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 Seprafilm® 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 Seprafilm®;

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[1] 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® 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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[1] 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® 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 Seprafilm® 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 Seprafilm® 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.

AGREED:

FOR GENZYME CORPORATION:

8/31/15

TRACEY L. QUARLES
Senior Vice President and General Counsel

Genzyme Corporation
500 Kendall Street
Cambridge, MA 02142

Date

KATHY B. WEINMAN
Attorney for Genzyme Corporation

Collora LLP
100 High Street, 20th Floor
Boston, MA 02110

Date

Complete Agreement

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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

Date

Kathy B. Weinman

KATHY B. WEINMAN
Attorney for Genzyme Corporation

Collora LLP
100 High Street, 20th Floor
Boston, MA 02110

August 31, 2015
Date

August 31, 2015

JONATHAN L. DIESENHAUS
Attorney for Genzyme Corporation

Date

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

Melissa B Tearney August 31, 2015

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

Date

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

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

A. LEE BENTLEY III
United States Attorney

August 31, 2015
Date

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

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

MICHAEL S. BLUME
Director

August 31, 2015
Date

ROSS S. GOLDSTEIN
Trial Attorney

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

ATTACHMENT A

STATEMENT OF FACTS

This Statement of Facts is incorporated by reference as part of the Deferred Prosecution Agreement (the "Agreement") dated August 31, 2015 between the United States Department of Justice, Consumer Protection Branch, the United States Attorney's Office for the Middle District of Florida (collectively, the "Government"), and Genzyme Corporation ("Genzyme"). Genzyme hereby agrees and stipulates that the following information is true and accurate. Genzyme admits, accepts, and acknowledges that it is responsible for the acts of its employees as set forth below. Should the Government pursue the prosecution that is deferred by this Agreement, Genzyme agrees that it will neither contest the admissibility of, nor contradict, this Statement of Facts in any such proceeding.

Genzyme Corporation

1. During the time period from January 1, 2005, through May 18, 2010, Genzyme was a biotechnology company organized under the laws of the Commonwealth of Massachusetts, with its headquarters located in Cambridge, Massachusetts. Genzyme organized its business into several unincorporated business units, one of which was Genzyme Biosurgery, which was responsible for the sale, marketing, and promotion of the Seprafilm® adhesion barrier, a clear piece

of thin film that is used during open abdominal and pelvic surgery to reduce the incidence, extent, and severity of postoperative adhesions.

Post-Operative Adhesions

2. Post-operative adhesions are bands of tissue that may form between tissues and organs after surgery. Essentially, an adhesion is internal scar tissue that connects other tissues not normally connected, causing organs and tissues to stick together.

3. Adhesion formation is an almost inevitable consequence of abdominal and pelvic surgery. As a result, efforts have been made to develop products and therapies which create a physical barrier between the affected tissues. Because the tissues are no longer in physical contact with each other following injury, no scar tissue forms between them. The Seprafilm® Adhesion Barrier is such a product.

Seprafilm®

4. Seprafilm®, manufactured and marketed by Genzyme during the relevant time period, is a clear piece of film that is applied during pelvic and abdominal surgery. It is composed of two chemically modified sugars: hyaluronic acid and carboxymethylcellulose. Hyaluronic acid ("HA") is a naturally occurring polysaccharide expressed throughout the human body. Carboxymethlcellulose (CMC"), also a polysaccharide, is a derivative of cellulose. Both are common components in pharmaceuticals, food, and cosmetics.

5. Pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 *et seq*., hereinafter "FDCA"), Seprafilm® is a medical device subject to the regulation of the United States Food and Drug Administration ("FDA"). Under the FDCA and its regulations, all medical devices fall into one of three classes based on their risk to the health, safety, or welfare of the patient. Class III devices include devices that are preventing impairment of health, or present a potential unreasonable risk of illness or injury. These devices are subject to the highest level of regulation in order to provide reasonable assurance of safety and effectiveness for their intended use. Genzyme's Seprafilm® is categorized as a Class III medical device.

6. Because Seprafilm® is a Class III medical device, Genzyme was required to submit and obtain FDA approval of a premarket approval application ("PMA") before it could lawfully market Seprafilm® in the United States. To be approved, a PMA must provide FDA with sufficient information to demonstrate that there is a reasonable assurance that the device is safe and effective under the conditions of use recommended in the proposed labeling.

7. The FDA approved Genzyme's PMA for Seprafilm® on or about August 12, 1996. According to the product's FDA-approved labeling:

> Seprafilm Adhesion Barrier is indicated for use in patients undergoing abdominal or pelvic laparotomy [open surgery] as an adjunct intended to reduce the incidence, extent and severity of postoperative adhesions between the abdominal wall and the underlying viscera such as omentum, small bowel, bladder, and stomach, and between the uterus and surrounding structures such as tubes and ovaries, large bowel, and bladder.

8. Adhesion prevention is accomplished by applying Seprafilm® to the internal tissues and physically separating traumatized, adhesiogenic tissues and organs while normal tissue healing takes place. After it is placed in the body and comes into contact with body fluids, Seprafilm® becomes a gel within 24 to 48 hours. This gel remains in place during the critical seven-day healing period – the time during which new adhesions typically form. It slowly resorbs and is excreted from the body in less than 28 days.

Seprafilm® Slurry

The Rise of Minimally Invasive Surgery

9. As discussed above, Seprafilm® "is indicated for use in patients undergoing abdominal or pelvic laparotomy." The incision used in a laparotomy allows the surgeon to gain access to the internal organs of the abdominal cavity using standard surgical instruments.

10. Laparoscopic surgery, also called minimally invasive surgery, is a surgical technique in which short, narrow tubes (called trocars) are inserted into the abdomen through small incisions. Through these trocars, long, narrow instruments are inserted. The surgeon uses these instruments to manipulate, cut, and sew tissue. Fundamental to this surgery is the use of a laparoscope. This small camera, inserted into the abdominal or pelvic cavities through one of the trocars, is linked to a video monitor. This allows the surgeon to view the abdominal or pelvic contents. Clamps, scissors, and sutures on the end of long, narrow instruments are inserted through other trocar(s).

11. In general, laparoscopic surgery is perceived to have several advantages for the patient over laparotomy, including:

a. Reduced blood loss;

b. Several small incisions (rather than one large incision), reducing pain, shortening recovery time, as well as reducing post-operative scarring;

c. Less pain, resulting in less need for pain medications, such as habit-forming narcotics;

d. Shorter hospital stays; and

e. Reduced exposure to infectious contaminants.

12. As a result, minimally invasive procedures have gained in popularity at the expense of the traditional open procedures. With respect to abdominal surgeries, the shift from laparotomy to laparoscopic surgery gained significant momentum beginning in 2005.

13. Seprafilm® has never been indicated or FDA-approved for use in laparoscopic procedures.

Seprafilm® Slurry

14. To prevent adhesions in laparoscopic surgeries, some surgeons began to turn sheets of Seprafilm® into a viscous gel-like fluid that could be introduced into the abdominal cavity through a trocar, ostensibly coating injured tissues with the solution. Although there are minor variations in the formula and technique, this slurry was created in the operating room by cutting the Seprafilm® into narrow sheets, and hydrating it with saline. This mixture is then agitated until the desired consistency is

reached. The slurry is then drawn into a large syringe connected to a catheter that can be introduced through the trocar onto the affected area.

15. This process transformed the original Seprafilm® into a new and different Class III medical device for which FDA has determined neither its safety nor effectiveness.

16. Beginning in 2007, Genzyme made increasing efforts to discourage sales representatives from promoting slurry. Although Genzyme prohibited "off-label promotion," Genzyme permitted its sales representatives to discuss slurry with physicians with certain caveats. For example, sales representatives were supposed to tell surgeons that using Seprafilm® slurry was "off-label" and that Genzyme had no data on its safety or effectiveness. However, sales representatives were permitted to refer surgeons to other surgeons who had experiences with Seprafilm® slurry.

17. Genzyme instituted additional compliance training for sales representatives in early 2007 that advised them that although they were permitted to be present in the operating room during a procedure in which slurry was being used, they "should not comment on the use of the product in this fashion if you observe it." Similarly, a presentation for new hires given in August 2007 communicated that off-label promotion was prohibited and that "Laparoscopic surgery is off-label .... They [surgeons] may choose to use a product as they see fit – However, you cannot guide them to off-label use."

18. In addition, at a mandatory compliance training in January 2008, sales representatives were reminded that off-label promotion was prohibited and that "Clearly Seprafilm is not indicated in laparoscopic use or in a slurry." Sales representatives were told that ***any*** discussions in the field regarding slurry were no longer permitted, and that sales representatives had to abide by a series of new restrictions on their promotional activities designed to limit opportunities for off-label promotion. These messages were reiterated at the Genzyme Biosurgery National Sales Meeting in February 2008.

19. Throughout 2008 and into 2009, Genzyme management continued to prohibit slurry promotion, but surgeons' use of slurry continued to increase. In February 2009, Genzyme prohibited sales representatives from being present in the operating room during surgeries where slurry might be used, i.e., laparoscopic procedures.

20. In addition to continuing to reaffirm the "no slurry" message, Genzyme reduced the sales quotas in 2008, 2009 and 2010 to recognize the shrinking on-label market for Seprafilm®.

21. Prior to learning of the Government's investigation into Seprafilm® slurry, Genzyme fired its most successful sales representative, "Genzyme Sales Representative A," in late 2009 for promoting slurry. Far and away the most productive Seprafilm® sales representative, this employee was responsible for generating millions of dollars of Seprafilm® sales for Genzyme each year, and trained several district managers and sales representatives.

22. After Genzyme learned of the Government's investigation into these matters, Genzyme conducted its own broader internal investigation into the promotion of Seprafilm® slurry, which resulted in the termination of several additional Genzyme sales personnel.

23. Despite these compliance efforts, at times between January 1, 2005, and continuing through May 18, 2010, certain Genzyme sales representatives, acting within the course and scope of their employment, guided surgical staff and directly participated in the preparation of Seprafilm® slurry for use in surgical patients.

24. The following are examples of misconduct engaged in by certain members of Genzyme's sales force:

a. On or about October 23, 2007, Genzyme Sales Representative A directed the preparation of slurry during a surgical procedure by providing direction to a subordinate Genzyme employee, who was present in the operating room during the procedure. Sales Representative A emailed the following instructions to the other Genzyme employee:

> Crush up two sheets of film. Add 40cc's of saline. Stir mixture up with the Toomey syringe. Take the tip of [sic] and suck it in and out 10 times. Put the tip back on the syring [sic] and suck it back amd [sic] forth again 8 more times. This guarantees that its [sic] mixed up really well and can go through the tip nice and smooth. Add the RED robin catheter if the patient is lrg. A 16 french for 5mm trocars and 20 french for 8mm or higher. Cut the red robin end about 6 inches from the bottom. Make sure the surgeon who applies the slurry holds the red robin onto the Toomey. If they kink it or don't hold onto the tip, the red robin can slip off and the slurry goes everywhere. Not good.

b. On or about May 27, 2009, Genzyme Sales Representative B participated in and guided the preparation of slurry during a surgical procedure in a hospital in Florida.

c. On or about September 26, 2007, Genzyme Sales Representative C while attending a surgical procedure, acted in concert with Sales Representative A, to prepare Seprafilm® slurry as evinced by the email exchange between the two:

> *C to A*: "After mixing w saline, let set 30, then take mix in and out of toomey [syringe] before shooting down 15 port???"
>
> *A to C*: "Suck it up into the toomey [sic] back and forth at lease [sic] 10 times to make sure it will be mixed up well enough to go the [sic] tip of the toomey."
>
> *C to A*: "Ok, doing that now …no red robin w 15 port, correct?"
>
> *A to C (two hours later)*: "How did it go?"
>
> *C to A*: "Good, thanks."
>
> *A to C*: "You the man …woman. Congrats."

Genzyme's Accountability

25. Genzyme acknowledges that these acts taken by its sales representatives were within the scope of their employment at Genzyme and intended, at least in part, to benefit Genzyme through these actions. Genzyme further acknowledges that during the relevant time period, it had not supplied evidence to FDA to provide reasonable assurance that the use of Seprafilm® slurry in laparoscopic procedures is safe and effective.

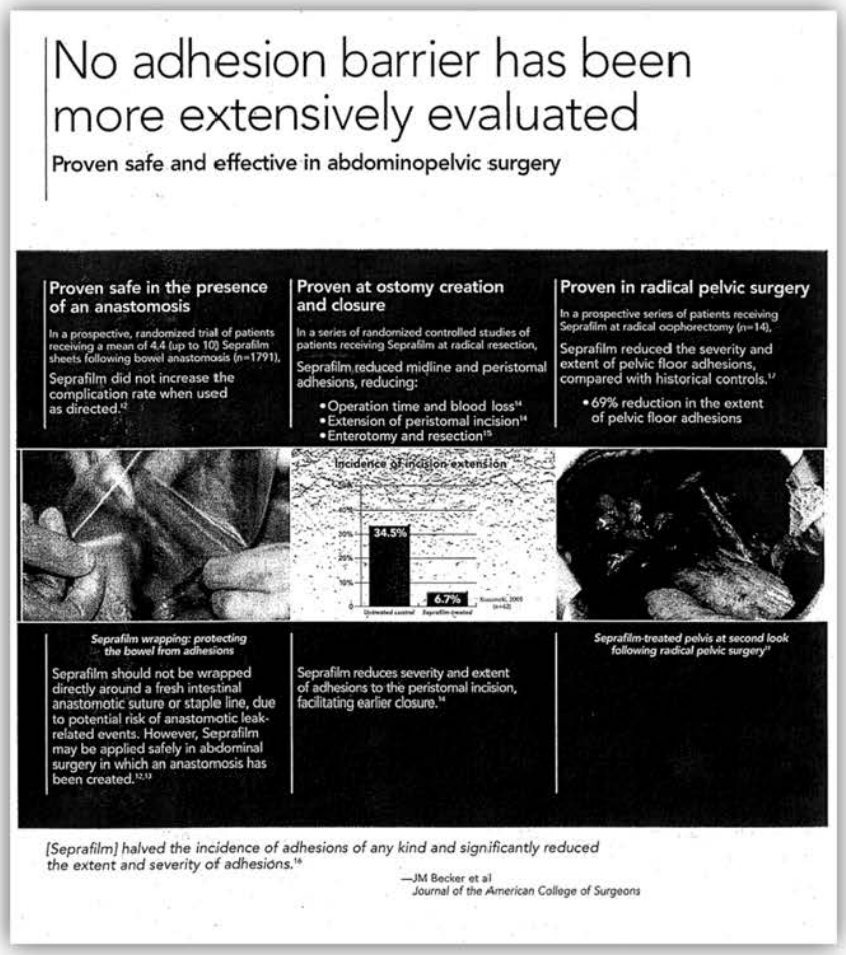
Promotional Brochure

26. Genzyme made available to its sales representatives a number of materials they could use in their efforts to promote Seprafilm®.

27. Beginning in or about January 2008 and continuing until 2010, a Genzyme-approved Seprafilm® promotional brochure was available to the Seprafilm® sales team to aid them in their marketing of Seprafilm® to health care providers.

28. The brochure included statements concerning the potential effects of post-surgical adhesions and various studies of the efficacy and safety of Seprafilm®, and an abbreviated version of the FDA-approved label.

29. The third page of the brochure is illustrated below.



It was titled "No adhesion barrier has been more extensively evaluated/Proven safe and effective in abdominopelvic surgery." A section on that page claimed that Seprafilm® was "Proven in radical pelvic surgery" and stated further that "In a prospective series of patients receiving Seprafilm at radical oophorectomy (n=14), / Seprafilm reduced the severity and extent of pelvic floor adhesions, compared with historical controls. / 69% reduction in the extent of pelvic floor adhesions."

30. The claim that Seprafilm® was "Proven in radical pelvic surgery" was misleading, because the patient population in the study on which that claim was based involved fourteen patients and, therefore, was too small to support that claim.

31. In the fall of 2013, Genzyme voluntarily disclosed to the Government the promotional use of the brochure and implemented steps to prevent such promotional claims from being made in the future.

ATTACHMENT B

ENHANCED COMPLIANCE MEASURES AND CERTIFICATIONS

After the conduct described in the Information had ceased and prior to entering into the Deferred Prosecution Agreement (the "Agreement"), Genzyme Corporation ("Genzyme") was acquired by the Sanofi Group. Following the acquisition, Genzyme became affiliated with Sanofi US Services Inc. and Sanofi-Aventis U.S. LLC (collectively, "Sanofi US") and Sanofi US subsequently became responsible for the sale, marketing, and promotion of Seprafilm® in the United States. Sanofi US, together with its affiliated company, Genzyme (collectively "Sanofi"), both agree to the provisions set forth in this Attachment to the Agreement ("Attachment").

I. Compliance and Ethics Program

Sanofi US has in place and will maintain a compliance program ("Sanofi NA Compliance Program"), which applies to the United States business operations of Sanofi US and Genzyme. The purpose of the Sanofi NA Compliance Program is to: (a) prevent, detect, and correct violations of law and company policy and procedures; (b) assure the establishment of compliance-related policies and procedures for business operations; (c) assure development of training and other programs designed to educate employees regarding applicable policies, procedures and standards; (d) conduct auditing and monitoring of the effectiveness of applicable policies, procedures and standards; (e) implement a mechanism for internal reporting of questionable or

inappropriate activities to enable timely investigation and resolution; and (f) assure appropriate corrective action is taken to prevent recurrence of misconduct.

The Sanofi NA Compliance Program includes a Compliance Committee, which meets at least quarterly, and a Sanofi NA Compliance Officer (the "Compliance Officer"). The mission of the Compliance Committee includes ensuring the implementation and effectiveness of all components of the Sanofi NA Compliance Program. The Compliance Officer reports to the Global Compliance Officer of the parent company of Sanofi and is responsible for overseeing the administration and implementation of the Sanofi NA Compliance Program. The Compliance Officer also reports at least quarterly on the Sanofi NA Compliance Program operations to, among others, the Compliance Committee. The Compliance Officer has direct access to senior executives vested with the authority to direct and implement compliance-related changes in the organization as necessary. The Compliance Officer has the authority to exercise independent judgment in assessing compliance-related matters. The Compliance Officer has authority to seek advice from independent legal counsel or other outside experts when appropriate. The Compliance Officer is authorized to report issues of any kind directly to officers and directors of Sanofi.

Sanofi US does and will continue to maintain policies and procedures designed to prevent, detect, and correct violations of federal healthcare program requirements and the Federal Food, Drug, and Cosmetic Act ("FDCA") regarding the sale, marketing, and promotion of prescription pharmaceutical products and medical devices, including policies and procedures on the following subjects.

A. Sales Compensation and Incentives

Sanofi US will establish and will maintain policies and procedures that shall (1) be designed to ensure that financial incentives do not inappropriately motivate Seprafilm® sales representatives or their managers to engage in improper promotion, sales, and marketing of Seprafilm®; and (2) include mechanisms, where appropriate, that are designed to exclude from incentive compensation sales that may indicate promotion of an indication that is not within the Food and Drug Administration ("FDA")-approved labeling for Seprafilm® and that would constitute misbranding pursuant to FDA requirements ("Off-Label Promotion").

B. Off-Label Promotion and Unsolicited Medical Information Requests

Sanofi US has in place and will maintain policies that require US Seprafilm® sales representatives to discuss only those product uses that are consistent with the indications on the FDA-approved package labeling and to: (1) forward requests for information about non-FDA approved uses of Seprafilm® to the Medical Affairs Group via a completed Medical Information Request Form signed by the individual making the request, including the individual's full contact information and the question posed, which confirms that the request was unsolicited; or (2) respond to the request via another mechanism in accordance with Sanofi US policy (e.g., provide the medical information number for the physician to call directly, forward an unsolicited email to Medical Affairs).

C. Prohibition on Sales Representative Support of Off-Label Uses

Sanofi US will maintain existing policies, and implement policies to the extent they do not yet exist, that prohibit Seprafilm® sales representatives from providing technical assistance to healthcare professionals, and being present in the operating theatre, during surgical or other medical procedures in which Seprafilm® would likely be used in a way that is inconsistent with Seprafilm's® labeling. This prohibition does not apply when: (1) the procedure is performed as part of a clinical investigation in accord with an Investigational Device Exemption pursuant to 21 C.F.R. § 812, approved by both the FDA and the appropriate institutional review board; and (2) the clinical investigator has determined that the presence of a Seprafilm® sales representative is necessary for the safe and effective use of the device.

D. Activity Relating to Oncology Procedures

Sanofi US has in place and will maintain policies regarding the sale and marketing of Seprafilm® for use in oncology procedures which include the following provisions:

1. Sales representatives may have discussions with oncology specialists and attend oncology surgeries only according to the following provisions.

2. Sanofi US must:

    a) require sales representatives to limit discussion with healthcare professionals to the Indications for Use statement and data that is included in the FDA-approved labeling or that is consistent with such data;

b) require sales representatives to assure that healthcare professionals are apprised of the malignancies Precaution included in the Seprafilm® label;

c) use sales training materials that do not reference adhesion reduction or clinical outcomes related to the use of Seprafilm® in surgeries in the presence of malignancies; and

d) require sales representatives to respond to any requests for data related to adhesion reduction in the presence of malignancies, the impact of Seprafilm® on oncology outcomes and treatments, or the safety of Seprafilm® in the presence of malignancies in accordance with Section I.B.

3. In connection with the sale and marketing of Seprafilm®, Sanofi US will not:

a) permit sales representatives to distribute reprints that discuss adhesion prevention or clinical outcomes related to the use of Seprafilm® in the presence of malignancies. Any future distribution of reprints containing this data by sales representatives will be conducted in accordance with the FDA's Good Reprint Practices;

b) distribute marketing materials, including brochures, speaker decks and webpages, that refer to studies that discuss adhesion prevention or clinical outcomes related to the use of Seprafilm® in the presence of malignancies;

c) make promotional claims about: (i) adhesion reduction in the presence of malignancies; (ii) the impact of Seprafilm® on oncology outcomes and treatments; or (iii) the safety of Seprafilm® in the presence of malignancies;

d) have a commercial presence at oncology congresses or conventions;

e) invite oncology specialists to serve as speakers or attend speaker programs; or

f) conduct promotional speaker programs about the use of Seprafilm® in the presence of malignancies.

4. Sanofi US will conduct the Seprafilm® sale and marketing activity relating to oncology procedures in compliance with federal healthcare program requirements,

the FDCA, and any future approved modifications to the Seprafilm® label, and will consult with the Government prior to changing the policies set forth in Section D.

II. Notice to Healthcare Providers and Entities

Within forty-five (45) days after the Effective Date of the Agreement, Sanofi US shall send, by first class mail, postage prepaid, a notice containing the language set forth below to all institutional healthcare providers within the United States who are known to have purchased Seprafilm® within the year prior to the Effective Date, along with a request that the notice be conspicuously posted in a place where it will be readily observed by surgeons and operating room staff for a period of at least 30 days. This notice shall be dated and shall be signed by the President, North America Pharmaceutical Operations, Sanofi US (the "President"). The body of the notice shall state the following:

PLEASE PROMINENTLY POST THIS NOTICE IN CONSPICUOUS AREA(S) WHERE IT WILL BE READILY OBSERVABLE BY PHYSICIANS AND SURGICAL STAFF

As you may be aware, in April 2011, Genzyme Corporation ("Genzyme") was acquired by the Sanofi Group. As a result of that acquisition, Genzyme became an affiliate of Sanofi US Services Inc. and Sanofi-Aventis U.S. LLC (collectively, "Sanofi US"). Based on the conduct of some Genzyme employees before the acquisition, Genzyme agreed to enter into civil and criminal settlements with the United States of America in connection with the promotion and use of Genzyme's Seprafilm® adhesion barrier, currently marketed and sold by Sanofi US. This letter provides you with additional information about the settlements, explains our commitments going forward, and tells you how to obtain more information about those commitments.

In general terms, before 2011, certain Genzyme sales representatives unlawfully advocated and assisted healthcare providers in converting Seprafilm® adhesion barrier into a slurry for use in minimally invasive surgeries. Seprafilm®

adhesion barrier is not approved by the U.S. Food and Drug Administration ("FDA") for use in laparoscopic surgery. Manufacturers of Class III medical devices such as Seprafilm® adhesion barrier must first demonstrate to FDA's satisfaction that there is a reasonable assurance of safety and effectiveness before the product can be lawfully marketed in the United States. The slurry—a medical device consisting of a suspension of sodium hyaluronate and carboxymethylcellulose—has not been approved by FDA. In addition, before 2011, a Genzyme promotional brochure was misleading because it represented that Seprafilm® was "proven safe and effective" in radical pelvic surgeries based on a study of 14 patients.

To resolve these matters, Genzyme entered into a Deferred Prosecution Agreement ("DPA") with the U.S. Department of Justice and the U.S. Attorney's Office for the Middle District of Florida, in which the United States agreed to discontinue and defer its criminal prosecution of Genzyme for violating the Federal Food, Drug, & Cosmetic Act, subject to certain conditions, including Genzyme's payment of a monetary penalty of over $32.5 million. In addition, the federal government and several individual states alleged that Genzyme's conduct violated their False Claims Acts. To resolve those allegations, Genzyme entered into a separate civil settlement whereby Genzyme agreed to reimburse federal and state healthcare programs an additional $22.2 million. Copies of and more information about these settlements may be found at the following websites:

http://www.justice.gov/civil/current-and-recent-cases
http://www.genzyme.com/Products/Resources-for-Health-Care-Professionals.aspx

As part of the DPA, we pledged to maintain our existing comprehensive compliance program, to undertake certain actions designed to advance compliance with federal healthcare program and FDA requirements, and to make periodic compliance certifications to the Department of Justice. We also agreed to provide this notice to Seprafilm® adhesion barrier purchasers to inform them of the criminal and civil settlements and to remind them that they are encouraged to report any questionable practices by our employees to Sanofi's North America Compliance Department (1-800-648-1297, NA.Compliance@sanofi.com) or the FDA (1-888-INFO-FDA).

You should direct any medical questions or concerns about our prescription products to Medical Information Services, 1-800-633-1610, option 1, or https://contactus.sanofiaventis.us/medicalinquiry.aspx.

The Compliance Officer (or a designee) shall maintain a log of all calls and messages received by the Sanofi NA Compliance Program in response to the notice. The log shall include a record and summary of each call and message received

(whether anonymous or not), the status of the call or message, and any corrective action taken in response to the call or message.

III. Log, Certification and Board Resolution

There shall be two review periods ("Review Period") during the term of the Agreement. The first Review Period shall commence on the Effective Date, as defined by the Agreement, and shall conclude ten months after the Effective Date. The second Review Period shall commence ten months after the Effective Date of the Agreement, and shall conclude twenty-two months after the Effective Date.

Sanofi US shall provide the Log required in Section II and the following Certification and Board Resolution to the U.S. Department of Justice within sixty (60) calendar days following the end of each Review Period as follows:

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

The Certification shall be sworn to under penalty of perjury and shall set forth that the representations contained therein may be provided to, relied upon and material to the government of the United States, and that a knowing and material false statement could result in criminal or civil liability for the signatory.

A. Sanofi North America Pharmaceuticals Operations President's Certification

The President shall conduct a review of the effectiveness of the Sanofi NA Compliance Program as it relates to the marketing, promotion, and sale of Seprafilm® by Sanofi US during each Review Period. The President may, in his or her discretion, rely on an outside consultant/reviewer to perform the review. Based on the review, the President shall submit to the United States a signed certification stating that, to the best of his or her knowledge based on a reasonable inquiry into the operations of the Sanofi NA Compliance Program, during each Review Period: (1) the Sanofi NA Compliance Program continued to include the policies and procedures set forth in the section of this Attachment entitled Enhanced Compliance Measures & Certifications, and (2) Sanofi US has implemented an effective Sanofi NA Compliance Program to meet federal healthcare program requirements and the FDCA regarding the sale, marketing, and promotion of Seprafilm®. The certification shall summarize the review described above. If the President is unable to certify that Sanofi US has implemented an effective Sanofi NA Compliance Program as described above, he or she shall provide a detailed explanation of why the Sanofi NA Compliance Program was not effective, and the steps Sanofi US is taking to ensure the effectiveness of the Sanofi NA Compliance Program. This detailed explanation will satisfy Part (2) of the certification requirement above.

B. Board of Directors Resolution

The Board of Directors of Sanofi-Aventis U.S. LLC, or a designated Committee thereof (the "Board"), shall conduct a review of the effectiveness of the Sanofi NA

Compliance Program as it relates to the sale, marketing, and promotion, of Seprafilm® during each Review Period. This review shall include, but not be limited to, updates and reports by the Compliance Officer and other personnel regarding compliance matters. The Board shall evaluate the effectiveness of the Sanofi NA Compliance Program, including, among other means, by receiving updates about the activities of the Compliance Officer and Compliance Committee. The Board review shall not require the retention of third party experts. Based on its review, the Board shall submit to the United States a resolution (the "Board Resolution") that summarizes its review and oversight of Sanofi US's compliance with federal healthcare program requirements and FDCA requirements regarding the sale, marketing, and promotion of Seprafilm® and, at a minimum, includes the following language:

> The Board of Directors of Sanofi-Aventis U.S. LLC has made a reasonable inquiry as described in Section III.B of the Attachment to the Deferred Prosecution Agreement with Genzyme Corporation (Attachment B) into the operations of the Sanofi NA Compliance Program for the applicable time period ***[insert time period],*** including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Sanofi US has implemented an effective compliance program, as defined in the United States Sentencing Commission Guidelines Manual, Chapter 8: Sentencing of Organizations (2012), to meet the requirements of federal healthcare programs, the Federal Food, Drug, and Cosmetic Act regarding sales, marketing, and promotion of Seprafilm,® and as set forth in Attachment B to the Deferred Prosecution Agreement.

If the Board is unable to provide any part of this statement, it shall include in the resolution a written explanation of the reasons why it is unable to provide such a statement.

C. Notifications to Government[1]

Sanofi US agrees to provide the Government with its submissions pursuant to Sections III.H (Notification of Government Investigation or Legal Proceedings), III.I. (Reportable Events), and III.J (Notification of Communications with FDA) of the Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Sanofi, that relate to the sale, marketing, and promotion of Seprafilm®. Sanofi US agrees to provide to the Government, at its request, all relevant non-privileged information concerning the allegations and any resulting disciplinary and remedial measures.

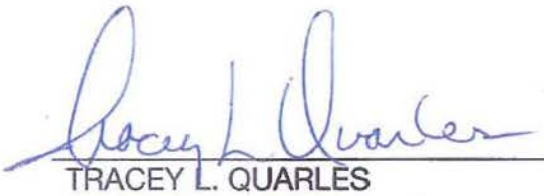
IV. Breach of this Attachment

Sanofi US recognizes that each of the terms in this Attachment constitutes a material term of this Attachment. Sanofi US and the United States agree that failure to comply with the obligations set forth in this Attachment will be considered a breach of the DPA and may subject Genzyme to prosecution in the United States District Court for the Middle District of Florida as set forth in that Agreement.

[1] Consistent with the Department of Justice's Freedom of Information Act ("FOIA") procedures, the government shall make reasonable effort to notify Sanofi US prior to any release by DOJ of information submitted by Sanofi US pursuant to its obligations under this Deferred Prosecution Agreement and identified upon submission by Sanofi US as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Sanofi US shall have the rights set forth under said procedures.

AGREED:

FOR GENZYME CORPORATION:



8/31/15

TRACEY L. QUARLES
Senior Vice President and General Counsel

Genzyme Corporation
500 Kendall Street
Cambridge, MA 02142

Date

KATHY B. WEINMAN
Attorney for Genzyme Corporation

Collora LLP
100 High Street, 20th Floor
Boston, MA 02110

Date

JONATHAN L. DIESENHAUS
Attorney for Genzyme Corporation

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

Date

AGREED:

FOR GENZYME CORPORATION:

TRACEY L. QUARLES
Senior Vice President and General Counsel

Genzyme Corporation
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Date

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August 31, 2015
Date

JONATHAN L. DIESENHAUS
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August 31, 2015
Date

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

Choate Hall & Stewart LLP
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Boston, MA 02110

Date

FOR SANOFI US:

8/26/15

ROBERT DEBERARDINE
Senior Vice President and General Counsel

Sanofi North America
55 Corporate Drive
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Date

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August 31, 2015
Date

FOR SANOFI US:

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August 31, 2015
Date

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Melissa B Tray August 31, 2015

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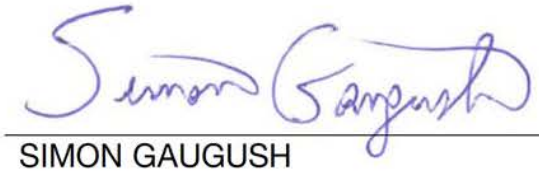
FOR THE UNITED STATES ATTORNEY'S OFFICE
FOR THE MIDDLE DISTRICT OF FLORIDA:

A. LEE BENTLEY III
United States Attorney



August 31, 2015
Date

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

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

MICHAEL S. BLUME
Director

August 31, 2015
Date

ROSS S. GOLDSTEIN
Trial Attorney

U.S. Department of Justice
Consumer Protection Branch
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