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IN THE DISTRICT COURT OF SHAWNEE COUNTY, KANSAS
Division 12

FILED BY CLERK
DISTRICT COURT
THIRD JUDICIAL DIST.
TOPEKA, KS

2009 FEB 12 A 8:37

STATE OF KANSAS, ex rel.
Steve Six, Attorney General

Plaintiff,

-vs-

BAYER CORPORATION,

Defendant.

NO. 07 C 88

ORDER MODIFYING CONSENT DECREE

This cause coming before the Court on a Joint Motion to Modify the Consent Decree, due notice having been given, and the Court being fully advised in the premises,

IT IS HEREBY ORDERED:

1. The Joint Motion To Modify the Consent Decree is hereby granted;
2. The Consent Decree entered on January 23, 2007, remains in full force and effect.

In addition to the terms contained therein, the Consent Decree is modified to add the following terms as set forth below which shall be incorporated into the Consent Decree by this reference as though set forth fully therein:

- a. Section I. Definitions is modified to add Paragraphs X and Y as follows:
 - i. Paragraph X. "Modification Signatory Attorneys General" shall mean the Attorney General, or his or her designee, of each of the following states that have agreed to this modification of the Consent Decree: Arizona, Arkansas, California, Connecticut, Delaware, Florida, Idaho, Illinois, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Mississippi, Montana,

Nevada, North Carolina, Ohio, Oregon, Pennsylvania, South Dakota, Tennessee, Texas, Washington, and Wisconsin.

- ii. Paragraph Y. "YAZ®" shall mean the oral contraceptive product composed of a combination of drospirenone and ethinyl estradiol approved for marketing by FDA pursuant to NDAs 21-676, 21-873, and 22-045 under the brand name "YAZ®."
- b. Section II. Background is modified to add Paragraphs 6 and 7 as follows:
- i. Paragraph 6. Bayer enters into this Modification solely for the purpose of resolving the Modification Signatory Attorneys General's investigation under both the Consent Decree and their respective states consumer protection statutes into the issues identified in the Warning Letter issued by FDA's Division of Drug Marketing, Advertising, and Communications ("DDMAC") dated October 3, 2008 (attached as Exhibit 1 and hereafter referred to as "Warning Letter"), to avoid unnecessary expense, inconvenience, and uncertainty without admitting any violation of the Consent Decree or state consumer protection statutes and without admitting any wrongdoing and for settlement purposes only.
 - ii. Paragraph 7. This Modification is made without adjudication of any issue of fact or law or finding of wrongdoing or liability of any kind. It is the intent of both Bayer and the Modification Attorneys General that this Modification shall not be admissible in any other matter or proceeding, and shall not bind Bayer in any respect other

than in connection with the enforcement of this Modification.

Except in an action by the Modification Attorneys General to enforce this Modification, this Modification shall not be construed or used as a waiver or limitation of any defense otherwise available to Bayer or of Bayer's right to defend itself, or make arguments, in any other matter related to the issues identified in the Warning Letter.

- c. In addition to the terms contained in the Consent Decree, "Section XIII. YAZ® Advertising" is added with the following Paragraphs:
 - i. Bayer shall disseminate corrective advertising that addresses the issues identified in the Warning Letter. The corrective advertising campaign shall consist of a television advertisement and a print advertisement that have been approved by DDMAC and reviewed by the Modification Signatory Attorneys General prior to submission of this Joint Motion. The television advertisement shall be broadcast on national cable and network television and the print advertisement shall be published in magazines with national distribution. The specific content and timing of this advertising campaign shall be as specified and approved by DDMAC and reviewed by the Modification Signatory Attorneys General prior to the submission of this Joint Motion. Bayer shall spend at least \$20 million on this corrective advertising campaign. Bayer's dissemination of the advertising described in this paragraph shall

not be construed as an admission by Bayer that the advertisements identified in the Warning Letter were false, misleading, or deceptive in any manner. Nor shall Bayer's dissemination of the advertising described in this paragraph be considered evidence of any liability, wrongdoing, or fault by Bayer.

- ii. Bayer agrees to submit all new Direct to Consumer ("DTC") television advertising campaigns for YAZ® to FDA for pre review, wait until Bayer receives a response from FDA prior to running the advertising campaign, and to modify such advertising consistent with any final written comments received from FDA. Non-material modifications to existing advertising campaigns are not covered by this paragraph.
- iii. Bayer shall not run print advertising for YAZ suggesting or marketing YAZ®'s effectiveness at treating selected symptoms of the FDA-approved indication(s) unless the drug's specific FDA-approved indication(s) is/are stated as clearly and conspicuously in the same promotional spread as the symptoms referenced.
- iv. Bayer's obligations with respect to paragraphs ii and iii shall remain in effect for six years following the date this Order Modifying Consent Decree is entered by the court.
- v. Bayer shall submit to each Modification Signatory Attorney General on the anniversary of the Effective Date of this

Modification a written affirmation setting forth Bayer's compliance with Section XIII.

- d. In addition to the terms contained in the Consent Decree, Section XIV RELEASE RE YAZ® is added and with the following paragraphs.
- i. Section XIV shall pertain to the product YAZ® only and does not alter or modify the release set forth in Section VII of the Consent Decree.
 - ii. Based upon their investigation into Bayer's promotional and marketing practices regarding YAZ® and whether those practices violate the Consent Decree, the Modification Signatory Attorneys General have concluded that the Consent Decree as modified per this Order Modifying Consent Decree is the appropriate resolution of any alleged violations of the Consent Decree by Bayer regarding its marketing and promotion of the product YAZ® as described by the Warning Letter attached as Exhibit 1 and incorporated by this reference as though set forth in full.
 - iii. In Consideration of the terms set forth in Section XIII, by execution of this modification of Consent Decree, each Modification Signatory Attorney General, as defined in Section I, Paragraph X, releases and forever discharges, to the fullest extent permitted by law, Bayer and all of its past and present officers, directors, shareholders, employees, affiliates, subsidiaries, predecessors, assigns and successors (hereinafter referred to

collectively as the “Released Parties”), from contempt proceedings that were or could have been asserted against the Released Parties by the Modification Signatory Attorneys General for the marketing and promotion of YAZ® by engaging in only the specific conduct described in the Warning Letter attached hereto as Exhibit 1 and incorporated by this reference as though set forth in full.

- iv. The Modification Signatory Attorneys General also release and forever discharge, to the fullest extent permitted by law, the Released Parties from any other claims or causes of action under the following consumer protection statutes: ARIZONA - Consumer Fraud Act, A.R.S. § 44-1521, et seq.; ARKANSAS - Deceptive Trade Practices Act, Ark. Code Ann. § 4-88-101 et seq.; CALIFORNIA - Bus. & Prof. Code, § 17200 et seq.; CONNECTICUT - Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. § 42-110a et seq.; DELAWARE - Delaware Consumer Fraud Act, 6 Del. C. § 2511, et seq. and Deceptive Trade Practices Act, 6 Del. C. §2532 et seq.; FLORIDA - Deceptive and Unfair Trade Practices Act, Fla. Stat. Ch. 501.201 et seq.; IDAHO - Consumer Protection Act, Idaho Code § 48-601 et seq.; ILLINOIS - Consumer Fraud and Deceptive Business Practices Act, 815 ILCS § 505/1 et seq.; IOWA - Iowa Consumer Fraud Act, Iowa Code Section 714.16; KANSAS - Consumer Protection Act, K.S.A. 50-623 et seq.; KENTUCKY - Consumer Protection

Statute, KRS 367.170; MAINE - Unfair Trade Practices Act, 5 M.R.S.A. § 205-A et seq.; MARYLAND - Consumer Protection Act, Md. Code Ann., Com. Law § 13-101 et seq.; MASSACHUSETTS - Consumer Protection Act, M.G.L. c. 93A et seq.; MICHIGAN - Consumer Protection Act, Mich. Comp. Laws § 445.901 et seq.; MISSISSIPPI - Consumer Protection Act, Miss. Code Ann. § 75-24-1 et seq.; MONTANA - Mont. Code Ann. § 30-14-101 et seq.; NEVADA - Deceptive Trade Practices Act, Nevada Revised Statutes 598.0903 et seq.; NORTH CAROLINA - Unfair and Deceptive Trade Practices Act, N.C. Gen. Stat. § 75-1.1 et seq.; OHIO - Consumer Sales Practices Act, R.C. 1345.01 et seq.; OREGON - Unlawful Trade Practices Act, ORS 646.605 et seq.; PENNSYLVANIA - Unfair Trade Practices and Consumer Protection Law, 73 P.S. § 201-1 et seq.; SOUTH DAKOTA - Deceptive Trade Practices Act, S.D. Codified Laws § 37-24, et seq.; TENNESSEE - Tennessee Consumer Protection Act, Tenn. Code Ann. §§ 47-18-101 et seq.; TEXAS - Deceptive Trade Practices - Consumer Protection Act, Tex. Bus. and Com. Code § 17.47, et seq.; WASHINGTON - Unfair Business Practices/Consumer Protection Act, R.C.W. 19.86 et seq.; WISCONSIN – Wis. Stat. § 100.18 et seq. (Fraudulent Representations) and Wis. Stat. § 100.182 et seq. (Fraudulent Drug Advertising) that were or could have been asserted against the

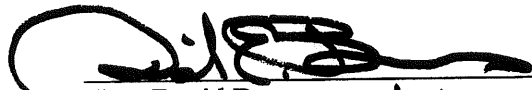
Released Parties by the Modification Signatory Attorneys General for the marketing and promotion of YAZ® by engaging in only the specific conduct described in the Warning Letter attached hereto as Exhibit 1 and incorporated by this reference as though set forth in full. This release does not extend to conduct or advertisements by the Released Parties that were not specifically described in the Warning Letters attached hereto as Exhibit 1 including, but not limited to, conduct that occurred prior to or subsequent to the described conduct, conduct pertaining to advertisements not addressed in the Warning Letter, or conduct beyond the scope of what is described in the Warning Letter.

- e. Notwithstanding any term of this Modification, specifically reserved and excluded from the Released Claims as to any entity or person, including Released Parties, are any and all of the following:
 - i. Any criminal liability that any person or entity, including Released Parties, has or may have to any or all of the Signatory Attorneys General;
 - ii. Any civil or administrative liability that any person or entity, including Released Parties, has or may have to any or all of the Signatory Attorneys General, under any statute, regulation or rule not expressly covered by the release in Paragraph iii. above, including, but not limited to, any and all of the following claims:
 - 1. State or federal antitrust violations;

2. Reporting practices, including "best price", "average wholesale price" or "wholesale acquisition cost";
 3. Medicaid violations, including federal Medicaid drug rebate statute violations, Medicaid fraud or abuse, and/or kickback violations related to any State's Medicaid program;
 4. State false claims violations; and,
 5. Claims to enforce the terms and conditions of this Modification.
- iii. Any liability under the above-cited consumer protection laws of any or all of the Modification Signatory Attorneys General which any person or entity, including Released Parties, has or may have to individual consumers or State program payors of said Individual States, and which have not been specifically enumerated as included herein.

3. The Clerk is ordered to enter this Order Modifying Consent Decree forthwith.

IT IS HEREBY ORDERED:



Hon. David Bruns 2/11/09

APPROVED:
PLAINTIFF, THE STATE OF
KANSAS

By: 

Emilie Burdette, #22094
Assistant Attorney General
Office of the Kansas Attorney General
120 SW 10th Ave., 2nd Floor
Topeka, Kansas 66612

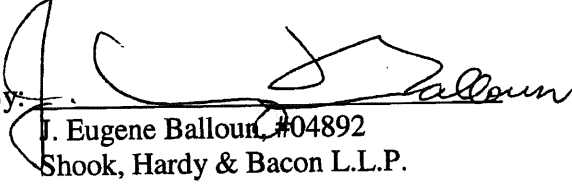
APPROVED:
DEFENDANT, BAYER CORPORATION

By: *George J. Lykos*

George J. Lykos
Chief Legal Officer
Bayer Corporation
100 Bayer Road
Pittsburgh, PA 15205

Date: *Feb. 2, 2009*

Approved as to form:

By: 

Date: January 30, 2009

J. Eugene Balloun, #04892
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Attorney for Bayer Corporation