

FILED
CHARLOTTE, NC

JAN 12 2017

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA

US District Court
Western District of NC

CASE NO. 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.

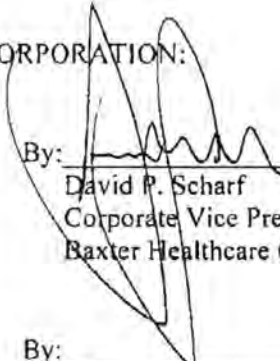
Complete Agreement

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: IAN 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

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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

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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 A. Perry
Kelli Perry
Assistant U.S. Attorney

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

Date: 1/11/2017

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