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.

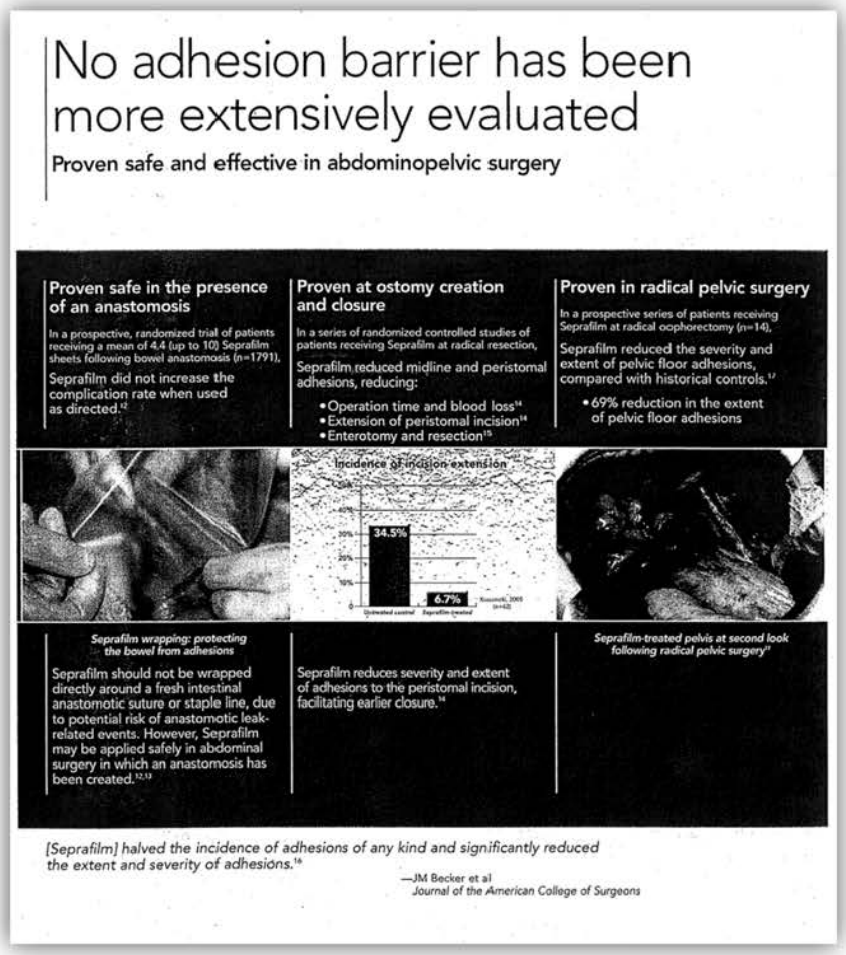
Promotional Brochure

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.