

CAUSE NO. _____

STATE OF TEXAS,	§	IN THE DISTRICT COURT OF
	§	
Plaintiff,	§	
	§	
vs. BAYER CORPORATION	§	DALLAS COUNTY, T E X A S
	§	
Defendant.	§	___ JUDICIAL DISTRICT

FINAL JUDGMENT AND AGREED PERMANENT INJUNCTION

Plaintiff, the STATE OF TEXAS, acting by and through Attorney General Greg Abbott (“State of Texas”), and Defendant Bayer Corporation (hereinafter referred to as “Bayer”), having consented to the entry of this Final Judgment and Agreed Permanent Injunction (“Judgment”), and before any testimony is taken in this case and without Defendant admitting to any violations of the Texas Deceptive Trade Practices - Consumer Protection Act, TEX. BUS. & COM. CODE ANN. §17.41 *et seq.* (“DTPA”) or any other law, have jointly moved that the Court enter this Judgment for the purposes of settlement only, without this Judgment constituting evidence against or any admission by any party, and without trial of any issue of fact or law.

NOW THEREFORE, upon the consent of the parties hereto IT IS HEREBY ORDERED, ADJUDGED AND DECREED AS FOLLOWS:

I. PARTIES

1. The State of Texas is the plaintiff in this case.
2. Bayer Corporation and its U.S.-based affiliates, subsidiaries, predecessors, successors, and assigns, (hereafter collectively referred to as “Bayer”) is the Defendant in this case. Bayer has its principal place of business at 100 Bayer Rd., Pittsburgh, PA 15205-9707..

II. BACKGROUND

3. Bayer is in the business of, among other things, researching, developing, manufacturing, distributing, selling, and promoting drugs for use in treating various illnesses and diseases.

4. Baycol[®], a prescription drug, was approved initially by the FDA in 1997 as safe and effective as an adjunct to diet for the reduction of elevated total and LDL cholesterol levels in patients with primary cholesterolemia and mixed dyslipidemia (Fredrickson Types IIa and IIb) when the response to dietary restriction of saturated fat and cholesterol and other non-pharmacological measures alone was not adequate. Bayer voluntarily withdrew Baycol[®] from the market in August 2001.

5. The States¹ have concerns that Bayer failed to adequately warn prescribers and consumers of potential adverse side effects of Baycol[®], and, in particular, the State of Texas has concerns that such failure violated the Texas Deceptive Trade Practices - Consumer Protection Act, TEX. BUS. & COM. CODE ANN. §17.41 *et seq.*

6. Bayer denies that it failed to adequately warn prescribers and consumers of potential adverse side effects of Baycol[®] and denies that it violated the Texas Deceptive Trade Practices - Consumer Protection Act, TEX. BUS. & COM. CODE ANN. §17.41 *et seq.*

7. Bayer enters into this Judgment for the purpose of resolving the State of Texas' and the Signatory Attorneys' General investigation into Bayer's promotional and marketing practices regarding Baycol[®] for compliance with the States' consumer protection statutes,

¹ The Attorneys General or other entities of the States and Commonwealths of Arizona, Arkansas, California, Connecticut, Delaware, Florida, Idaho, Illinois, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Mississippi, Montana, Nevada, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, Washington, and Wisconsin (hereinafter referred to as "Signatory Attorneys General"), participated in the investigation, and shall, for purposes of this Judgment, be referred to as the "Signatory Attorneys General".

including the DTPA in Texas², arriving at a complete and total settlement and resolution of any disagreement as to the matters addressed in this Judgment to avoid unnecessary expense, inconvenience, and uncertainty, without admitting any violation of law and without admitting any wrongdoing, and for settlement purposes only.

III. FINDINGS

8. This Court has jurisdiction of the subject matter of this case and of the parties consenting hereto pursuant to TEX. BUS. & COM. CODE § 17.47(b).

9. Venue of this lawsuit lies in Dallas County, Texas pursuant to TEX. BUS. & COM. CODE § 17.47(b).

² ARIZONA Consumer Fraud Act, Ariz. Rev. Stat. §44-1521, *et. seq.*]; ARKANSAS - Deceptive Trade Practices Act, Ark. Code Ann. § 4-88-101 *et seq.*; CALIFORNIA Business and Professions Code § 17200 *et seq* 17500 *et seq* ; CONNECTICUT – Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. §42-110 *et seq.*; DELAWARE - Consumer Fraud Act, 6 Del.C. Section 2511, *et seq.*, UDTPA, 6 Del.C. Section 2531, *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.* (2002); IOWA - Iowa Consumer Fraud Act, Iowa Code Section 714.16; KANSAS – 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. section 205-A *et. seq*; MARYLAND - Consumer Protection Act, Maryland Commercial Law Code Annotated § 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.* (2004); 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.G.S. § 75-1.1 *et seq.*; OHIO - Consumer Sales Practices Act, R.C. § 1345.01 *et seq.*; OREGON - Unlawful Trade Practices Act, ORS 646.605 to 646.656; PENNSYLVANIA - Unfair Trade Practices and Consumer Protection Law, 73 P.S. § 201-1 *et seq.*; SOUTH CAROLINA - Unfair Trade Practices Act, Sections 39-5-10 *et seq.*; SOUTH DAKOTA – Deceptive Trade Practices and Consumer Protection Law, SDCL Chapter 37-24; TENNESSEE - Consumer Protection Act, Tenn. Code Ann. § 47-18-101 *et seq.*, (1977); TEXAS - Deceptive Trade Practices and Consumer Protection Act, Tex. Bus. And Com. Code § 17.41 *et seq.*, (Vernon 2002); VERMONT - Consumer Fraud Act, 9 V.S.A. § 2451 *et seq.*; VIRGINIA - Virginia Consumer Protection Act, 59.1 -196 *et seq.*; WASHINGTON - Washington Consumer Protection Act – R.C.W. 1986 *et seq*; WISCONSIN - Wis. Stat. § 100.18 (Fraudulent Representations).

10. Defendant has done business in Texas by promoting and marketing Baycol[®] to persons who are consumers in Texas.

11. Defendant has, by signature of its counsel hereto, waived any right to appeal, petition for certiorari, or move to reargue or rehear this Judgment.

12. Entry of this Judgment is in the public interest.

13.. Entry of this Judgment is not a finding of liability against Defendant.

IV. DEFINITIONS

14. The following definitions shall be used in construing this Judgment:

- A. “Adverse Events” shall mean an adverse event associated with the use of a drug in humans. “Serious Adverse Events” are those that, at any dose, are fatal, life-threatening, disabling or incapacitating; result in hospitalization; prolong a hospital stay; or are associated with congenital abnormality. In addition, any event not meeting the above criteria may still be deemed Serious if such an event jeopardizes the patient and may require medical or surgical intervention to prevent one of the outcomes listed above.
- B. “Baycol[®]” shall mean cerivastatin sodium.
- C. Bayer” shall mean the Bayer Corporation and its U.S.-based affiliates, subsidiaries, predecessors, successors, and assigns.
- D. Bayer Website” shall mean Bayer’s main Internet site, currently <http://www.pharma.bayer.com>, or a link from that site.
- E. Bayer-Sponsored” shall mean Bayer is responsible for regulatory approvals, site selection, protocol development, initiation, monitoring, safety reporting, and Data analysis, even if some or all of these activities

are transferred to another party (e.g. Clinical Research Organization). A Clinical Study is not “Bayer-Sponsored” if it is initiated by a third party for which Bayer provides some support, for example by way of a grant or supply of medication, but with sponsor responsibilities for study initiation and management agreed in writing to reside with the third party. For purposes of this Judgment only, studies conducted by Bayer’s parent entity and its foreign affiliates shall be considered Bayer-Sponsored.

- F. “Clinical Study” shall mean any research project that prospectively assigns human subjects to intervention and concurrent comparison/control groups to study the cause-and-effect relationship between a medical intervention and a health outcome. The term “Clinical Study” is not limited to a research study that is randomized or blinded; and is not limited to studies conducted in the United States.
- G. “Clinical Study Report” shall mean a description of the Protocol, a summary of all the Data, a description and the results of statistical analyses of the Data, a listing of the common Adverse Events and a more detailed listing of the Serious Adverse Events, and the clinically relevant conclusions drawn from the Data in a Bayer-Sponsored Clinical Study, including the answers to the questions posed in the Protocol.
- H. “Compliance Provisions” shall mean Paragraphs 15 through 26 of this Judgment.
- I. “Covered Conduct” shall mean Bayer’s promotional and marketing practices regarding the prescription drug Baycol[®].

- J. “Data” shall mean all of the results and outcome measurements obtained from a Clinical Study.
- K. “Effective Date” shall mean the date by which all Parties have executed the Judgment and the Judge has signed such Judgment.
- L. “Exploratory Phase II Clinical Study” shall mean a study with less than fifty (50) participants and where a health outcome is not a predefined endpoint of the study.
- M. “Individual State” and “State” shall mean Texas and/or each State represented by its Signatory Attorney General who is participating in the Multistate Working Group.
- N. “Multistate Working Group” (“MSWG”) shall mean the Attorneys General and their staffs representing the States and Commonwealths of Arizona, Arkansas, California, Connecticut, Delaware, Florida, Idaho, Illinois, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Mississippi, Montana, Nevada, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, Washington, and Wisconsin.
- O. “Non-Exploratory Phase II Clinical Study” shall mean a study with fifty (50) or more participants or where a health outcome is a pre-defined endpoint of the study.
- P. “Parties” shall mean Bayer and the State of Texas.
- Q. “Post” information shall mean to provide access to the information on an Internet site that provides no-cost and unrestricted access to both the site and the information Bayer has provided through the site. The Posting

obligations exclusively reside with Bayer as defined in Section IV, paragraph 14.C, not Bayer's parent entity or its foreign affiliates. Bayer does not fulfill a requirement to Post information under this Judgment if it does so on an Internet site, other than the Bayer Website, that contains any advertisement by any pharmaceutical company or for any pharmaceutical product.

- R. "Products" shall mean any pharmaceutical or biological product manufactured, distributed, sold, marketed or promoted in any way by Bayer, solely or in conjunction with other companies in the United States.
- S. "Protocol" shall mean the investigational plan that is used to conduct the Clinical Study. The Protocol for an acute phase of a Clinical Study is separate from the Protocol of a continuation or extension phase of a Clinical Study.
- T. "Signatory Attorney General" shall mean the Texas Attorney General, or his or her designee, for the State of Texas and the Attorney General of each state in the Multistate Working Group investigating Bayer's promotion and marketing practices regarding Baycol.[®]
- U. "State Consumer Protection Laws" shall mean the consumer protection laws under which the Signatory Attorneys General have conducted their investigation which for the State of Texas is the Texas Deceptive Trade Practices Act, as identified in footnote 2 of this Judgment.
- V. "Subject Matter of this Judgment" shall mean the State of Texas' and the other Signatory Attorneys' General investigation under the DTPA for Texas and the State Consumer Protection Laws of the other participating

States of Bayer's promotional and marketing practices regarding the prescription drug Baycol®.

- W. "Study Completion Date" shall mean the date on which the last observation is made either of the last patient who remains enrolled in the Clinical Study or following a decision to terminate the Clinical Study early, whichever happens first.

V. INJUNCTION

15. Bayer shall comply with all applicable laws and regulations relating to the marketing, sale and promotion of its Products. Bayer shall not make any false, misleading or deceptive representation regarding any of its Products in violation of all applicable laws and regulations.

16. Any terms that are not defined above in Section IV above shall be interpreted to have the same meaning as they have in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidelines for Industry: Structure and Content of Clinical Study Reports (July 1996), which is annexed as Exhibit 1.

17. Bayer shall register all Non-Exploratory Phase II, and all Phase III and IV Bayer-Sponsored Clinical Studies on ClinicalTrials.gov in accordance with the following requirements:

- a. Bayer shall register Non-Exploratory Phase II, and all Phase III and IV Bayer-Sponsored Clinical Studies on ClinicalTrials.gov at the time such studies are initiated.
- b. At the time of registration of a Non-Exploratory Phase II Bayer-Sponsored Clinical Study, Bayer will post 15 of the 20 data set items established by the World Health Organization ("WHO"), attached as Exhibit 2, to ClinicalTrials.gov

(that is, all data set items except 10, 13, 17, 19 and 20) and, if there is a change in status, update data set 18 in a timely manner. Bayer will populate the remaining five WHO data fields either when the Product reaches Phase III (and a Phase III Bayer-Sponsored Clinical Study is initiated), or when the Summary of the Clinical Study Report is Posted, whichever occurs first. In the event that a Non-Exploratory Phase II Bayer-Sponsored Clinical Study of a Bayer Product that is approved for marketing and is commercially available in the United States is terminated prior to one or more of its endpoints, Bayer will populate the remaining five WHO data fields no later than 30 days following termination of the study.

- c. At the time of registration of a Phase III or IV Bayer-Sponsored Clinical Study, Bayer will post all 20 data set items to [ClinicalTrials.gov](https://clinicaltrials.gov).

18. Bayer shall Post on [ClinicalStudyResults.org](https://clinicalstudyresults.org) Summaries of Clinical Study Reports (“Summaries of Clinical Study Reports”) for all Phase II, III and IV Bayer-Sponsored Clinical Studies of Bayer Products that are approved for marketing and are commercially available in the United States. Should a publicly funded website for such postings become available after the Date of this Judgment, Bayer shall also Post on that website as well. Such summaries shall conform to ICH E3 principles and to the template published in the Federal Register, Vol. 61, July 17, 1996, Page 37320 *et seq.*

19. For studies initiated after the date of this Judgment, Bayer will also make all reasonable efforts to encourage the publication of, or in the alternative, secure the right to Post, Summaries of Clinical Study Reports in which Bayer had significant participation but did not sponsor.

20. The Summaries of Clinical Study Reports that Bayer Posts shall accurately reflect the methodology used to conduct the Clinical Study and summaries of the Data obtained during the Clinical Study. The Summaries of Clinical Study Reports that Bayer Posts shall include not only the generic and brand names of the Bayer Products, but also a listing of all aliases under which the Bayer Products may be known at the time of Posting, including the serial numbers, code names and chemical descriptions.

21. Bayer shall Post the Summaries of Clinical Study Reports in accordance with the following time requirements:

- a. With respect to Products approved for marketing and commercially available in the United States for any indication prior to the Date of this Judgment
 - (i) Studies completed prior to the Date of this Judgment: Summaries of Phase II, III and IV Clinical Study Reports and summaries of any other studies material to a physician's judgment in relation to prescribing Products in the United States, with a Study Completion Date that occurred between July 1, 2005, and the Date of this Judgment will be posted within 120 days of the Effective Date of this Judgment or within twelve months of the Study Completion Date, whichever is later.
 - (ii) Studies completed after the Date of Judgment: Summaries of Clinical Study Reports for Phase II, III and IV Clinical Studies and summaries of any other studies material to a physician's judgment in relation to prescribing Products in the United States, completed

after the Date of this Judgment will be Posted within twelve months of the Study Completion Date.

- b. With respect to Products approved for marketing and commercially available in the United States for an initial indication after the Date of this Judgment, Summaries of Clinical Study Reports and summaries of any other studies material to a physician's judgment in relation to prescribing Products in the United States will be posted within twelve months of the Study Completion Date or first marketing, whichever is later.
- c. The Parties recognize that, in some instances, there may be a delay in Posting complete Summaries of Clinical Study Reports because Bayer must seek intellectual-property protection or comply with policies of Peer Reviewed Journals to which manuscripts have been submitted for publication; and, further, that Bayer may be required to withhold certain Summaries of Clinical Study Reports to comply with confidentiality provisions in agreements with other parties.
- d. In regard to confidentiality agreements, in all future Clinical Studies Bayer will use reasonable efforts to exclude provisions limiting the publication of Summaries of Clinical Study Reports. For all past Clinical Studies with such confidentiality agreements, Bayer will make reasonable efforts to secure the right to Post the Summaries of Clinical Study Reports.
- e. The State of Texas and the Signatory Attorneys General and Bayer do not intend Bayer's determination of materiality for posting to be admissible in

private litigation or to constitute an admission by Bayer that the information posted is in fact material to prescribing decisions.

22. Bayer shall clearly and conspicuously state on the Home Page of the Bayer Website that the Posted information is available at ClinicalTrials.gov and ClinicalStudyResults.org. and shall prominently feature links to those websites on the Home Page of the Bayer Website.

23. Within two weeks of the Date of this Judgment, Bayer shall arrange and pay for the publication of the advertisement, annexed hereto as Exhibit 3, to run in the next available print and electronic editions (for at least one month on the electronic editions) of each of the following journals: Journal of the American Medical Association, New England Journal of Medicine, Annals of Internal Medicine, Journal of the American Board of Family Practice, Pharmacotherapy, Annals of Pharmacotherapy, and the Journal of Clinical Pharmacology & Therapeutics. Bayer shall arrange and pay for each of the advertisements to be placed between the front cover and the first article in each journal. Letters to the editor do not constitute articles for the purpose of this paragraph. Each advertisement must be at least one-half page in size.

24. Nothing in this Judgment shall require Bayer to:
- a. take an action that is prohibited by the FDCA or any regulation promulgated thereunder, or by FDA; or
 - b. fail to take an action that is required by the FDCA or any regulation promulgated thereunder, or by FDA. Any written or oral promotional claim subject to this Judgment which is the same or substantially the same as the language prescribed by FDA shall not constitute a violation of this Judgment.

25. Bayer shall:
- a. provide a copy of the Compliance Provisions of this Judgment to all current employees having direct responsibility for Posting Clinical Study information; and will make this Judgment accessible on Bayer's intranet site to all current employees having responsibility for marketing and promoting its Products. ("Relevant Persons");
 - b. obtain certifications from the Relevant Persons that they have received and/or reviewed a copy of the Compliance Provisions of this Judgment, have read them, understand their responsibilities and duties in accordance therewith, and will abide by the Compliance Provisions; and
 - c. submit to the Texas Attorney General and to each Signatory Attorney General, on the anniversary of the Effective Date of this Judgment, a written affirmation setting forth Bayer's compliance with this paragraph.

VI. DISBURSEMENT OF PAYMENTS: PAYMENT TO THE STATES

26. Within thirty (30) days of the Effective Date of this Judgment, Bayer shall pay \$8,000,000.00 to the States by electronic fund transfer made payable to the Oregon Attorney General's Office which shall divide and distribute these funds as designated by and in the sole discretion of the Signatory Attorneys General as part of the consideration for the termination of their respective investigations under the State Consumer Protection Laws regarding the Subject Matter of this Judgment. Said payment shall be used by the States as and for attorneys' fees and other costs of investigation and litigation, or to be placed in, or applied to, the consumer protection enforcement fund, consumer education, litigation or local consumer aid fund or revolving fund, used to defray the costs of the inquiry leading hereto, or for other uses permitted by state law, at the sole discretion of each Signatory Attorney General.

VII. REPRESENTATIONS AND WARRANTIES

27. Bayer acknowledges that it is a proper party to this Judgment. Bayer further warrants and represents that the individual signing this Judgment on behalf of Bayer is doing so in his or her official capacity and is fully authorized by Bayer to enter into this Judgment and to legally bind Bayer to all of the terms and conditions of the Judgment.

28. Each of the Parties represents and warrants that it negotiated the terms of this Judgment in good faith.

29. The State of Texas through its Attorney General warrants and represents that he or his representative is signing this Judgment in his official capacity, and that he is fully authorized by his state to enter into this Judgment, including but not limited to the authority to grant the release contained in Section VIII, Paragraph 32 of this Judgment, and to legally bind Texas to all of the terms and conditions of this Judgment.

30. Bayer acknowledges and agrees that the State of Texas has relied on all of the representations and warranties set forth in this Judgment and that, if any representation is proved false, deceptive, misleading, or inaccurate in any material respect, the State of Texas has the right to seek any relief or remedy afforded by law or equity.

VIII. RELEASE

31. Based upon their investigation into Bayer's promotional and marketing practices regarding Baycol, the State of Texas has concluded that this Judgment is the appropriate resolution of any alleged violations of the DTPA. The State of Texas acknowledges by its execution hereof that this Judgment terminates its investigation under the DTPA into Bayer's promotional practices regarding Baycol® prior to the Effective Date of this Judgment.

32. In consideration of the Injunction, payments, undertakings and acknowledgments provided for in this Judgment, and conditioned upon Bayer's full payment of the amount

specified in Section VI, Paragraph 26 and subject to the reservations set forth below in Section VIII, Paragraph 33, by its execution of this Judgment, the State of Texas, 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, affiliates, predecessors, assigns and successors (hereinafter referred to collectively as the “Released Parties”), from the following: all civil claims, causes of action, counterclaims, set-offs, demands, actions, suits, rights, liabilities, damages, restitution, fines, costs and penalties under the above-cited statutes arising from the Covered Conduct, also defined as the Subject Matter of this Judgment in Section IV, Paragraph 14.V., as described in Section II, Paragraph 5 of the Judgment, that were or could have been asserted against the Released Parties by the State of Texas on or after February 18, 1998. This release does not apply to any conduct occurring after the Effective Date of this Judgment.

33. Notwithstanding any term of this Judgment, specifically reserved and excluded from the Released Claims as to any entity or person, including Released Parties, are any and all of the following:

- a. Any criminal liability that any person or entity, including Released Parties, has or may have to any or all of the Signatory Attorneys General;
- b. 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 32 above, including, but not limited to, any and all of the following claims:
 - (i) State or federal antitrust violations;

- (ii) Reporting practices, including “best price”, “average wholesale price” or “wholesale acquisition cost”;
 - (iii) Medicaid violations, including federal Medicaid drug rebate statute violations, Medicaid fraud or abuse, and/or kickback violations related to any State’s Medicaid program;
 - (iv) State false claims violations; and,
 - (v) Claims to enforce the terms and conditions of this Judgment.
- c. Any liability under the above-cited consumer protection laws of any or all of the Signatory Attorneys General which any person or entity, including Released Parties, has or may have to individual consumers or State program payors of Texas or other said Individual States, and which have not been specifically enumerated as included herein.

IX. NO ADMISSION OF LIABILITY

34. This Judgment does not constitute an admission by Bayer for any purpose, of any fact or of a violation of any state law, rule, or regulation, nor does this Judgment constitute evidence of any liability, fault, or wrongdoing. Bayer enters into this Judgment for the purpose of resolving the concerns of the State of Texas and the Signatory Attorneys General regarding Bayer’s promotional and marketing practices for Baycol[®]. Bayer does not admit any violation of the DTPA or State Consumer Protection Laws, and does not admit any wrongdoing that could have been alleged by the Signatory Attorneys General.

35. This Judgment shall not be construed or used as a waiver or any limitation of any defense otherwise available to Bayer. This Judgment is made without trial or adjudication of any issue of fact or law or finding of liability of any kind. Nothing in this Judgment, including this paragraph, shall be construed to limit or to restrict Bayer’s right to use this Judgment to

assert and maintain the defenses of res judicata, collateral estoppel, payment, compromise and settlement, accord and satisfaction, or any other legal or equitable defenses in any pending or future legal or administrative action or proceeding.

X. DISPUTES REGARDING COMPLIANCE

36. For the purposes of resolving disputes with respect to compliance with this Judgment, should the State of Texas have cause to believe that Bayer has violated a provision of this Judgment subsequent to the Effective Date of this Judgment, then the Texas Attorney General shall notify Bayer in writing of the specific objection, identify with particularity the provisions of this Judgment and/or the State Consumer Protection Law that the practice appears to violate, and give Bayer thirty (30) business days to respond to the notification; provided, however, that the State of Texas may take any action where the State of Texas concludes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

37. Upon giving Bayer thirty (30) business days to respond to the notification described in above Paragraph 36 of this Section, the State of Texas shall be permitted to serve a document request for relevant, non-privileged, non-work-product records and documents in the possession, custody or control of Bayer that relate to Bayer's compliance with each provision of this Judgment as to which legally sufficient cause has been shown. In response to that document request, Bayer will make responsive documents available to the State of Texas.

XI. PENALTIES FOR FAILURE TO COMPLY

38. The State of Texas may assert any claim that Bayer has violated this Judgment in a separate civil action to enforce this Judgment, or to seek any other relief afforded by law. In any such action or proceeding, relevant evidence of conduct that occurred before the Effective Date shall be admissible on any material issue, including alleged willfulness, intent, knowledge,

contempt or breach, to the extent permitted by law. Bayer does not waive any objection it may have to the admissibility of any such evidence, as permitted by law.

XII. COMPLIANCE WITH ALL LAWS

39. Except as expressly provided in this Judgment, nothing in this Judgment shall be construed as:

- a. relieving Bayer of its obligation to comply with all applicable state laws, regulations or rules, or granting permission to engage in any acts or practices prohibited by such law, regulation or rule; or
- b. limiting or expanding in any way any right the State of Texas may otherwise have to obtain information, documents or testimony from Bayer pursuant to any applicable state law, regulation or rule, or any right Bayer may otherwise have to oppose any subpoena, civil investigative demand, motion, or other procedure issued, served, filed, or otherwise employed by the State pursuant to any such state law, regulation, or rule.

XIII. NOTICES UNDER THIS JUDGMENT

40. Any notices that must be sent to the State of Texas, Signatory Attorneys General, or to Bayer under this Judgment shall be sent by overnight United States mail. The documents shall be sent to the following addresses:

For the MSWG:

Suzanne D. Sonneborn
Assistant Attorney General, Consumer Protection Division
G Mennen Williams Building, 6th Floor
525 West Ottawa Street
Post Office Box 30213
Lansing, Michigan 48909
Telephone: 517.335.0855
Facsimile: 517.335.1935

David Anthony Hart
Assistant Attorney General
1162 Court Street NE
Salem, Oregon 97301-4096
Telephone: 503. 947-4333
Facsimile: 503. 378-5017

For the State of Texas:

Joyce Wein Iliya
Assistant Attorney General
Consumer Protection and Public Health Division
State Bar No. 00784319
1410 Main St., Suite 810
Dallas, Texas 75202
(214) 969-7639, ext. 111
Facsimile: (214) 969-7615

For Bayer:

Kristin Graham Koehler, Esquire
Sidley Austin LLP
1501 K Street, N.W.
Washington, D.C. 20005
Telephone: 202.736.8359
Facsimile: 202.736.8711

and

Chief Legal Officer
Bayer Corporation
100 Bayer Road
Pittsburgh, PA 15205
Telephone: 412.777.5774
Facsimile: 412.777.4417

XIV. ADDITIONAL PROVISIONS

41. The injunctive provisions of this Judgment are applicable to Bayer, its officers, agents, employees, and attorneys, and all those persons or entities in active concert or participation with them, whether acting directly or through any entity, corporation, subsidiary, division, or other device. This Judgment shall be governed by the laws of Texas.

42. This Judgment is entered into by the Parties as their own free and voluntary act and with full knowledge and understanding of the nature of the proceedings and the obligations and duties imposed by this Judgment.

43. Nothing in this Judgment constitutes any agreement by the Parties concerning the characterization of the amounts paid pursuant to this Judgment for purposes of the Internal Revenue Code or any state tax laws.

44. This Judgment does not constitute an approval by the State of Texas or any of the Signatory Attorneys General of any of Bayer's business practices, including its promotional or marketing practices, and Bayer shall make no representation or claim to the contrary.

45. This Judgment sets forth the entire agreement between the Parties hereto and supersedes all prior agreements or understandings, whether written or oral, between the Parties and/or their respective counsel with respect to the subject matter hereof. This Judgment may be amended by written agreement between the Parties, subject to any further requirements under an individual Signatory Attorney General's state law.

46. This Judgment may be executed in counterparts, and by different signatories on separate counterparts, each of which shall be deemed to constitute an original counterpart hereof, and all of which shall together constitute one and the same Judgment. One or more counterparts of this Judgment may be delivered by facsimile or electronic transmission with the intent that it or they shall constitute an original counterpart hereof.

47. This Judgment shall become effective on the Effective Date and Bayer's obligations to Post information and otherwise publish its Clinical Study Reports shall remain in effect for Ten (10) years following the Effective Date.

48. Defendants shall pay all costs of the Court.

49. The clerk of the Court is authorized to issue such writs of execution or other process necessary to collect and enforce this Judgment.

50. The Court retains jurisdiction to enforce this Final Judgment and Agreed Permanent Injunction .

51. All relief not granted herein is hereby denied.

SO ORDERED, this ____ day of _____ 2007.

District Judge

FOR BAYER:

By: _____

George J. Lykos
Chief Legal Officer
Bayer Corporation
100 Bayer Road
Pittsburgh, PA 15205
Telephone: 412.777.5774
Facsimile: 412.777.4417

Date: _____

Approved as to form:

By: _____

Kristin Graham Koehler, Partner
Bar No: 464422
Sidley Austin LLP
1501 K Street, N.W.
Washington, D.C. 20005
Telephone: 202.736.8359
Facsimile: 202.736.8711

Date: _____

Approved as to form:

By: _____

Jonathan B. Skidmore
S.B. # 18462500
Fulbright & Jaworski L.L.P.
2200 Ross Ave., Suite 2800
Dallas, Texas 75201
Telephone: 214.855.8038
Facsimile: 214.855.8200

Date: _____

Approved as to form:

FOR THE STATE OF TEXAS:

GREG ABBOTT
Attorney General of Texas

KENT C. SULLIVAN
First Assistant Attorney General

ED D. BURBACH
Deputy Attorney General for Litigation

PAUL D. CARMONA
Assistant Attorney General
Chief, Consumer Protection and Public Health Division

JOYCE WEIN ILIYA
Assistant Attorney General
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