taken to address and remediate the situation, including whether Genzyme believes a breach occurred, whether such breach was material, and whether such breach was knowingly or willfully committed. The Government agrees to consider such explanation in determining whether to institute a prosecution.

21. In the event that the Government determines that Genzyme has breached this Agreement:

a. The attached Statement of Facts, and any testimony given by Genzyme before a grand jury, any court or tribunal, or at 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 Government against Genzyme; and

b. Genzyme and its counsel will stipulate that the Statement of Facts may be read to the jury or other finder of fact in whole or in part, as elected by the Government, as a stipulation to which Genzyme has agreed.

22. Whether conduct or statements of any current director or employee, or any person acting on behalf of, or at the direction of Genzyme will be imputed to Genzyme for the purpose of determining whether Genzyme has violated any

provision of this Agreement, shall be in the sole discretion of the Government, applying standards consistent with applicable law.

23. Genzyme acknowledges that the Government has made no representations, assurances, or promises concerning what sentence may be imposed by the Court if Genzyme breaches this Agreement and this matter proceeds to judgment and conviction. Genzyme further acknowledges that 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 or Merger**

24. Genzyme agrees that in the event it sells, merges or transfers all or substantially all of its business operations as they exist as of the date of this Agreement, whether such sale is structured as a sale, asset sale, merger, or transfer, it shall include in any contract for sale, merger, or transfer a provision binding the purchaser, or any successor in interest thereto, to the obligations described in this Agreement unless otherwise agreed to by the Government.

#### **Public Statements**

25. Genzyme expressly agrees that it shall not, through present or future attorneys, officers, directors, employees, agents, or any other person authorized to speak about this Agreement for Genzyme, Sanofi US, or their subsidiaries or affiliates, make any public statement, in litigation or otherwise, contradicting the acceptance of responsibility by Genzyme set forth above or the facts described in

the attached Statement of Facts. Any such contradictory statement shall, subject to cure rights of Genzyme described below, constitute a breach of this Agreement and Genzyme thereafter shall be subject to prosecution as set forth in this Agreement.

26. If the Government determines that a public statement by any such person contradicts in whole or in part a statement contained in the Statement of Facts, the Government shall so notify Genzyme, and Genzyme may avoid a breach of this Agreement by publicly repudiating such statement(s) within five (5) business days after notification. Genzyme shall be permitted to raise defenses and to assert affirmative claims in other proceedings related 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. No statement made by a present or former officer, director, employee or agent of Genzyme made in the course of any criminal, regulatory, or civil case initiated against such individual shall be imputed to Genzyme, unless such individual is authorized to speak and speaks on behalf of Genzyme.

#### **Limitations on Binding Effect of Agreement**

27. This Agreement is binding on Genzyme, the United States Attorney's Office for the Middle District of Florida, and the Consumer Protection Branch of the United States Department of Justice. This Agreement specifically does not bind any other federal agencies, or any state, local, or foreign law enforcement or regulatory agencies, or any other authorities, although the Government will bring the



cooperation of Genzyme and its compliance with other obligations under this Agreement to the attention of such agencies and authorities if requested to do so by Genzyme.

### **Notice**

28. Any notice to the Government under this Agreement shall be given by personal delivery or overnight delivery by a recognized delivery service addressed to the following:

Chief, Criminal Division  
U.S. Attorney's Office,  
Middle District of Florida  
400 N. Tampa Street  
Tampa, FL 33602

Director, Consumer Protection Branch  
U.S. Department of Justice  
P.O. Box 386  
Washington, DC 20044

29. Any notice to Genzyme under this Agreement shall be given by personal delivery or overnight delivery by a recognized delivery service addressed to:

General Counsel  
Genzyme Corporation  
500 Kendall Street  
Cambridge, MA 02142

With a copy to:

General Counsel  
Sanofi North America  
55 Corporate Drive  
Bridgewater, NJ 08807

**Complete Agreement**

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

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**AGREED:**

**FOR GENZYME CORPORATION:**



TRACEY L. QUARLES  
*Senior Vice President and  
General Counsel*

Genzyme Corporation  
500 Kendall Street  
Cambridge, MA 02142

8/31/15  
Date

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KATHY B. WEINMAN  
*Attorney for Genzyme Corporation*

Collora LLP  
100 High Street, 20<sup>th</sup> Floor  
Boston, MA 02110

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Date

**Complete Agreement**

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**AGREED:**

**FOR GENZYME CORPORATION:**

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TRACEY L. QUARLES  
*Senior Vice President and  
General Counsel*

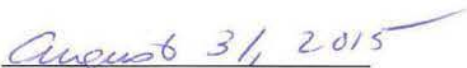
Genzyme Corporation  
500 Kendall Street  
Cambridge, MA 02142

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Date

  
KATHY B. WEINMAN  
*Attorney for Genzyme Corporation*

Collora LLP  
100 High Street, 20<sup>th</sup> Floor  
Boston, MA 02110

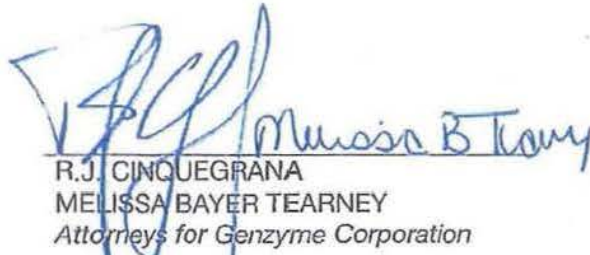
  
Date



JONATHAN L. DIESENHAUS  
*Attorney for Genzyme Corporation*

Hogan Lovells US LLP  
555 Thirteenth Street, NW  
Washington, DC 20004

August 31, 2015  
Date



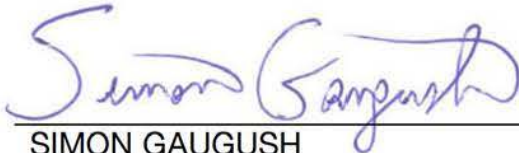
R.J. CINQUEGRANA  
MELISSA BAYER TEARNEY  
*Attorneys for Genzyme Corporation*

Choate Hall & Stewart LLP  
Two International Place  
Boston, MA 02110

August 31, 2015  
Date

FOR THE UNITED STATES ATTORNEY'S OFFICE  
FOR THE MIDDLE DISTRICT OF FLORIDA:

A. LEE BENTLEY III  
*United States Attorney*



SIMON GAUGUSH  
*Assistant United States Attorney  
Chief, Major Crimes Section*

U.S. Attorney's Office for the  
Middle District of Florida  
400 N. Tampa Street, #3200  
Tampa, FL 33602

August 31, 2015

Date

FOR THE UNITED STATES DEPARTMENT OF JUSTICE,  
CONSUMER PROTECTION BRANCH:

MICHAEL S. BLUME  
*Director*



ROSS S. GOLDSTEIN  
*Trial Attorney*

U.S. Department of Justice  
Consumer Protection Branch  
P.O. Box 386  
Washington, DC 20044

August 31, 2015

Date