

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA)	Criminal No.
)	
)	Violation: 15 U.S.C. § 1
v.)	
)	Filed:
HERITAGE PHARMACEUTICALS INC.,)	
)	
Defendant.)	
_____)	

DEFERRED PROSECUTION AGREEMENT

The United States Department of Justice, Antitrust Division (“United States”) and HERITAGE PHARMACEUTICALS INC. (“Heritage”), a corporation organized and existing under the laws of Delaware, by and through its undersigned representative, pursuant to authority granted by its board of directors, enter into this Deferred Prosecution Agreement, the terms and conditions of which are as follows:

Criminal Information and Acceptance of Responsibility

1. Heritage acknowledges and agrees that the United States will file a one-count criminal Information in the United States District Court for the Eastern District of Pennsylvania. The Information will charge Heritage with conspiring to suppress and eliminate competition by allocating customers, rigging bids, and fixing and maintaining prices for glyburide sold in the United States, from in or about April 2014 and continuing until at least December 2015, in violation of the Sherman Antitrust Act, 15 U.S.C. § 1. In so doing, Heritage:

(a) knowingly waives its right to indictment on these charges, 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 the purposes of this Agreement and for the purposes of any charges by the United States arising out of the conduct described in the Statement of Facts (attached hereto as Attachment A and incorporated by reference into this Agreement) 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 Eastern District of Pennsylvania.

The United States agrees to defer prosecution of Heritage pursuant to the terms and conditions described below.

2. Heritage admits, accepts, and acknowledges that it is responsible under United States law for the acts of its officers, directors, employees, and agents as charged in the Information and as set forth in the Statement of Facts and that the allegations in the Information and the facts set forth in the Statement of Facts are true and accurate. Should the United States pursue the prosecution that is deferred by this Agreement, Heritage agrees that it will neither contest the admissibility of, nor contradict, any of the facts set forth in the Statement of Facts in any such proceeding, including any guilty plea or sentencing proceeding. Neither this Agreement nor the criminal Information is a final adjudication of the matters addressed in such documents.

Parties to and Scope of the Agreement

3. Heritage is organized under the laws of Delaware and headquartered in New Jersey. This Agreement binds Heritage and the United States Department of Justice Antitrust Division. It 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. This Agreement also creates contingent rights and obligations for Heritage's officers, directors, and employees as of the date of the signature of this Agreement and the

former officers, directors, and employees listed in Attachment C (filed under seal), who will be collectively referred to as “Covered Individuals.”

Length of the Agreement

4. This Agreement is effective for a period beginning on the date on which the Information is filed and ending three (3) years from that date (the “Term”), except for the obligations set forth in Paragraphs 6–8 below. Heritage agrees that in the event that the United States determines, in its sole discretion, that Heritage or any of its subsidiaries has knowingly violated any provision of this Agreement, an extension or extensions of the term of the Agreement may be imposed by the United States, in its sole discretion, for up to a total additional time period of one year, without prejudice to the United States’ right to proceed as provided in Paragraphs 17–21 below. Any extension of the Agreement extends all terms of this Agreement for an equivalent period.

Relevant Considerations

5. The United States enters into this Agreement based on the individual facts and circumstances of this case. Among the facts considered were the following: (a) Beginning in July 2016, Heritage provided substantial cooperation with the United States’ investigation into price-fixing, bid-rigging, and market-allocation conspiracies among generic drug manufacturers, including disclosing to the United States information regarding criminal antitrust violations involving drugs other than what is described in the Information and the Statement of Facts; (b) Heritage’s cooperation has included facilitating the interviews of current and former employees; (c) Heritage agreed to cooperate in the United States’ ongoing investigation into criminal antitrust violations among generic drug manufacturers; (d) Heritage’s cooperation has allowed the United States to advance its investigation into criminal antitrust conspiracies among other

manufacturers of generic pharmaceuticals; (e) Heritage's cooperation remains ongoing; (f) Heritage has agreed to resolve all civil claims relating to federal health care programs arising from its conduct; (g) a conviction (including a guilty plea) would likely result in Heritage's mandatory exclusion from all federal health care programs under 42 U.S.C. § 1320a-7 for a period of at least five years, which would result in substantial consequences to the corporation's employees and customers outside the federal health care programs; and (h) this Agreement can ensure that integrity has been restored to Heritage's operations and preserve its financial viability while preserving the United States' ability to prosecute it should material breaches occur.

Cooperation Obligations

6. Until the date upon which all investigations and prosecutions, whether of former employees of the Company or other individuals or entities, arising out of the conduct described in this Agreement are concluded, whether or not they are concluded within the three-year period specified in paragraph 4, Heritage shall cooperate fully and truthfully with the United States in the current federal investigation of violations of federal antitrust and related criminal laws involving the production and sale in the United States of glyburide and those generic pharmaceutical products enumerated in Attachment B (filed under seal), and any litigation or other proceedings arising or resulting from such investigation to which the United States is a party (collectively "Federal Proceeding"). Federal Proceeding includes, but is not limited to, an investigation, prosecution, litigation, or other proceeding regarding obstruction of, the making of a false statement or declaration in, the commission of perjury or subornation of perjury in, the commission of contempt in, or conspiracy to commit such offenses in the current federal investigation of violations of federal antitrust and related criminal laws involving the production and sale in the United States of glyburide and those generic pharmaceutical products enumerated

in Attachment B (filed under seal). The full, truthful, and continuing cooperation of Heritage will include but not be limited to:

(a) producing to the United States all documents, information, and other materials, wherever located, not protected under the attorney-client privilege or the work-product doctrine, and with translations into English, in the possession, custody, or control of Heritage, that are requested by the United States in connection with any Federal Proceeding; and

(b) using its best efforts to secure the full, truthful, and continuing cooperation of the Covered Individuals as may be requested by the United States. Such efforts will include, but not be limited to, making these persons available in the United States and at other mutually agreed-upon locations at Heritage's expense for interviews and the provision of testimony in grand jury, trial, and other judicial proceedings in connection with any Federal Proceeding.

7. The full, truthful, and continuing cooperation of Covered Individuals will be subject to the procedures and protections of this paragraph, and will include, but not be limited to:

(a) producing in the United States and at other mutually agreed-upon locations, not at the expense of the United States, all documents, including claimed personal documents, and other materials, wherever located, not protected under the attorney-client privilege or the work-product doctrine, and with translations into English, that are requested by attorneys and agents of the United States in connection with any Federal Proceeding;

(b) being available for interviews in the United States and at other mutually agreed-upon locations, not at the expense of the United States, upon the request of attorneys and agents of the United States in connection with any Federal Proceeding;

(c) responding fully and truthfully to all inquiries of the United States in connection with any Federal Proceeding, without falsely implicating any person or intentionally withholding any

information, subject to the penalties of making a false statement or declaration (18 U.S.C. §§ 1001, 1623), obstruction of justice (18 U.S.C. § 1503 *et seq.*), or conspiracy to commit such offenses;

(d) otherwise voluntarily providing to the United States any material or information not requested in (a)–(c) of this paragraph and not protected under the attorney-client privilege or work-product doctrine that he or she may have that is related to any Federal Proceeding;

(e) when called upon to do so by the United States in connection with any Federal Proceeding, participating in affirmative investigative techniques, including but not limited to making telephone calls, recording conversations, and introducing law enforcement officials to other individuals, with all such activity being conducted only at the express direction and under the supervision of attorneys and agents of the United States;

(f) when called upon to do so by the United States in connection with any Federal Proceeding, testifying in grand jury, trial, and other judicial proceedings in the United States fully, truthfully, and under oath, subject to the penalties of perjury (18 U.S.C. § 1621), making a false statement or declaration in grand jury or court proceedings (18 U.S.C. § 1623), contempt (18 U.S.C. §§ 401–402), and obstruction of justice (18 U.S.C. § 1503 *et seq.*); and

(g) agreeing that, if the agreement not to prosecute him or her pursuant to this Agreement is void, the statute of limitations period for any offense will be tolled for the period between the date of signature of this Agreement and six months after the date that the United States gave notice of its intent to void its obligations to that person under this Agreement. (Nothing in Paragraph 7 creates any obligations by or for any person who is not a Covered Individual.)

8. In addition to the obligations described above, during the Term of the Agreement, should Heritage learn of credible evidence or allegations of criminal violations of United States

law affecting the competitive process by Heritage or its subsidiaries, or by any present or former officers, directors, employees, or agents, Heritage shall promptly report such evidence or allegations to the United States. Any information that Heritage thus discloses to the United States will likely include proprietary, financial, confidential, and competitive business information. Public disclosure of the information and reports could discourage cooperation, impede pending or potential government investigations, and thus undermine the United States' objectives in obtaining such reports. For these reasons, among others, the information and reports and the contents thereof are intended to remain and shall remain nonpublic, except as otherwise agreed to by the parties in writing, or except to the extent that the United States determines in its sole discretion that disclosure would be in furtherance of its discharge of its duties and responsibilities or is otherwise required by law.

Penalty and Restitution

9. The United States and Heritage agree that Heritage will pay a monetary penalty in the amount of \$225,000 to the United States Treasury. Heritage must pay this sum within ten (10) days of acceptance of this Agreement to the United States District Court for the Eastern District of Pennsylvania. Heritage and the United States agree that this penalty is appropriate given the facts and circumstances of this case, including Heritage's cooperation, internal investigation, and remediation in this matter.

10. The penalty set forth in Paragraph 9 is final and shall not be refunded. Furthermore, nothing in this Agreement shall be deemed an agreement by the United States that \$225,000 is the maximum penalty that may be imposed in any future prosecution in the event of a breach of this Agreement, and the United States is not precluded from arguing in any future prosecution that the Court should impose a higher fine, although the United States 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. Heritage acknowledges that no tax deduction may be sought, and agrees that no tax deduction will be sought, in the United States, Republic of India, or elsewhere in connection with the payment of any part of this penalty.

11. In light of the availability of civil causes of action, and civil cases already filed against Heritage, including the multidistrict litigation *In Re: Generic Pharmaceuticals Pricing Antitrust Litigation*, Case No. 2:16-md-2724, consolidated in the United States District Court for the Eastern District of Pennsylvania, this Agreement does not include any provision for restitution.

Conditional Release from Liability

12. In return for the full and truthful cooperation of Heritage, and compliance with the other terms and conditions of this Agreement:

(a) The United States agrees that, except as provided by this Agreement, it will not bring criminal charges against:

- (i) Heritage, or
- (ii) any Covered Individual.

for any act or offense committed before the date of signature of this Agreement, in furtherance of an antitrust conspiracy involving the production or sale in the United States of glyburide or related to antitrust conspiracies involving the production or sale in the United States of those generic pharmaceutical products enumerated in Attachment B (filed under seal).

(b) Failure by any company or person to comply fully with his or her cooperation obligations under Paragraphs 6–8 will void the United States' agreement in Paragraph 12(a), and

any such company or person may be prosecuted criminally for any federal crime of which the United States has knowledge.

(c) The United States' agreement in Paragraph 12(a) does not apply to subornation of perjury (18 U.S.C. § 1622), false statements (18 U.S.C. § 1001), obstruction of justice (18 U.S.C. § 1503 *et seq.*), contempt (18 U.S.C. §§ 401–402), or conspiracy to commit such offenses. Its agreement in Paragraph 12(a) also does not apply to civil matters of any kind, any civil or criminal violation of the federal tax or securities laws or conspiracy to commit such offenses, or any crimes of violence.

(d) The United States' agreement in Paragraph 12(a) does not extend to Jeffrey A. Glazer or Jason T. Malek.

Related Administrative Proceedings

13. Heritage understands that it may be subject to suspension or debarment action by state or federal agencies other than the United States Department of Justice, Antitrust Division based upon this Agreement, and that this Agreement in no way controls what action, if any, other agencies may take. However, the United States agrees that, if requested, it will advise the appropriate officials of any governmental agency considering such action of the fact, manner, and extent of the cooperation of Heritage as a matter for that agency to consider before determining what action, if any, to take.

Corporate Compliance Program

14. Heritage represents that it has implemented and will continue to implement a compliance program designed to prevent and detect criminal antitrust violations throughout its operations, including those of its subsidiaries. Implementation of these policies and procedures shall not be construed in any future enforcement proceeding as providing immunity or amnesty for any crimes not disclosed to the Antitrust Division as of the date of this Agreement for which Heritage would otherwise be responsible.

Deferred Prosecution

15. In consideration of: (a) the past and future cooperation of Heritage described in Paragraphs 6–8; (b) Heritage’s payment of a criminal penalty; and (c) Heritage’s implementation and maintenance of remedial measures described above, the United States agrees that any prosecution of Heritage for the conduct set forth in the attached Statement of Facts be and hereby is deferred for the Term of this Agreement.

16. The United States further agrees that if Heritage fully complies with all obligations under this Agreement, the United States will not continue the criminal prosecution of Heritage described in Paragraph 1 and, at the conclusion of the Term, this Agreement shall expire, except for the Cooperation Obligations provided in Paragraphs 6–8. Within thirty (30) days of the Agreement’s expiration, the United States shall seek dismissal with prejudice of the criminal Information described in Paragraph 1.

Breach

17. If, during the Term of this Agreement, the United States determines, in its sole discretion, that Heritage (a) committed any felony under United States federal law subsequent to the signing of this Agreement, (b) at any time provided to the United States in connection with this Agreement deliberately false, incomplete, or misleading information, (c) fails to cooperate as set forth in Paragraphs 6-8 of this Agreement, or (d) otherwise breached the Agreement, Heritage

shall thereafter be subject to prosecution for any federal criminal violation related to the production and sale in the United States of glyburide and those generic pharmaceutical products enumerated in Attachment B (filed under seal) of which the United States has knowledge, including the charges in the Information described in Paragraph 1, which may be pursued by the United States in the United States District Court for the Eastern District of Pennsylvania or any other appropriate venue. Any such prosecution may be premised on information provided by Heritage, or their current or former officers, directors, employees, or agents. Any such prosecution that is not time barred by the applicable statute of limitations on the date of the signing of this Agreement may be commenced against Heritage 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, Heritage 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.

18. In the event that the United States determines that Heritage has breached this Agreement, the United States agrees to provide Heritage with written notice of such breach prior to instituting any prosecution resulting from such breach. Heritage shall, within thirty (30) days of receipt of such notice, have the opportunity to respond to the United States in writing to explain the nature and circumstances of such breach, as well as the actions Heritage has taken to address and remediate the situation, which explanation the United States shall consider in determining whether to institute a prosecution.

19. In the event that the United States determines that Heritage has breached this Agreement: (a) all statements made by or on behalf of Heritage to the United States or to the Court, including the attached Statement of Facts, and any testimony given by Heritage before a

grand jury, a court, or any tribunal, or at any legislative hearings, whether prior or subsequent to this Agreement, and any leads derived from such statements or testimony, shall be admissible in evidence in any and all criminal proceedings brought by the United States against Heritage; and (b) Heritage 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 law or rule that statements made by or on behalf of Heritage prior or subsequent to this Agreement, or any leads derived therefrom, should be suppressed. The decision whether the conduct or statements of any current director or employee, or any person acting on behalf of, or at the direction of, Heritage will be imputed to Heritage for the purpose of determining whether Heritage has breached any provision of this Agreement shall be in the sole discretion of the United States.

20. Heritage acknowledges that the United States has made no representations, assurances, or promises concerning what sentence may be imposed by the Court if Heritage breaches this Agreement and this matter proceeds to judgment. Heritage 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.

21. On the date that the period of deferred prosecution specified in this Agreement expires or on the first business day thereafter Heritage, by the Chief Executive Officer of the Company and the Chief Financial Officer of the Company, will certify to the United States that Heritage has met its disclosure obligations pursuant to Paragraph 8 of this Agreement. Each certification will be deemed a material statement and representation by Heritage to the executive branch of the United States for purposes of 18 U.S.C. §§ 1001 and 1519, and it will be deemed to have been made in the judicial district in which this Agreement is filed.

Sale or Merger of Heritage

22. Except as may otherwise be agreed by the parties in connection with a particular transaction, Heritage agrees that in the event that, during the Term, it undertakes any change in corporate form, including if it sells, merges, or transfers business operations that are material to its consolidated operations, or to the operations of any subsidiaries or affiliates involved in the conduct described in the attached Statement of Facts, as they exist as of the date of this Agreement, whether such sale is structured as a sale, asset sale, merger, transfer, or other change in corporate form, it shall include in any contract for sale, merger, transfer, or other change in corporate form a provision binding the purchaser, or any successor in interest thereto, to the obligations described in this Agreement. The purchaser or successor in interest must also agree in writing that the United States' ability to enforce all provisions of this Agreement, including to determine that it has been breached, is applicable in full force to that entity. Heritage agrees that the failure to include these provisions in the transaction will make any such transaction null and void. Heritage shall provide notice to the United States at least thirty (30) days prior to undertaking any such sale, merger, transfer, or other change in corporate form. The United States shall notify Heritage prior to such transaction (or series of transactions) if it determines that the transaction(s) will have the effect of circumventing or frustrating the enforcement purposes of this Agreement. If at any time during the Term Heritage engages in a transaction(s) that has the effect of circumventing or frustrating the purposes of this Agreement, the United States may deem it a breach of this Agreement pursuant to Paragraphs 17–21 of this Agreement. Nothing herein shall restrict Heritage from indemnifying (or otherwise holding harmless) the purchaser or successor in interest for penalties or other costs arising from any conduct that may have occurred prior to the date of the transaction, so long as such indemnification does not have

the effect of circumventing or frustrating the purposes of this Agreement, as determined by the United States.

Public Statements by Heritage

23. Heritage expressly agrees that it shall not, through present or future attorneys, officers, directors, employees, agents or any other person authorized to speak for Heritage or its subsidiaries, make any public statement, in litigation or otherwise, contradicting the acceptance of responsibility by Heritage set forth above or any of the facts set forth in the Statement of Facts. Any such contradictory statement shall, subject to cure rights of Heritage described below, constitute a breach of this Agreement and Heritage thereafter shall be subject to prosecution as set forth in 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 Heritage for the purpose of determining whether it has breached this Agreement shall be at the sole discretion of the United States. If the United States determines that a public statement by any such person contradicts in whole or in part any fact(s) set forth in the Statement of Facts, the United States shall so notify Heritage, and Heritage may avoid a breach of this Agreement by publicly repudiating such statement(s) within five (5) business days after notification. Heritage 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, any fact(s) set forth in the Statement of Facts. This Paragraph does not apply to any statement made by any present or former officer, director, employee, or agent of Heritage in the course of any criminal, regulatory, or civil case initiated against such individual, unless such individual is speaking on behalf of Heritage.

24. Heritage agrees that if it or any of its direct or indirect subsidiaries issues a press release or holds any press conference in connection with this Agreement, Heritage shall first consult the United States to determine (a) whether the text of the release or proposed statements at the press conference are true and accurate with respect to matters between the United States and Heritage; and (b) whether the United States has no objection to the release. Statements at any press conference concerning this matter shall be consistent with such a press release.

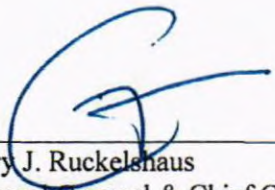
Notice

25. Any notice to the United States under this Agreement shall be given by personal delivery, overnight delivery by a recognized delivery service, or registered or certified mail, addressed to Kalina M. Tulley, 209 S. LaSalle Street, Suite 600, Chicago, IL 60302. Any notice to Heritage under this Agreement shall be given by personal delivery, overnight delivery by a recognized delivery service, or registered or certified mail, addressed to the General Counsel of Heritage Pharmaceuticals Inc. Notice shall be effective upon actual receipt by the United States or Heritage.

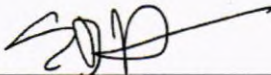
Complete Agreement

26. This Agreement and its attachments set forth all the terms of this Deferred Prosecution Agreement between Heritage and the United States. No amendments, modifications or additions to this Agreement shall be valid unless they are in writing and signed by the United States, the attorneys for Heritage, and a duly authorized representative of Heritage.

DATED: May 30, 2019

BY: 

Gary J. Ruckelshaus
General Counsel & Chief Compliance Officer
Heritage Pharmaceuticals Inc.

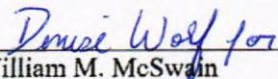
BY: 

Scott D. Hammond
Counsel for Heritage Pharmaceuticals Inc.

Respectfully submitted,

BY: 

Kalina M. Tulley
Acting Chief, Chicago Office
U.S. Department of Justice
Antitrust Division
209 S. LaSalle Street, Suite 600
Chicago, IL 60302
(312) 984-7200

BY: 

William M. McSwain
United States Attorney
Eastern District of Pennsylvania

Attachment A: Statement of Facts

From in or about April 2014 and continuing until at least December 2015 (the “Relevant Period”), Heritage was a corporation organized and existing under the laws of Delaware and had its principal place of business in Eatontown, New Jersey. During the Relevant Period, Heritage was a generic pharmaceutical company engaged in the acquisition, licensing, production, marketing, sale, and distribution of generic pharmaceutical products, including glyburide, was engaged in the sale of that drug in the United States.

Glyburide is a generic drug used in the treatment of diabetes. During the Relevant Period, Heritage produced and distributed glyburide in tablet form in four dosage strengths and sold approximately \$1.6 million worth of glyburide in the United States.

During the Relevant Period, Heritage, through certain of its officers and employees, including certain of its high-level personnel, participated in a conspiracy with other persons and entities engaged in the production and sale of generic pharmaceutical products, including glyburide, a purpose of which was to suppress and eliminate competition by allocating customers and fixing and maintaining prices for glyburide sold in the United States. To further the conspiracy, Heritage, through certain of its officers and employees, including certain of its high-level personnel, engaged in discussions with co-conspirators involved in the production and sale of glyburide. During these discussions, agreements were reached to allocate customers, rig bids, and fix and maintain the prices of glyburide sold in the United States.

During the Relevant Period, glyburide sold by one or more of the conspirators, and equipment and supplies necessary to the production and distribution of glyburide, as well as payments for glyburide, traveled in interstate commerce. The business activities of Heritage and its co-conspirators in connection with the production and sale of glyburide affected by this

conspiracy were within the flow of, and substantially affected, interstate trade and commerce. Glyburide was sold by one or more of the conspirators to customers in this District and acts in furtherance of this conspiracy were carried out within the Eastern District of Pennsylvania.