STATE OF WASHINGTON
KING COUNTY SUPERIOR COURT

STATE OF WASHINGTON, Plaintiff, v. BAYER CORPORATION, Defendant.	NO. 07-2-03323-8 SEA COMPLAINT

COMES NOW Plaintiff, State of Washington, Office of the Attorney General, Consumer Protection Division, by its attorneys, Rob McKenna, Attorney General, and Robert Lipson, Assistant Attorney General, and brings this action against the defendant named herein, alleging as follows:

I. STATEMENT OF THE CASE

1.1. This is a civil action brought under the Washington Consumer Protection Act, RCW 19.86 et seq., "CPA." Defendant, Bayer Corporation ("Bayer"), failed to adequately warn prescribers and consumers and/or made false, misleading, or deceptive representations regarding the adverse side effects, safety, and efficacy of Bayer's prescription drug, Baycol. Bayer's conduct constitutes unfair and/or deceptive acts and practices in violation of the CPA.

ATTORNEY GENERAL OF WASHINGTON
Consumer Protection Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104
(206) 464-7745

II. JURISDICTION AND PARTIES

2.1. The Attorney General is authorized under the CPA to seek a judgment which enjoins fraudulent or illegal business acts or practices, including any misrepresentation, concealment or suppression of a material fact, and to seek damages, restitution, civil penalties, and attorneys fees for such acts.

2.2. Defendant Bayer Corporation (hereinafter "Bayer") is a corporation organized and existing under the laws of the State of Indiana and is registered to conduct business in the state of Washington. Bayer is engaged in the trade or commerce of researching, developing, manufacturing, distributing, selling, and promoting drugs for use by Washington State consumers in treating various illnesses and diseases. Bayer's principal place of business is in the State of Pennsylvania at 100 Bayer Road, Pittsburgh, Pennsylvania, 15205-9741.

III. FACTUAL ALLEGATIONS

3.1. 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.[1]

3.2. Baycol, a "statin" cholesterol-lowering prescription drug, was approved by the FDA in 1997, and launched in the prescription market by Bayer in May of 1998.

3.3. While statin drugs carry a known risk of myopathy and rhabdomyolysis, the risk of these adverse side effects with Baycol was significantly higher compared to other statins, particularly at higher doses and when combined with genfibrozil, another cholesterol-lowering drug.

[1] Whenever reference is made in this complaint to any act or practice of the Defendant, such allegation shall be deemed to mean that the principals, officers, directors, employees, agents, and representatives of said Defendant did, or authorized, such act or practice, on behalf of said Defendant while actively engaged in the scope of their duties.

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Consumer Protection Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104
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3.4. Bayer failed to adequately warn prescribers and consumers of the greater risk of adverse side effects of Baycol, including but not limited to myopathy and rhabdomyolysis

3.5. Bayer has made or caused to be made, directly or indirectly, explicitly or by implication, representations and omissions which are material, false and likely to mislead, including, but not limited to the following:

a. That Baycol did not pose an increased risk of myopathy and rhabdomyolysis as compared to other statin drugs in mono-therapy.

b. Failure to adequately disclose that use of genfibrozil with Baycol is contraindicated.

3.6. Contrary to Bayer's representations and omissions, Bayer:

a. Knew or had reason to know that Baycol posed an increased risk of myopathy and rhabdomyolysis as compared to other statin drugs in mono-therapy.

b. Knew or had reason to know that Baycol posed an increased risk of myopathy and rhabdomyolysis as compared to other statin drugs when prescribed in combination with genfibrozil.

3.7. As a result of Bayer's misrepresentations and omissions, consumers of Baycol, including state agencies that purchased or paid for Baycol pursuant to prescription drug programs, were not aware of the increased risk of myopathy and rhabdomyolysis associated with the use of Baycol.

IV. CAUSE OF ACTION

UNFAIR OR DECEPTIVE ACTS OR PRACTICES

4.1. The CPA authorizes the Attorney General to bring an action to enjoin a defendant from engaging in a method, act, or practice that is unlawful under the CPA.

4.2. By engaging in the acts and practices described above, Bayer has engaged in unfair or deceptive acts and practices in violation of the CPA.

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Consumer Protection Division
800 Fifth Avenue, Suite 2000
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4.3. Bayer engaged in the acts and practices described above when it knew, or should have known, that its conduct was unfair or deceptive in violation of CPA.

V. PRAYER FOR RELIEF

WHEREFORE, the State of Washington respectfully request that a judgment and order be entered that:

5.1. Permanently enjoins Bayer from making any false, misleading or deceptive representation regarding any of its pharmaceutical or biological products in violation of all applicable laws and regulations.

5.2. Directs Bayer to comply with all applicable laws and regulations relating to the marketing, sale, and promotion of its pharmaceutical and biological products.

5.3. Directs Bayer to establish and maintain a clinical trial registry upon which Bayer shall post summaries of all clinical study reports for all studies conducted by Bayer on its pharmaceutical or biological products.

5.4. Directs Bayer to pay civil penalties for each willful violation of the CPA.

5.5. Awards Plaintiffs costs and attorneys fees, pursuant to the CPA.

5.6. Grants all other relief as the Court deems appropriate.

DATED at Seattle, Washington, this 23 day of January, 2007.

ROB MCKENNA
Attorney General

ROBERT LIPSON WSBA #11889
Assistant Attorney General
Attorneys for Plaintiff
State of Washington

ATTORNEY GENERAL OF WASHINGTON
Consumer Protection Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104
(206) 464-7745

THE STATE OF WASHINGTON
KING COUNTY SUPERIOR COURT

S TATE OF WASHINGTON,

Plaintiff,

v.

Bayer Corp.,

Defendant.

NO. 07-2-03323-8 SEA

CONSENT DECREE AND JUDGMENT RESOLVING STATE'S CLAIMS FOR VIOLATIONS OF THE CONSUMER PROTECTION ACT

(CLERK'S ACTION REQUIRED)

I. JUDGMENT SUMMARY

1.1.	**Judgment Creditor:**	State of Washington, by and through Rob McKenna, Attorney General for the State of Washington.
1.2.	**Judgment Debtor:**	Bayer Corporation
1.3.	**Principal Judgment Amount:**	Compliance Provisions and other terms herein including $8,000,000 to be deposited with the Attorney General of Oregon on behalf of the Signatory Attorneys General to divided at their sole discretion and used for any lawful purpose, and for Washington state, in lieu of direct restitution, the funds may be used for recovery of costs and fees and consumer education cy pres.
1.4.	**Pre-judgment Interest:**	None.

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Consumer Protection Division
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1.5. Post-judgment Interest: At the rate of 9% (nine percent) per annum thereof from the date 30 days after entry of the State of Oregon's Stipulated General Judgment.

1.6. Attorneys Fees and Consumer Education Cy Pres: see above.

1.7. Attorney for Judgment Creditor: Robert A. Lipson, Assistant Attorney General

1.8. Attorney for Judgment Debtor: Bert Markovich of Schwabe, Williamson & Wyatt in Seattle and Kristin Koehler of Sidley Austin in Washington D.C.

Plaintiff, STATE OF WASHINGTON, acting by and through Attorney General Rob McKenna has brought this action pursuant to the RCW 19.86 et seq, having filed a complaint against the Defendant, BAYER CORPORATION ("BAYER") and the parties having consented to the entry of this Consent Decree and Judgment (hereinafter referred to as "Consent") for the purposes of settlement only, without this Consent 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:

PREAMBLE

This Consent is entered into between the Attorneys General or other entities[1] 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

[1] For the purposes of this agreement, when the entire group is referred to as "Signatory Attorneys General," such designation, as it pertains to CONNECTICUT, shall refer to the Commissioner of the Department of Consumer Protection, who enters this Consent pursuant to the Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. Sec. 42-110j, acting by and through his counsel, Richard Blumenthal, Attorney General for the State of Connecticut. For MONTANA, shall refer to the Consumer Protection Office of the Department of Justice who enters into this settlement pursuant to The Montana Unfair Trade and Consumer Protection Act of 1973 MCA 30-14-101 et al., acting by and through his counsel, Mike McGrath, Attorney General for the State of Montana.

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Consumer Protection Division
800 Fifth Avenue, Suite 2000
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referred to as "Signatory Attorneys General"), acting on behalf of their respective states, and pursuant to their respective consumer protection statutes; and Bayer Corporation (hereinafter referred to as "Bayer").

II. DEFINITIONS

The following definitions shall be used in construing this Consent:

2.1. "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.

2.2. "Baycol®" shall mean cerivastatin sodium.

2.3. "Bayer" shall mean the Bayer Corporation and its U.S.-based affiliates, subsidiaries, predecessors, successors, and assigns.

2.4. "Bayer Website" shall mean Bayer's main Internet site, currently http://www.pharma.bayer.com or a link from that site.

2.5 "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 Consent only, studies conducted by Bayer's parent entity and its foreign affiliates shall be considered Bayer-Sponsored.

2.6. "Clinical Study" shall mean any research project that prospectively assigns human subjects to intervention and concurrent comparison/control groups to study the cause-

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Consumer Protection Division
800 Fifth Avenue, Suite 2000
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(206) 464-7745

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.

2.7. "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.

2.8. "Compliance Provisions" shall mean Paragraphs 4.1 through 4.11 of this Consent.

2.9. "Covered Conduct" shall mean Bayer's promotional and marketing practices regarding the prescription drug Baycol®.

2.10. "Data" shall mean all of the results and outcome measurements obtained from a Clinical Study.

2.11. "Effective Date" shall mean the date by which all Parties have executed the Consent.

2.12. "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.

2.13. "Individual State" and "State" shall mean each Signatory Attorney General who is participating in the Multistate Working Group.

2.14. "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.

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2.15. "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.

2.16. "Parties" shall mean Bayer and the Individual States.

2.17. "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 paragraph 2.3, not Bayer's parent entity or its foreign affiliates. Bayer does not fulfill a requirement to Post information under this Consent 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.

2.18. "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.

2.19. "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.

2.20. "Signatory Attorney General" shall mean the Attorney General, or his or her designee, of each state in the Multistate Working Group investigating Bayer's promotion and marketing practices regarding Baycol.®

2.21. "State Consumer Protection Laws" shall mean the consumer protection laws under which the Signatory Attorneys General have conducted their investigation.[2]

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[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

2.22. "Subject Matter of this Consent" shall mean the Signatory Attorneys' General investigation under the State Consumer Protection Laws of Bayer's promotional and marketing practices regarding the prescription drug Baycol®.

2.23. "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.

III. BACKGROUND

3.1. 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.

3.2. 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.

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 RCW 19.86 *et seq.*; WISCONSIN - Wis. Stat. § 100.18 (Fraudulent Representations).

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Consumer Protection Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104
(206) 464-7745

3.3. The States have concerns that Bayer failed to adequately warn prescribers and consumers of potential adverse side effects of Baycol®, and, in particular, that such failure violated the States' Consumer Protection Laws.

3.4. Bayer denies that it failed to adequately warn prescribers and consumers of potential adverse side effects of Baycol® and denies that it violated any of the States' Consumer Protection Laws.

3.5. Bayer enters into this Consent for the purpose of resolving the Signatory Attorneys' General investigation into Bayer's promotional and marketing practices regarding Baycol®, arriving at a complete and total settlement and resolution of any disagreement as to the matters addressed in this Consent to avoid unnecessary expense, inconvenience, and uncertainty, without admitting any violation of law and without admitting any wrongdoing, and for settlement purposes only.

IV. COMPLIANCE PROVISIONS

4.1. 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.

4.2. Any terms that are not defined above in Section I 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.

4.3. 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.

4.4. Bayer shall Post on 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 Consent, 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.*

4.5. For studies initiated after the date of this Consent, 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.

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800 Fifth Avenue, Suite 2000
Seattle, WA 98104
(206) 464-7745

4.6. 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.

4.7. 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 Consent

(1) Studies completed prior to the Date of this Consent: 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 Consent will be posted within 120 days of the Effective Date of this Consent or within twelve months of the Study Completion Date, whichever is later.

(2) Studies completed after the Date of Consent: 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 Consent 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 Consent, 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.

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800 Fifth Avenue, Suite 2000
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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 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.

4.8. 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.

4.9. Within two weeks of the Date of this Consent, 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

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(206) 464-7745

articles for the purpose of this paragraph. Each advertisement must be at least one-half page in size.

4.10. Nothing in this Consent 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 Consent which is the same or substantially the same as the language prescribed by FDA shall not constitute a violation of this Consent.

4.11. Bayer shall:

a. provide a copy of the Compliance Provisions of this Consent Decree to all current employees having direct responsibility for Posting Clinical Study information; and will make this Consent Decree 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 Consent, have read them, understand their responsibilities and duties in accordance therewith, and will abide by the Compliance Provisions; and

c. submit to each Signatory Attorney General, on the anniversary of the Effective Date of this Consent, a written affirmation setting forth Bayer's compliance with this paragraph.

V. DISBURSEMENT OF PAYMENTS: PAYMENT TO THE STATES

5.1. Within thirty (30) days of the Effective Date of this Consent, 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

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Consumer Protection Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104
(206) 464-7745

their respective investigations under the State Consumer Protection Laws regarding the Subject Matter of this Consent. 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.[3]

VI. GENERAL PROVISIONS

6.1. This Consent shall be governed by the laws of the above-named states.

6.2. This Consent 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 Consent.

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

6.4. This Consent does not constitute an approval by 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.

6.5. This Consent 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 Consent may be

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[3] For ARKANSAS, the money shall be placed in the Arkansas Attorney General's Consumer Education and Enforcement Fund and held in trust for purposes directly related to Arkansas consumer protection efforts. For California payment will go to the California Unfair Competition Fund, DELAWARE'S payment will go to the Consumer Protection Fund. In MASSACHUSETTS, the money shall be deposited into the Local Consumer Aid Fund pursuant to M.G.L. c. 12, section 11G. In OREGON, the money shall be deposited to the Consumer Protection and Education Revolving Account established pursuant to ORS 180.095. In PENNSYLVANIA, funds distributed to the Pennsylvania Office of Attorney General may be used for costs of investigation, attorney fees and for future consumer protection and public protection purposes. For WASHINGTON STATE, in lieu of direct restitution, the funds may be used for recovery of costs and fees and consumer education cy pres.

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800 Fifth Avenue, Suite 2000
Seattle, WA 98104
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amended by written agreement between the Parties, subject to any further requirements under an individual Signatory Attorney General's state law.

6.6. This Consent 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 Consent. One or more counterparts of this Consent may be delivered by facsimile or electronic transmission with the intent that it or they shall constitute an original counterpart hereof.

6.7. This Consent 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.

VII. REPRESENTATIONS AND WARRANTIES

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

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

7.3. Each of the Signatory Attorneys General warrants and represents that he or she is signing this Consent in his or her official capacity, and that he or she is fully authorized by his or her state to enter into this Consent, including but not limited to the authority to grant the release contained in Paragraphs 8.1-8.3 of this Consent, and to legally bind his or her state to all of the terms and conditions of this Consent.

7.4. Bayer acknowledges and agrees that the Signatory Attorneys General have relied on all of the representations and warranties set forth in this Consent and that, if any representation is proved false, deceptive, misleading, or inaccurate in any material respect, the

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800 Fifth Avenue, Suite 2000
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Signatory Attorneys General have the right to seek any relief or remedy afforded by law or equity in their respective states.

VIII. RELEASE

8.1. Based upon their investigation into Bayer's promotional and marketing practices regarding Baycol, the Signatory Attorneys General have concluded that this Consent is the appropriate resolution of any alleged violations of the State Consumer Protection Laws. The Signatory Attorneys General acknowledge by their execution hereof that this Consent terminates their investigation under the State Consumer Protection Laws into Bayer's promotional practices regarding Baycol® prior to the Effective Date of this Consent.

8.2. In consideration of the Compliance Provisions, payments, undertakings and acknowledgments provided for in this Consent, and conditioned upon Bayer's full payment of the amount specified in Paragraph 5.1 and subject to the reservations set forth in Paragraph 8.3 by its execution of this Consent, each Signatory Attorney General, as defined in Section II, Paragraph 2.20, releases and forever discharges, to the fullest extent permitted by law, Bayer and all of its past and present officers, directors, shareholders, employees, 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 Consent in Section II, Paragraph 2.22, as described in Section III, Paragraph 3.3 of the Consent, that were or could have been asserted against the Released Parties by the Signatory Attorneys General on or after February 18, 1998. This release does not apply to any conduct occurring after the Effective Date of this Consent.

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

ATTORNEY GENERAL OF WASHINGTON
Consumer Protection Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104
(206) 464-7745

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 8.2 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 Consent.

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 said Individual States, and which have not been specifically enumerated as included herein.

IX. NO ADMISSION OF LIABILITY

9.1. This Consent 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 Consent constitute evidence of any liability, fault, or wrongdoing. Bayer enters into this Consent for the purpose of resolving the concerns of the Signatory Attorneys General regarding Bayer's promotional and marketing practices for Baycol®. Bayer does not admit any violation of the State Consumer Protection Laws, and does not admit any wrongdoing that could have been alleged by the Signatory Attorneys General.

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

10.1. For the purposes of resolving disputes with respect to compliance with this Consent, should any of the Signatory Attorneys General have cause to believe that Bayer has violated a provision of this Consent subsequent to the Effective Date of this Consent, then such Attorney General shall notify Bayer in writing of the specific objection, identify with particularity the provisions of this Consent 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 a Signatory Attorney General may take any action where the Signatory Attorney General concludes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

10.2. Upon giving Bayer thirty (30) business days to respond to the notification described in Paragraph 10.1 above, the Signatory Attorney General 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 Consent as to which legally sufficient cause has been shown. In response to that document request, Bayer will make responsive documents available to the Signatory Attorneys General.

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XI. PENALTIES FOR FAILURE TO COMPLY

11.1. The State may assert any claim that Bayer has violated this Consent in a separate civil action to enforce this Consent, 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

12.1. Except as expressly provided in this Consent, nothing in this Consent 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 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 CONSENT

13.1. Any notices that must be sent to the State or to Bayer under this Consent shall be sent by overnight United States mail. The documents shall be sent to the following addresses:

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