UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA

CASE NO. 1:17 mj 10

UNITED STATES OF AMERICA

v.

BAXTER HEALTHCARE CORPORATION,

Defendant.

_____/

DEFERRED PROSECUTION AGREEMENT

Defendant Baxter Healthcare Corporation ("Baxter"), by its undersigned representatives, pursuant to authority granted by Baxter's Board of Directors; and the Office of the United States Attorney for the Western District of North Carolina and the United States Department of Justice, Consumer Protection Branch (collectively, "the Government"), enter into this deferred prosecution agreement (this "Agreement"), the terms and conditions of which are as follows:

Criminal Information and Acceptance of Responsibility

1. Baxter acknowledges and agrees that the Government will file a one-count criminal Information in the United States District Court for the Western District of North Carolina charging Baxter with one misdemeanor count of introducing and causing the introduction into interstate commerce of an adulterated drug in violation of Title 21, United States Code, Sections 331(a), 333(a)(1), and 351(a)(2)(B) arising out of the conduct described in the Statement of Facts, attached hereto as Attachment A and incorporated by reference into this Agreement. In so doing, Baxter: (a) knowingly waives its right to indictment on this charge, as

well as all rights to a speedy trial pursuant to the Sixth Amendment to the United States Constitution, Title 18, United States Code, Section 3161, and Federal Rule of Criminal Procedure 48(b); and (b) knowingly waives for purposes of this Agreement and any charges by the United States arising out of the conduct described in the Statement of Facts, any objection with respect to venue in the United States District Court for the Western District of North Carolina.

2. Baxter admits, accepts, and acknowledges that it is responsible under United States law for the acts of its officers, directors, employees, and agents as set forth in the Statement of Facts, and that the facts in the Statement of Facts are true and accurate. Should the Government pursue the prosecution that is deferred by this Agreement, Baxter stipulates to the admissibility of the Statement of Facts in any proceeding, including any trial, guilty plea, or sentencing proceeding, and will not contradict anything in the Statement of Facts at any such proceeding.

Term of the Agreement

3. This Agreement is effective for a period beginning on the date on which the Information is filed (the "Effective Date") and ending thirty (30) months after that date (the "Term"). Baxter agrees, however, that, in the event the Government determines, in its sole discretion, that Baxter has knowingly violated any material 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 time period of twelve months, without prejudice to the Government's right to proceed as provided in Paragraphs 18–21 below. Any extension of the Agreement extends all terms of this Agreement, including the terms of the Enhanced Compliance

Measures in Attachment B, for an equivalent period. In the event the Government determines that an extension of the Term of this Agreement is or may be warranted, the Government will notify Baxter 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, Baxter may respond to the Government in writing to explain the nature and circumstances of any alleged breach, as well as the actions Baxter has taken to address and remediate the situation, including whether Baxter 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 extend the term of the Agreement.

Relevant Considerations

4. The Government enters into this Agreement based on the individual facts and circumstances presented by this case and Baxter. Among the factors considered were the following: (a) the acknowledgment by Baxter of its conduct and Baxter's acceptance of responsibility for that conduct; (b) the cooperation by Baxter in the investigation of this matter and Baxter's commitment to continue that cooperation as provided in Paragraph 5 below; (c) Baxter's compliance efforts and Baxter's commitment to continue to enhance its compliance measures; (d) the payment by Baxter of $8,000,000 in monetary penalties; (e) the forfeiture by Baxter of $8,000,000; (f) the commitment by Baxter to maintain a system of controls designed to prevent violations of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, ("FDCA"); and (g) the commitment by Baxter to fulfill all of the terms of this Agreement.

Future Cooperation Requirements

5. Baxter shall cooperate fully with the Government and any other agency

designated by the Government in any and all matters relating to the conduct described in this Agreement and the Statement of Facts ("Covered Conduct"), subject to applicable law and regulations, until the date upon which all investigations and potential prosecutions arising out of such conduct are concluded, whether or not those investigations and prosecutions are concluded within the term specified in Paragraph 3. At the request of the Government, Baxter shall also cooperate fully with other law enforcement and regulatory authorities and agencies in any investigation of Baxter, its parent company or its affiliates, or any of its present or former officers, directors, employees, agents, and consultants, or any other party, in any and all matters relating to the Covered Conduct. Baxter agrees that its cooperation pursuant to this paragraph shall include, but not be limited to, the following:

a. Baxter shall truthfully disclose all factual information related to the Covered Conduct not protected by a valid claim of attorney-client privilege or work product doctrine with respect to its activities, those of its parent company and affiliates, and those of its former, present and future directors, officers, employees, agents, and consultants, including any evidence or allegations and internal or external investigations, about which Baxter has any knowledge or about which the Government may inquire. This obligation of truthful disclosure includes, but is not limited to, the obligation of Baxter to provide to the Government, upon request, any document, record or other tangible evidence related to the Covered Conduct about which the Government may inquire of Baxter.

b. Upon request of the Government, Baxter shall designate knowledgeable employees, agents or attorneys to provide to the Government the information and materials described in Paragraph 5(a) above on behalf of Baxter. It is further understood that Baxter must

at all times provide complete, truthful, and accurate non-privileged information.

c. Baxter shall use its best efforts to make available for interviews or testimony concerning the Covered Conduct, as requested by the Government, former, present and future officers, directors, employees, agents and consultants of Baxter. This obligation includes, but is not limited to, sworn testimony before a federal grand jury or in federal trials, as well as interviews with law enforcement and regulatory authorities. Cooperation under this paragraph shall include identification of witnesses who, to the knowledge of Baxter, may have material information regarding the Covered Conduct.

d. With respect to any information, testimony, documents, records or other tangible evidence provided to the Government pursuant to this Agreement, Baxter consents to any and all disclosures, subject to applicable law and regulations, to other governmental authorities of such materials as the Government, in its sole discretion, shall deem appropriate.

Payment of Monetary Penalty

6. Baxter agrees to pay a monetary penalty in the amount of $8,000,000 to the United States Treasury within ten (10) business days of the Effective Date of this Agreement by wire transfer, or within ten (10) business days of the date the wire instructions are provided by the Government, whichever is later. Baxter and the Government agree that this penalty is appropriate given the facts and circumstances of this case. The $8,000,000 penalty is final and shall not be refunded. Furthermore, nothing in this Agreement shall be deemed an agreement by the Government that $8,000,000 is the maximum penalty that may be imposed in any future prosecution, and the Government is not precluded from arguing in any future prosecution that the Court should impose a higher fine, although the Government agrees that under those

circumstances, it will recommend to the Court that any amount paid under this Agreement should be offset against any fine the Court imposes as part of a future judgment. Baxter agrees that it will not claim, assert, or apply for a tax deduction or tax credit with regard to any federal, state, local or foreign tax in connection with the payment of any part of this $8,000,000 penalty. If Baxter fails to timely make the payment required in this paragraph, interest (at the rate specified in Title 28, United States Code, Section 1961) shall accrue on the unpaid balance through the date of payment, unless the Government, in its sole discretion, chooses to reinstate prosecution pursuant to Paragraphs 18 and 19 below.

Forfeiture

7. As a result of the Covered Conduct, Baxter agrees to pay to the United States $8,000,000 (the "Stipulated Forfeiture Amount") representing the proceeds resulting from the Covered Conduct. Baxter agrees that the facts set forth in the Statement of Facts are sufficient to establish that the Stipulated Forfeiture Amount is subject to civil forfeiture to the United States and that this Agreement and the Statement of Facts may be attached to and incorporated into the Civil Forfeiture Complaint to be filed against the Stipulated Forfeiture Amount. By this Agreement, Baxter waives service of said Civil Forfeiture Complaint and agrees that a Final Order of Forfeiture may be entered against the Stipulated Forfeiture Amount. Upon payment of the Stipulated Forfeiture Amount, Baxter shall release any and all claims it may have to such funds and execute such documents as necessary to accomplish the forfeiture of the funds. Baxter agrees that it will not file a claim with the Court or otherwise contest the civil forfeiture of the Stipulated Forfeiture Amount and will not assist a third party in asserting any claim to the Stipulated Forfeiture Amount. The forfeiture of the Stipulated Forfeiture Amount shall be final

and shall not be refunded.

8. Baxter agrees that Stipulated Forfeiture Amount shall be treated as a penalty paid to the United States government for all purposes, including all tax purposes. Baxter agrees that it will not claim, assert, or apply for a tax deduction or tax credit with regard to any federal, state, local or foreign tax in connection with the payment of any part of the forfeiture paid pursuant to this Agreement.

9. Baxter shall transfer $8,000,000 to the United States within ten (10) business days of the Effective Date of this Agreement, or within ten (10) business days of the date the wire instructions are provided by the Government, whichever is later. Such transfer shall be made by wire transfer to the United States Marshals Service, pursuant to wire instructions provided by the Government. If Baxter fails to timely make the payment required in this paragraph, interest (at the rate specified in Title 28, United States Code, Section 1961) shall accrue on the unpaid balance through the date of payment, unless the Government, in its sole discretion, chooses to reinstate prosecution pursuant to Paragraphs 18 and 19 below.

10. Nothing in this Agreement shall be deemed an agreement by the Government that $8,000,000 is the maximum forfeiture that may be imposed should the Government later determine that Baxter has breached this Agreement and commences a prosecution against Baxter. However, in the event of a breach of this Agreement and subsequent prosecution, the Government agrees that it will recommend to the Court that the amounts paid pursuant to this Agreement be offset against whatever forfeiture the Court shall impose as part of its judgment. Baxter understands that such a recommendation will not be binding on the Court.

Conditional Release from Liability

11. Subject to Paragraphs 18–21 below, the Government agrees, except as provided herein, that it will not bring any criminal case against Baxter relating to any of the Covered Conduct. The Government, however, may use any information related to the Covered Conduct against Baxter: (a) in a prosecution for perjury, obstruction of justice, or making a false statement related to conduct occurring after November 21, 2012; or (b) in a prosecution or other proceeding relating to a violation of any provision of Title 26 of the United States Code.

12. This Agreement does not provide any protection against prosecution for any conduct outside of or unrelated to the Covered Conduct.

13. This Agreement does not provide any protection against prosecution for any future conduct by Baxter.

14. In addition, this Agreement does not provide any protection against prosecution of any former, present or future officer, director, employee, shareholder, agent, consultant, contractor, or subcontractor of Baxter for any violations committed by them.

Compliance Measures

15. Baxter will maintain, or as necessary, establish, internal controls, policies, and procedures designed to prevent and detect violations of the FDCA as set forth in Attachment B, which is incorporated by reference into this Agreement.

Deferred Prosecution

16. In consideration of: (a) the past and future cooperation of Baxter described in Paragraphs 4 and 5 above; (b) Baxter's payment of a monetary penalty of $8,000,000; (c) Baxter's forfeiture of $8,000,000; and (d) Baxter's agreement to implement and maintain the

compliance measures as described in Paragraph 15 above, the Government agrees that any prosecution of Baxter for the Covered Conduct is hereby deferred for the Term of this Agreement. Baxter and the Government understand that this Agreement must be approved by the Court. Should the Court decline to approve this Agreement for any reason, both Baxter and the Government are released from any obligation imposed upon them by this Agreement, and this Agreement is null and void, except for the tolling provisions in Paragraph 18 below.

17. The Government further agrees that if Baxter fully complies with all of its obligations under this Agreement, the Government will not continue the criminal prosecution against Baxter described in Paragraph 1 and, at the conclusion of the Term, this Agreement shall expire. Within thirty (30) days of this Agreement's expiration, the Government shall seek dismissal with prejudice of the criminal Information filed against Baxter described in Paragraph 1, and agrees not to file charges in the future against Baxter based on the Covered Conduct.

Breach of the Agreement

18. If, during the Term of this Agreement, Baxter (a) commits any felony under United States federal law; (b) provides in connection with this Agreement deliberately false, incomplete, or misleading information; (c) fails to cooperate as set forth in Paragraph 5 of this Agreement; (d) fails to implement compliance measures as set forth in Paragraph 15 of this Agreement and Attachment B; (e) commits any acts that would be a material violation of the FDCA relating to its products and fails to take timely and reasonable corrective action; or (f) otherwise materially fails to perform or fulfill each of Baxter's obligations under this Agreement, Baxter shall thereafter be subject to prosecution for any federal criminal violation of which the Government has knowledge, including, but not limited to, the charge in the Information

described in Paragraph 1, which may be pursued by the Government in the United States District Court for the Western District of North Carolina or any other appropriate venue. Determination of whether Baxter has materially breached the Agreement and whether to pursue prosecution of Baxter shall be in the Government's sole discretion and is not subject to review in any court or tribunal. Any such prosecution may be premised on information provided by Baxter. Any such prosecution relating to the Covered Conduct or relating to conduct associated with the Covered Conduct and known to the Government before the date on which this Agreement was signed that is not time-barred by the applicable statute of limitations on the date of the signing of this Agreement may be commenced against Baxter, notwithstanding the expiration of the statute of limitations, between the signing of this Agreement and the expiration of the Term plus one year. Thus, by signing this Agreement, Baxter agrees that the statute of limitations with respect to any such prosecution that is not time-barred on the date of the signing of this Agreement shall be tolled for the Term plus one year.

19. In the event the Government determines that Baxter has materially breached this Agreement, the Government agrees to provide Baxter with written notice of such breach before instituting any prosecution resulting from such breach. Within thirty (30) days of receipt of such notice, Baxter shall have the opportunity to respond to the Government in writing to explain the nature and circumstances of such breach, as well as the actions Baxter has taken to address and remediate the situation, including whether Baxter 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 pursue prosecution of Baxter, including factors such as whether the breach (a) was knowingly or willfully committed;

(b) was systematic; (c) resulted in actual or potential harm to the public; or (d) involves conduct the same as or similar to the Covered Conduct.

20. As a contractual remedy, Baxter and the Government agree that, in the Government's sole discretion, any material breach of this Agreement may lead to the imposition of a monetary payment of up to $5,000 per day for each day Baxter is in breach of this Agreement ("Stipulated Penalties"). The imposition of Stipulated Penalties will be in the alternative to instituting a prosecution due to a material breach of this Agreement. The Government will notify Baxter in writing of Baxter's failure to comply and the Government's exercise of its contractual right to demand payment of the Stipulated Penalties (the "Demand Letter"). The Demand Letter will set forth: (a) the provision materially breached; (b) the date of the breach; (c) a description of the breach sufficient to permit Baxter to cure (as described below); and (d) the amount of stipulated penalties claimed by the Government as of the date of the Demand Letter. Within fourteen (14) days after receipt of the Demand Letter, or such other period as the United States may agree in writing, Baxter will cure the breach to the Government's reasonable satisfaction ("Cure Period"). If Baxter cures the breach within the Cure Period, no Stipulated Penalties shall be due. If Baxter fails to cure the breach during the Cure Period, Stipulated Penalties calculated from the date of breach to the date of payment will be payable to the Government within ten (10) business days. The Stipulated Penalties will be paid by wire transfer according to wire instructions that will be provided by the Government. A joint reasonable determination by the United States Attorney's Office for the Western District of North Carolina and the United States Department of Justice's Consumer Protection Branch as to whether Baxter has failed to cure any material breach will be final and non-appealable. Baxter

agrees that the United States District Court for the Western District of North Carolina will have jurisdiction over any action to collect such a penalty. If Baxter fails to timely make a payment required in this paragraph, interest (at the rate specified in Title 28, United States Code, Section 1961) shall accrue on the unpaid balance through the date of payment.

21. In the event the Government institutes a prosecution due to Baxter's material breach of this Agreement: (a) all statements made by or on behalf of Baxter to the Government or to the Court, including the attached Statement of Facts, and any testimony given by Baxter before a grand jury, a court, or any tribunal, or at any legislative hearings, whether before or after 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 Baxter, provided such statements or testimony are otherwise admissible under the Federal Rules of Evidence, except for the attached Statement of Facts, which is admissible in whole; and (b) Baxter shall not assert any claim under the United States Constitution, Rule 11(f) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules of Evidence, or any other federal rule that any such statements or testimony made by or on behalf of Baxter before or after this Agreement, or any leads derived therefrom, should be suppressed or are otherwise inadmissible. The decision whether conduct or statements of any present or future director, officer or employee, or any person acting on behalf of, or at the direction of, Baxter, will be imputed to Baxter for the purpose of determining whether Baxter has violated any provision of this Agreement shall be in the sole discretion of the Government.

22. Baxter acknowledges that the Government has made no representations, assurances, or promises concerning what sentence may be imposed by the Court if Baxter

materially breaches this Agreement and this matter proceeds to judgment. Baxter further acknowledges that any such sentence is solely within the discretion of the Court and that nothing in this Agreement binds or restricts the Court in the exercise of such discretion.

Sale or Merger of Baxter

23. Except as may otherwise be agreed by the Government in connection with a particular transaction, Baxter 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. Baxter shall notify the Government in writing at least fifteen (15) days before any such transaction.

Public Statements by Baxter

24. Baxter expressly agrees that it shall not, through present or future attorneys, officers, directors, agents, management level employees or any other person authorized to speak for Baxter make any public statement, in litigation or otherwise, contradicting in whole or in part the acceptance of responsibility by Baxter set forth above or the facts described in the attached Statement of Facts. Any such contradictory statement shall, subject to cure rights of Baxter described in this paragraph below, constitute a material breach of this Agreement, and Baxter thereafter shall be subject to prosecution as set forth in Paragraphs 18–21 of this Agreement. The decision whether any public statement by any such person contradicting a fact contained in the Statement of Facts will be imputed to Baxter for the purpose of determining whether it has breached this Agreement shall be at the sole discretion of the Government. 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 Baxter, and Baxter may avoid a breach of this Agreement by publicly repudiating such statement(s) within five (5) business days after notification. Baxter shall be permitted to raise defenses and to assert affirmative claims in other proceedings relating to the matters set forth in the Statement of Facts provided that such defenses and claims do not contradict, in whole or in part, a statement contained in the Statement of Facts. No statement made by any former, present or future officer, director, employee, or agent of Baxter in the course of any criminal, regulatory, or civil case initiated against such individual shall be imputed to Baxter, unless such individual is speaking on behalf of Baxter.

Publication

25. Within ten (10) business days of the Effective Date of this Agreement, Baxter will (a) make this Agreement and the Statement of Facts available to the public through a link on its website, under the top navigation bar on baxter.com, under "Our Products & Expertise," under the link for "Important Product Updates," that will persist on the top-level page for "Important Product Updates" and not archive for the duration of this Agreement; and (b) communicate to all Baxter employees that Baxter has entered into this Agreement and make available this Agreement and Statement of Facts to all such employees.

Limitations on Binding Effect of Agreement

26. This Agreement is binding on Baxter and the Government but specifically does not bind any other component of the Department of Justice, other federal agencies, or any state, local or foreign law enforcement or regulatory agencies, or any other authorities, although the

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

Notice

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

Chief, Criminal Division
U.S. Attorney's Office
Western District of North Carolina
227 West Trade Street, Suite 1650
Charlotte, NC 28202

Director, Consumer Protection Branch
U.S. Department of Justice
450 5th Street NW, Room 6400 South
Washington, DC 20001

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

General Counsel
Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, IL 60015

Mitch Lazris
Michele Sartori
Hogan Lovells
555 13th St., NW
Washington, DC 20004

29. Notice shall be effective upon actual receipt by the Government or Baxter.

Complete Agreement

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

AGREED:

FOR BAXTER HEALTHCARE CORPORATION:

Date: JAN 03 2017 By: _____
David P. Scharf
Corporate Vice President, General Counsel
Baxter Healthcare Corporation

Date: _____ By: _____
Mitch Lazris
Michele Sartori
Hogan Lovells
Counsel for Baxter Healthcare Corporation

FOR THE U.S. ATTORNEY'S OFFICE, WESTERN DISTRICT OF NORTH CAROLINA:

Date: _____ By: _____
Kelli Ferry
Assistant U.S. Attorney

FOR THE U.S. DEPARTMENT OF JUSTICE, CONSUMER PROTECTION BRANCH:

Date: _____ By: _____
Allan Gordus
Senior Litigation Counsel
Shannon Pedersen
Trial Attorney

Complete Agreement

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AGREED:

FOR BAXTER HEALTHCARE CORPORATION:

Date: _____ By: _____
David P. Scharf
Corporate Vice President, General Counsel
Baxter Healthcare Corporation

Date: 1/3/17 By: Mitch Lazris
Mitch Lazris
Michele Sartori
Hogan Lovells
Counsel for Baxter Healthcare Corporation

FOR THE U.S. ATTORNEY'S OFFICE, WESTERN DISTRICT OF NORTH CAROLINA:

Date: _____ By: _____
Kelli Ferry
Assistant U.S. Attorney

FOR THE U.S. DEPARTMENT OF JUSTICE, CONSUMER PROTECTION BRANCH:

Date: _____ By: _____
Allan Gordus
Senior Litigation Counsel
Shannon Pedersen
Trial Attorney

Complete Agreement

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AGREED:

FOR BAXTER HEALTHCARE CORPORATION:

Date: _____ By: _____
David P. Scharf
Corporate Vice President, General Counsel
Baxter Healthcare Corporation

Date: _____ By: _____
Mitch Lazris
Michele Sartori
Hogan Lovells
Counsel for Baxter Healthcare Corporation

FOR THE U.S. ATTORNEY'S OFFICE, WESTERN DISTRICT OF NORTH CAROLINA:

Date: 1-12-17 By: _____
Kelli Berry
Assistant U.S. Attorney

FOR THE U.S. DEPARTMENT OF JUSTICE, CONSUMER PROTECTION BRANCH:

Date: 1/11/2017 By: _____
Allan Gordus
Senior Litigation Counsel
Shannon Pedersen
Trial Attorney

ATTACHMENT A

STATEMENT OF FACTS

The following Statement of Facts is incorporated by reference as part of the Deferred Prosecution Agreement (this "Agreement") between the Office of the United States Attorney for the Western District of North Carolina and the United States Department of Justice, Consumer Protection Branch (collectively, "the Government") and Baxter Healthcare Corporation ("Baxter"). Baxter hereby agrees and stipulates that the following information is true and accurate. Baxter admits, accepts, and acknowledges that it is responsible for the acts of its officers, directors, employees, and agents as set forth below. Baxter, through its employees, distributed products in interstate commerce that were adulterated within the meaning of the FDCA, 21 U.S.C. § 351(a)(2)(B). Should the Government pursue the prosecution that is deferred by this Agreement, Baxter agrees that it will neither contest the admissibility of, nor contradict, this Statement of Facts in any such proceeding. The Government and Baxter agree that the following facts are true and correct:

Background

1. During the relevant time period, from July 2011 to November 2012, Baxter was a Delaware corporation and a subsidiary of Baxter International, Inc., headquartered in Deerfield, Illinois. Baxter owned and operated the North Cove manufacturing facility in Marion, North Carolina ("North Cove"). At North Cove, Baxter manufactured large-volume sterile intravenous ("IV") solutions and related products. North Cove produced approximately 1.5 million bags of IV solution per day, supplying approximately 60% of the IV solutions used in the United States. North Cove had twelve production lines, occupied approximately 1.4 million square feet, and

was the largest IV solutions plant in the world.

2. Baxter employed over 2,000 people at North Cove. Baxter's employees at North Cove included quality employees, who were responsible for ensuring the quality of Baxter's products made at North Cove; human resources employees, who were responsible for employment matters at North Cove; and maintenance employees, who were responsible for maintaining the equipment and facilities Baxter used to make IV solutions at North Cove, including utilities and Heating, Ventilation, and Air Conditioning ("HVAC") systems, among numerous other types of employees at North Cove.

3. IV solutions were drugs that the United States Food and Drug Administration ("FDA") regulated under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399f ("FDCA"). The FDCA prohibited the introduction or delivery for introduction in interstate commerce of an adulterated drug. 21 U.S.C. § 331(a).

4. The FDA implemented Good Manufacturing Practices regulations which governed the manufacture of drugs including IV solutions. A drug was adulterated within the meaning of the FDCA, 21 U.S.C. § 351(a)(2)(B), if it was not manufactured according to FDA's current Good Manufacturing Practices regulations, 21 C.F.R. Parts 210 and 211.

Lines 10 and 11 at North Cove

5. From July 2011 to November 2012, Production Lines 10 and 11 at North Cove each had separate clean rooms used to fill bags with sterile IV solutions. Hospitals used these IV bags to treat their patients by putting the sterile IV solution directly into the bloodstreams of patients.

6. Approximately 20% of the IV bags made at North Cove, which is approximately

300,000 IV bags a day, were filled in the Line 11 clean room. Approximately 9% of all the IV bags used in the United States were filled in the Line 11 clean room.

7. Each of the clean rooms for Lines 10 and 11 had approximately 120 high-efficiency particulate absorption ("HEPA") filters installed in the ceiling of the room. Air was pushed into the clean rooms through the HEPA filters so that the filters could catch particles in the air before entering the clean rooms. The filters in the clean room for Line 10 and above belts A, B, C and D in the clean room for Line 11 had ceiling grates mounted underneath them. These filters were not visible without removing the ceiling grates or screens.

8. Once a year, Baxter shut down Lines 10 and 11 for regularly scheduled maintenance. Line 10's annual shutdown occurred in or about December, while Line 11's annual shutdown occurred in or about July. During these shutdowns, the HEPA filters installed in the ceilings of the clean rooms of Lines 10 and 11 were inspected and tested. According to North Cove policy and standard operating procedures, during these shutdowns, Baxter maintenance employees were required to replace HEPA filters that failed PAO (Poly Alpha Olefin) testing, which tested each filter's ability to filter the air. Baxter maintenance employees also sometimes replaced excessively stained or discolored filters, including those filters with discoloration from contaminants such as mold. Baxter maintenance employees were required to record the reason for each filter replacement.

Stained or Moldy HEPA Filters at North Cove

9. HEPA filters at North Cove occasionally became discolored or stained, including potentially with mold. When Baxter maintenance employees discovered such HEPA filters, they replaced them with a new filter. Baxter quality employees kept track of and documented the

number of HEPA filters that were replaced and the reasons therefor, including mold, stain, and discoloration.

10. In approximately 2006, Baxter HVAC employees were told to stop using the word "mold" on paperwork at North Cove to describe the condition of HEPA filters. Instead of using the word "mold," Baxter HVAC employees were told to use the words "stain" or "discoloration" to describe such HEPA filters on paperwork at North Cove. At about the same time, Baxter's quality trend reports that summarized the number of HEPA filters that were replaced and the reasons therefor, changed the title of one of the trending categories from "mold/stain" to "stain."

July 2011 Shutdown

11. In July 2011, during the regularly scheduled maintenance shutdown at North Cove, a Baxter HVAC Technician ("Reporting Employee") saw what he believed to be mold on approximately 15 HEPA filters in the Line 11 clean room. The suspected mold was on the side of the HEPA filters that faced the inside of the clean room. A co-worker of the Reporting Employee, another HVAC Technician at North Cove ("HVAC Technician #1") who was working with the Reporting Employee, also saw these suspected moldy HEPA filters. During this shutdown, the Reporting Employee showed a HEPA filter that had staining on it to the Superintendent of Utilities at North Cove.

12. The Superintendent of Utilities was a mid-level manager in the North Cove Maintenance Department and reported to the Director of Facilities. The Director of Facilities was the highest level maintenance employee at North Cove. The HVAC Supervisor reported to the Superintendent of Utilities. All of the HVAC Technicians at North Cove, including the

Reporting Employee, reported to the HVAC Supervisor.

13. The Reporting Employee and HVAC Technician #1 began replacing the HEPA filters they believed to be moldy. When approximately five of those HEPA filters remained to be changed in the Line 11 clean room, the HVAC Supervisor told the Reporting Employee and HVAC Technician #1 to stop changing the filters. As a result, the five remaining HEPA filters believed to be moldy, some of which were directly over equipment used to fill IV bags with solution, were left in the ceiling of the Line 11 clean room.

Line 11 HEPA Filter Maintenance Records for the July 2011 Shutdown

14. HVAC Technician #1 wrote on the July 2011 Shutdown maintenance record for the HEPA filters in the Line 11 clean room that certain filters were "changed prior to testing due to discoloration." Below this comment, the Reporting Employee wrote "Filters also had mold." The HVAC Supervisor saw these statements on the maintenance records and signed his name next to them to indicate his review of the statements. The Director of Facilities and the Superintendent of Utilities knew about these statements on the maintenance records, and understood them to mean that the filters at issue had been replaced. The Critical Systems Engineer in North Cove's Maintenance Department (the "Maintenance Critical Systems Engineer"), who did not supervise the Reporting Employee and was not involved with HEPA filters during the Shutdown, also saw these statements.

15. Three North Cove quality employees, including the Critical Systems Engineer in North Cove's Quality Department (the "Quality Critical Systems Engineer"), reviewed shutdown maintenance records for HEPA filters. The Quality Critical Systems Engineer reviewed and approved the July 2011 Shutdown maintenance record for the HEPA filters in the Line 11 clean

room on which the Reporting Employee wrote "Filters also had mold." The Quality Critical Systems Engineer understood the comments on this record to mean that the filters at issue had been replaced. The Quality Critical Systems Engineer complained to the Director of Facilities and Superintendent of Utilities that the Reporting Employee should not have written the word "mold" on this maintenance record because no one should write "mold" on Baxter records as no one could be sure a stain on a filter was mold until it was tested. No one, including the Quality Critical Systems Engineer, told any quality manager about the maintenance records with the notation regarding mold on them. Baxter took no action at that time to address the notation of mold.

Complaints of Moldy HEPA Filters to North Cove's Plant Manager

16. In late October 2011, North Cove's Plant Manager held a plant-wide, face-to-face meeting in which he emphasized that employees should come to him with any quality issues or concerns they might have. After this meeting, the Reporting Employee told North Cove's Plant Manager that approximately five moldy HEPA filters remained in the Line 11 clean room and that he feared his maintenance supervisors would retaliate against him for reporting the moldy filters. The Plant Manager was the highest level manager at North Cove and had overall responsibility for the entire plant. The Plant Manager assigned North Cove's Human Resources Director to investigate the Reporting Employee's moldy filter complaints and his fears of retaliation.

17. The Human Resources Director treated the investigation as a personnel problem between the Reporting Employee and his maintenance supervisors. The Human Resources Director had no knowledge of or experience with HEPA filters. The Human Resources Director

did not address the problem as a quality issue, nor did she tell anyone in the North Cove Quality Department about the Reporting Employee's complaints of moldy filters remaining in the Line 11 clean room or involve any quality employee in her investigation of these mold complaints.

18. When the Human Resources Director talked to the Reporting Employee about his complaints of approximately five moldy HEPA filters above the ceiling grates in the Line 11 clean room, the Reporting Employee gave the Human Resources Director a map showing which HEPA filters remained in the Line 11 clean room he identified as moldy.

19. During her investigation in November and December 2011, the Human Resources Director discussed the Reporting Employee's concerns about moldy HEPA filters remaining in the Line 11 clean room with all of the North Cove maintenance managers above the Reporting Employee, including the Director of Facilities, the Superintendent of Utilities, and the HVAC Supervisor. The Human Resources Director gave the Reporting Employee's map showing the filters he identified as moldy in the Line 11 clean room to the Director of Facilities and the Superintendent of Utilities, and kept a copy for her file.

20. In December 2011, the HVAC Supervisor along with other HVAC technicians inspected the HEPA filters identified by the Reporting Employee as moldy. The HVAC Supervisor reported to the Human Resources Director that they were not as "dirty" as other filters in the Line 11 clean room. The HVAC Supervisor also told the Reporting Employee that the "dirty" filters would be replaced the next time Line 11 would be shut down for its annual maintenance in July 2012. The HVAC Supervisor also told the Reporting Employee that the microbiology lab, which performs air testing in the Line 11 clean room, had not reported to him any air quality issues in Line 11. As a result, the filters that the Reporting Employee identified

as moldy continued to be used in the Line 11 clean room. The Reporting Employee was not satisfied with this decision. Baxter took no further action to address the Reporting Employee's identification of moldy filters at that time.

21. Despite the Reporting Employee's complaints of approximately five moldy HEPA filters in the Line 11 clean room, neither the Human Resources Director, the Director of Facilities, nor the Superintendent of Utilities at North Cove ever looked at the HEPA filters above the ceiling grates in the Line 11 clean room.

December 2011 Shutdown

22. In December 2011, during the regularly scheduled maintenance shutdown at North Cove, the Reporting Employee and HVAC Technician #1 saw seven discolored HEPA filters above the ceiling grates in the Line 10 clean room. The Reporting Employee and HVAC Technician #1 changed all seven filters. For four of the seven discolored filters, the Reporting Employee and HVAC Technician #1 noted on the filter maintenance record: "Changed due to discoloration and possible mold." For three of the seven discolored filters, the Reporting Employee and HVAC Technician #1 noted on the filter maintenance record: "Changed due to discoloration." Three North Cove quality employees, including the Quality Critical Systems Engineer, reviewed this shutdown maintenance record for the Line 10 HEPA filters. Baxter took no action at that time to address these notations of mold.

July 2012 Shutdown

23. During the July 2012 maintenance shutdown, the Reporting Employee and HVAC Technician #1 saw mold on 29 HEPA filters above the ceiling grates over Belts A-D in the Line 11 clean room. During this shutdown, the Maintenance Critical Systems Engineer came into the

Line 11 clean room. The Reporting Employee asked the Maintenance Critical Systems Engineer to come over and look at some of the HEPA filters in the Line 11 clean room. The HEPA filters were uncovered and visible because the ceiling grates were down as part of the shutdown. The Maintenance Critical Systems Engineer came over to where the Reporting Employee and HVAC Technician #1 were working. The Reporting Employee then showed the Maintenance Critical Systems Engineer stained HEPA filters in the Line 11 clean room.

24. Immediately after seeing the stained HEPA filters in the Line 11 clean room, the Maintenance Critical Systems Engineer went to talk to the Director of Facilities and the Superintendent of Utilities, who were nearby just outside of Line 11. The Maintenance Critical Systems Engineer told the Director of Facilities and the Superintendent of Utilities about the HEPA filters that the Reporting Employee had just showed him. The Superintendent of Utilities then walked away to place a call. The Director of Facilities told the Maintenance Critical Systems Engineer to tell the Reporting Employee and HVAC Technician #1 to "wipe it off." The Maintenance Critical Systems Engineer understood this to mean to wipe off the grid or grates because it was impossible to wipe off the HEPA filters without damaging them. Neither the Director of Facilities nor the Superintendent of Utilities went into the Line 11 clean room to look at the HEPA filters.

25. The Maintenance Critical Systems Engineer immediately returned to the Reporting Employee and HVAC Technician #1 and told them to "wipe it off." It was impossible to wipe stains or mold off of HEPA filters, so the Reporting Employee and HVAC Technician #1 did not try to do so.

26. The HVAC Supervisor told the Reporting Employee that as long as a HEPA filter

did not have a hole in it or leak air, he should not replace it simply because it was stained or discolored. After receiving these instructions, the Reporting Employee and HVAC Technician #1 left moldy HEPA filters in the ceiling of the Line 11 clean room.

27. During this shutdown, the Reporting Employee took photos of the moldy HEPA filters in the Line 11 clean room. These pictures were saved on the computer system at North Cove, but the Reporting Employee never showed the pictures to the Director of Facilities, the Superintendent of Utilities, the HVAC Supervisor, the Maintenance Critical Systems Engineer, the Human Resources Director, the Quality Systems Engineer, the Laboratory Services Quality Manager, or any other employee in Plant Management.

Line 11 HEPA Filter Maintenance Records for the July 2012 Shutdown

28. The Reporting Employee wrote "what appears to be mold on numerous filters" twice on the maintenance records for the HEPA filters in the Line 11 clean room. The HVAC Supervisor saw these statements on the maintenance records and signed his name next to them to indicate his review of the statements. The Maintenance Critical Systems Engineer saw these statements and discussed them with the Quality Critical Systems Engineer. The Maintenance Critical Systems Engineer asked the Reporting Employee how many of the filters still in the Line 11 clean room appeared to be moldy. The Reporting Employee told the Maintenance Critical Systems Engineer that there were 29 HEPA filters in the Line 11 clean room that appeared to be moldy. The Maintenance Critical Systems Engineer then passed this information on to the Director of Facilities.

29. The Quality Critical Systems Engineer showed the Reporting Employee's "mold" comments to the Laboratory Services Quality Manager, who was his immediate supervisor in

North Cove's Quality Department. The Laboratory Services Quality Manager showed the comments to the Director of Quality, the highest person in the North Cove Quality Department. The Director of Quality told the Laboratory Services Quality Manager to have an inspection of the filters done – to take down the ceiling grates to see if the filters were moldy, and if so, replace them. The Laboratory Services Quality Manager told the Quality Critical Systems Engineer that the Director of Quality wanted an inspection of the filters done – take down the ceiling grates to see if the filters were moldy, and if so, replace them. The Quality Critical Systems Engineer contacted the HVAC Supervisor and/or the Superintendent of Utilities and told them that the Laboratory Services Quality Manager and the Director of Quality had instructed them to inspect the filters and replace them as necessary. All of these conversations were short and undocumented.

Human Resources Investigation of Complaint of Moldy HEPA Filters in July 2012

30. In July 2012, the Human Resources Director learned that the Reporting Employee was again complaining that there were moldy HEPA filters above the ceiling grates over Belts A-D in the Line 11 clean room. The Human Resources Director started another investigation into these complaints by discussing the complaints with the Director of Facilities and collecting written statements from the Maintenance Critical Systems Engineer, the HVAC Supervisor, the Reporting Employee and HVAC Technician #1.

The Inspection of the Line 11 HEPA Filters in Late July 2012

31. In late July 2012, the Superintendent of Utilities directed the HVAC Supervisor to carry out the inspection (as directed by the Quality Department) of filters above the ceiling grates over Belts A-D in the Line 11 clean room using a map identifying the filters to be inspected. The

Superintendent of Utilities states he obtained the map from the Quality Critical Systems Engineer, and that the Quality Critical Systems Engineer created the map. The Quality Critical Systems Engineer denies creating such a map. The map was based on a blank maintenance record (the same type used during the shutdowns) showing the layout of the approximately 120 HEPA filters on Line 11. However, the filters identified on the map were not in the area where the Reporting Employee and HVAC Technician #1 had found mold, and no one consulted with them regarding the correct location of the moldy filters.

32. HVAC Technician #1 and another employee state that they told the HVAC Supervisor around the time of the re-inspection that the filters identified on the map were not where the Reporting Employee and HVAC Technician #1 had seen mold. The HVAC Supervisor inspected the identified filters with two HVAC technicians other than the Reporting Employee and HVAC Technician #1 and reported that they did not find any "discoloration" during their inspection. The HVAC Supervisor then made and signed the following statement on the same pages of the maintenance record where the Reporting Employee had made his mold comments: "On 07-29-12, a follow-up inspection was performed on HEPA filters on Filling Line 11. No discoloration was found on the HEPA filters. No HEPA filters were in need of replacement." The filter map used during this inspection was not kept in Baxter's records.

33. The Quality Critical Systems Engineer told the Laboratory Services Quality Manager that an inspection of the HEPA filters in the Line 11 clean room had been done and no mold was found. The Laboratory Services Quality Manager told the Director of Quality that an inspection was done and the HEPA filters were OK. These conversations were short and undocumented. Neither the Director of Quality, nor the Laboratory Services Quality Manager

asked how the inspection of the filters was done. No one from the Quality department ever looked at the HEPA filters above the ceiling grates over Belts A-D in the Line 11 clean room.

34. The HVAC Supervisor told the Human Resources Director that he had inspected the HEPA filters in the Line 11 clean room and showed the Human Resources Director his report of the results of his inspection written on the Line 11 HEPA filter maintenance record for the July 2012 Shutdown. The Human Resources Director relied on the HVAC Supervisor's written report of his inspection to conclude that the Reporting Employee's July 2012 complaints of moldy filters in the Line 11 clean room were resolved.

35. Despite the Reporting Employee's renewed complaints of moldy HEPA filters in the Line 11 clean room, neither the Human Resources Director, the Director of Facilities, nor the Superintendent of Utilities ever looked at the HEPA filters in the Line 11 clean room. The filters the Reporting Employee identified as moldy remained.

November 2012 FDA Inspection

36. From November 7 to 16, 2012, the FDA conducted an unannounced inspection of North Cove and found numerous moldy HEPA filters above the ceiling grates over Belts A-D in the Line 11 clean room. Subsequent testing revealed several mold species and other particulate matter on the filters.

No Evidence of Product Impact

37. Per the Environmental Monitoring Plans on file with the FDA and incorporated into the FDA-approved new drug applications for the products manufactured at North Cove, there are established limits for how much mold can be present in the air and on surfaces in the fill rooms. During the relevant time frame, Baxter's testing showed no "out of limits" results.

38. There are also established limits for how much mold can be in the solution before it is sterilized, as the purpose of North Cove's terminal sterilization process is to kill contaminates like mold prior to product release. There were no "out of limits" test results.

39. Mold is destroyed at temperatures below 194°F, whereas North Cove sterilizes all product at 250°F prior to release. Mold cannot survive at that temperature. North Cove conducts post-terminal sterilization endotoxin testing, which was at all relevant times within limits.

40. There was no evidence of impact on the IV solutions manufactured at North Cove from the mold found on the HEPA filters above the Line 11 clean room.

ATTACHMENT B

ENHANCED COMPLIANCE MEASURES & CERTIFICATIONS

Baxter Healthcare Corporation ("Baxter") agrees to the provisions set forth in this Attachment, which is incorporated by reference as part of the Deferred Prosecution Agreement (the "Agreement") between the Office of the United States Attorney for the Western District of North Carolina and the United States Department of Justice, Consumer Protection Branch (collectively, "the Government") and Baxter.

Quality Compliance Program

1. Baxter has in place and will maintain a Quality Compliance Program that governs Baxter's North Cove plant. The purpose of the Quality Compliance Program is to (a) prevent, detect, and correct potential violations of the Federal Food, Drug, and Cosmetic Act ("FDCA") and violations of Baxter's quality policies and procedures; (b) assure the establishment of quality compliance-related policies and procedures for business and quality operations; (c) assure development of training and other programs designed to educate employees regarding applicable policies, procedures, and standards; (d) implement a mechanism for deterring and detecting non-compliance issues; and (e) assure appropriate corrective action is taken to prevent recurrence of quality compliance issues.

2. Baxter will maintain, or as necessary, establish, policies and procedures designed to ensure compliance with current Good Manufacturing Practices ("cGMP") at North Cove in the areas of sterility and environmental controls, including, but not limited to:

a. Remediating conditions that may contribute to the development of mold in clean rooms used to manufacture drug products;

b. Performing appropriate environmental monitoring of clean rooms used to manufacture drug products;

c. Inspecting high-efficiency particulate absorption ("HEPA") filters on at least a quarterly basis and replacing any filters with evidence of contamination including mold or other discoloration or characteristics suggestive of mold, and reporting any such findings to quality personnel for appropriate investigation and remediation;

d. Maintaining a log of sterility test results and providing them within twenty-four hours upon request of the Government or the Food and Drug Administration ("FDA");

e. Maintaining a log of monthly environmental monitoring results and providing them within twenty-four hours upon request of the Government or the FDA; and

f. Submitting Field Alert Reports ("FARs") to FDA for every complaint received related to North Cove products and potential particulate matter in solution or mold until FDA deems them no longer necessary and subject to any guidance FDA may issue regarding FARs.

3. Baxter will maintain, or as necessary, establish, policies and procedures designed to ensure effective investigation of quality-related complaints through an enhanced corrective and preventative action ("CAPA") system, including, but not limited to:

a. Training all North Cove personnel that they must report all information that may reflect or impact the quality of North Cove's drug products to quality personnel, who in turn will review and determine whether corrective actions are required;

b. Tracking and trending quality-related complaints related to North Cove to identify issues that may require corrective actions;

c. Training relevant personnel on the CAPA process;

d. Installing a CAPA subject matter expert at North Cove to serve as the single point of accountability for the quality and timeliness of all CAPAs at North Cove;

e. Having a qualification process to ensure North Cove CAPA approvers and investigators are appropriately trained and qualified; and

f. Holding CAPA Review Board meetings at North Cove at regular intervals (at minimum, monthly).

4. Baxter will maintain, or as necessary, establish, policies and procedures designed to ensure appropriate handling of employee concerns at North Cove, including, but not limited to:

a. Publicizing a helpline number at North Cove, including with prominent posters on bulletin boards near employee entrances and exits of the plant;

b. Holding plant-wide, annual town hall meetings at North Cove emphasizing its compliance program and non-retaliation policy;

c. Training North Cove management and supervisors annually on the importance of compliance; and

d. Training North Cove human resources personnel annually on how to conduct effective investigations, including when to refer complaints to quality and/or elevate complaints within the organization.

5. Within 90 days of the Effective Date of the Agreement, Baxter will submit to the Government an implementation report summarizing the status of the implementation of its commitments under the Quality Compliance Program.

Certification and Board Resolution

6. Baxter will provide the following Certification and Board resolution to the Government on an annual basis for the Term of the Agreement. Each one-year period, beginning with the one-year period following the Effective Date of the Agreement, will be referred to as a "Review Period." Baxter will provide the Certifications and Board resolution to the Government within ninety (90) calendar days following the end of each Review Period.

7. On an annual basis, the President of Baxter's Hospital Products business (the "President") will conduct a review of the effectiveness of Baxter's Quality Compliance Program as described in paragraphs 1–4 above during the preceding Review Period. Based on his or her review, the President will submit to the Government a signed certification stating that, to the best of his or her knowledge, during the period [insert time period]: (1) the Quality Compliance Program continued to include the policies and procedures set forth in paragraphs 1–4; and (2) at the time of his or her certification, the President is unaware of any facts demonstrating that the aforementioned measures were ineffective in preventing material violations of cGMP related to North Cove's drug products. The certification by the President will summarize the review described above that he or she conducted to provide the required certification. If the President is unable to provide any part of this certification, he or she will provide a detailed explanation for why he or she is unable to provide such certification. The certification and detailed explanation will be sworn to under the pains and penalties of perjury and will set forth that its representations

may be provided to, relied upon, and material to the government of the United States, and that a knowing false statement could result in criminal or civil liability for the signatory.

8. On an annual basis, the Board of Directors, or a designated Committee thereof (the "Board"), will conduct a review of the effectiveness of Baxter's Quality Compliance Program as described in paragraphs 1–4 above during the preceding Review Period. This review will include, but not be limited to, updates and reports by North Cove's Plant Manager and Director of Quality about the adoption and implementation of policies, procedures, and practices designed to satisfy the compliance measures set forth in paragraphs 1–4 above. The Board review will not require the retention of third-party experts. Based on its review, the Board will submit to the Government a resolution that summarizes its review and oversight as set forth above and, at a minimum, includes the following language:

> The Board of Directors of Baxter Healthcare Corporation has made a reasonable inquiry as described in Paragraph 8 of Attachment B to the Deferred Prosecution Agreement with Baxter into the operations of the Quality Compliance Program for the applicable time period [insert time period], including the performance of North Cove's Plant Manager, Director of Quality Assurance, and other personnel employed by Baxter. The Board has concluded that, to the best of its knowledge, Baxter has implemented and maintained the Quality Compliance Program as set forth in Attachment B to the Deferred Prosecution Agreement, and that, to the best of its knowledge, it is unaware of any facts demonstrating that these measures were ineffective in preventing material violations of cGMP related to North Cove's drug products.

If the Board is unable to provide any part of this statement, it will include a thorough explanation of the reasons why it is unable to provide such a statement.

ATTACHMENT C

CERTIFICATE OF CORPORATE RESOLUTIONS

WHEREAS, Baxter Healthcare Corporation ("Baxter") has been engaged in discussions with the Office of the United States Attorney for the Western District of North Carolina and the United States Department of Justice, Consumer Protection Branch (collectively, "the Government") regarding issues arising in relation to the introduction into interstate commerce of adulterated drug products due to violations of current Good Manufacturing Practices; and

WHEREAS, in order to resolve such discussions, it is proposed that Baxter enter into a certain agreement with the Government; and

WHEREAS, Baxter's Corporate Vice President, General Counsel, David P. Scharf, together with outside counsel for Baxter, have advised the Board of Directors of Baxter of its rights, possible defenses, the Sentencing Guidelines' provisions, and the consequences of entering into such agreement with the Government;

Therefore, the Board of Directors has RESOLVED that:

1. Baxter (a) acknowledges the filing of the one-count Information charging Baxter with Title 21, United States Code, Sections 331(a), 333(a)(1), and 351(a)(2)(B); (b) waives indictment on such charges and enters into a deferred prosecution agreement with the Government; (c) agrees to accept a monetary penalty against Baxter totaling $8,000,000, and to pay such penalty to the United States Treasury with respect to the conduct described in the Information; and (d) agrees to forfeit $8,000,000 to the United States with respect to the conduct described in the Information.

2. Baxter accepts the terms and conditions of this Agreement, including, but not

limited to, (a) a knowing waiver of its rights to a speedy trial pursuant to the Sixth Amendment to the United States Constitution, Title 18, United States Code, Section 3161, and Federal Rule of Criminal Procedure 48(b); (b) a knowing waiver for purposes of this Agreement and any charges by the United States arising out of the conduct described in the attached Statement of Facts of 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 Western District of North Carolina; and (c) a knowing waiver of any defenses based on the statute of limitations for any prosecution relating to the conduct described in the attached Statement of Facts or relating to conduct known to the Government prior to the date on which this Agreement was signed that is not time-barred by the applicable statute of limitations on the date of the signing of this Agreement;

3. The Corporate Vice President, General Counsel of Baxter, David P. Scharf, is hereby authorized, empowered and directed, on behalf of Baxter, to execute the Deferred Prosecution Agreement substantially in such form as reviewed by this Board of Directors in connection with the execution of the resolutions with such changes as the Corporate Vice President, General Counsel of Baxter, David P. Scharf, may approve in his sole discretion;

4. The Corporate Vice President, General Counsel of Baxter, David P. Scharf, is hereby authorized, empowered and directed to take any and all actions as may be necessary or appropriate and to approve the forms, terms or provisions of any agreement or other documents as may be necessary or appropriate, to carry out and effectuate the purpose and intent of the foregoing resolutions; and

5. All of the actions of the Corporate Vice President, General Counsel of Baxter, David P. Scharf, which actions would have been authorized by the foregoing resolutions except

that such actions were taken prior to the adoption of such resolutions, are hereby severally ratified, confirmed, approved, and adopted as actions on behalf of Baxter.

Date: JAN 03 2017

By: Ellen K. McIntosh

Ellen K. McIntosh
Corporate Vice President, Corporate Secretary
Baxter Healthcare Corporation