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KING COUNTY  
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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.

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## 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.<sup>1</sup>

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.

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<sup>1</sup> 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.

1       **3.4.** Bayer failed to adequately warn prescribers and consumers of the greater risk  
2 of adverse side effects of Baycol, including but not limited to myopathy and rhabdomyolysis

3       **3.5.** Bayer has made or caused to be made, directly or indirectly, explicitly or by  
4 implication, representations and omissions which are material, false and likely to mislead,  
5 including, but not limited to the following:

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

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

10       **3.6.** Contrary to Bayer's representations and omissions, Bayer:

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

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

16       **3.7.** As a result of Bayer's misrepresentations and omissions, consumers of Baycol,  
17 including state agencies that purchased or paid for Baycol pursuant to prescription drug  
18 programs, were not aware of the increased risk of myopathy and rhabdomyolysis associated  
19 with the use of Baycol.

#### 20                                   **IV. CAUSE OF ACTION**

##### 21                                   **UNFAIR OR DECEPTIVE ACTS OR PRACTICES**

22       **4.1.** The CPA authorizes the Attorney General to bring an action to enjoin a  
23 defendant from engaging in a method, act, or practice that is unlawful under the CPA.

24       **4.2.** By engaging in the acts and practices described above, Bayer has engaged in  
25 unfair or deceptive acts and practices in violation of the CPA.

1       **4.3.** Bayer engaged in the acts and practices described above when it knew, or  
2 should have known, that its conduct was unfair or deceptive in violation of CPA.

3                                   **V. PRAYER FOR RELIEF**

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

6       **5.1.** Permanently enjoins Bayer from making any false, misleading or deceptive  
7 representation regarding any of its pharmaceutical or biological products in violation of all  
8 applicable laws and regulations.

9       **5.2.** Directs Bayer to comply with all applicable laws and regulations relating to the  
10 marketing, sale, and promotion of its pharmaceutical and biological products.

11       **5.3.** Directs Bayer to establish and maintain a clinical trial registry upon which  
12 Bayer shall post summaries of all clinical study reports for all studies conducted by Bayer on  
13 its pharmaceutical or biological products.


14       **5.4.** Directs Bayer to pay civil penalties for each willful violation of the CPA.

15       **5.5.** Awards Plaintiffs costs and attorneys fees, pursuant to the CPA.

16       **5.6.** Grants all other relief as the Court deems appropriate.

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

18                                   ROB MCKENNA  
19                                   Attorney General

20                                     
21                                   \_\_\_\_\_  
22                                   ROBERT LIPSON WSBA #11889  
23                                   Assistant Attorney General  
24                                   Attorneys for Plaintiff  
25                                   State of Washington  
26

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KING COUNTY  
SUPERIOR COURT

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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### 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<sup>1</sup> 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

<sup>1</sup> 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.

1 referred to as "Signatory Attorneys General"), acting on behalf of their respective states, and  
2 pursuant to their respective consumer protection statutes; and Bayer Corporation (hereinafter  
3 referred to as "Bayer").

## 4 II. DEFINITIONS

5 The following definitions shall be used in construing this Consent:

6 2.1. "Adverse Events" shall mean an adverse event associated with the use of a drug  
7 in humans. "Serious Adverse Events" are those that, at any dose, are fatal, life-threatening,  
8 disabling or incapacitating; result in hospitalization; prolong a hospital stay; or are associated  
9 with congenital abnormality. In addition, any event not meeting the above criteria may still be  
10 deemed Serious if such an event jeopardizes the patient and may require medical or surgical  
11 intervention to prevent one of the outcomes listed above.

12 2.2. "Baycol®" shall mean cerivastatin sodium.

13 2.3. "Bayer" shall mean the Bayer Corporation and its U.S.-based affiliates,  
14 subsidiaries, predecessors, successors, and assigns.

15 2.4. "Bayer Website" shall mean Bayer's main Internet site, currently  
16 <http://www.pharma.bayer.com> or a link from that site.

17 2.5 "Bayer-Sponsored" shall mean Bayer is responsible for regulatory approvals,  
18 site selection, protocol development, initiation, monitoring, safety reporting, and Data analysis,  
19 even if some or all of these activities are transferred to another party (e.g. Clinical Research  
20 Organization). A Clinical Study is not "Bayer-Sponsored" if it is initiated by a third party for  
21 which Bayer provides some support, for example by way of a grant or supply of medication,  
22 but with sponsor responsibilities for study initiation and management agreed in writing to  
23 reside with the third party. For purposes of this Consent only, studies conducted by Bayer's  
24 parent entity and its foreign affiliates shall be considered Bayer-Sponsored.

25 2.6. "Clinical Study" shall mean any research project that prospectively assigns  
26 human subjects to intervention and concurrent comparison/control groups to study the cause-

1 and-effect relationship between a medical intervention and a health outcome. The term  
2 "Clinical Study" is not limited to a research study that is randomized or blinded; and is not  
3 limited to studies conducted in the United States.

4 **2.7.** "Clinical Study Report" shall mean a description of the Protocol, a summary of  
5 all the Data, a description and the results of statistical analyses of the Data, a listing of the  
6 common Adverse Events and a more detailed listing of the Serious Adverse Events, and the  
7 clinically relevant conclusions drawn from the Data in a Bayer-Sponsored Clinical Study,  
8 including the answers to the questions posed in the Protocol.

9 **2.8.** "Compliance Provisions" shall mean Paragraphs 4.1 through 4.11 of this  
10 Consent.

11 **2.9.** "Covered Conduct" shall mean Bayer's promotional and marketing practices  
12 regarding the prescription drug Baycol®.

13 **2.10.** "Data" shall mean all of the results and outcome measurements obtained from a  
14 Clinical Study.

15 **2.11.** "Effective Date" shall mean the date by which all Parties have executed the  
16 Consent.

17 **2.12.** "Exploratory Phase II Clinical Study" shall mean a study with less than fifty  
18 (50) participants and where a health outcome is not a predefined endpoint of the study.

19 **2.13.** "Individual State" and "State" shall mean each Signatory Attorney General who  
20 is participating in the Multistate Working Group.

21 **2.14.** "Multistate Working Group" ("MSWG") shall mean the Attorneys General and  
22 their staffs representing the States and Commonwealths of Arizona, Arkansas, California,  
23 Connecticut, Delaware, Florida, Idaho, Illinois, Iowa, Kansas, Kentucky, Maine, Maryland,  
24 Massachusetts, Michigan, Mississippi, Montana, Nevada, North Carolina, Ohio, Oregon,  
25 Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia,  
26 Washington, and Wisconsin.



1       **2.15.** "Non-Exploratory Phase II Clinical Study" shall mean a study with fifty (50) or  
2 more participants or where a health outcome is a pre-defined endpoint of the study.

3       **2.16.** "Parties" shall mean Bayer and the Individual States.

4       **2.17.** "Post" information shall mean to provide access to the information on an  
5 Internet site that provides no-cost and unrestricted access to both the site and the information  
6 Bayer has provided through the site. The Posting obligations exclusively reside with Bayer as  
7 defined in paragraph 2.3, not Bayer's parent entity or its foreign affiliates. Bayer does not  
8 fulfill a requirement to Post information under this Consent if it does so on an Internet site,  
9 other than the Bayer Website, that contains any advertisement by any pharmaceutical company  
10 or for any pharmaceutical product.

11       **2.18.** "Products" shall mean any pharmaceutical or biological product manufactured,  
12 distributed, sold, marketed or promoted in any way by Bayer, solely or in conjunction with  
13 other companies in the United States.

14       **2.19.** "Protocol" shall mean the investigational plan that is used to conduct the  
15 Clinical Study. The Protocol for an acute phase of a Clinical Study is separate from the  
16 Protocol of a continuation or extension phase of a Clinical Study.

17       **2.20.** "Signatory Attorney General" shall mean the Attorney General, or his or her  
18 designee, of each state in the Multistate Working Group investigating Bayer's promotion and  
19 marketing practices regarding Baycol.<sup>®</sup>

20       **2.21.** "State Consumer Protection Laws" shall mean the consumer protection laws  
21 under which the Signatory Attorneys General have conducted their investigation.<sup>2</sup>

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22       <sup>2</sup> ARIZONA Consumer Fraud Act, Ariz. Rev. Stat. §44-1521, *et seq.*]; ARKANSAS - Deceptive Trade  
23 Practices Act, Ark. Code Ann. § 4-88-101 *et seq.*; CALIFORNIA Business and Professions Code § 17200 *et seq.*  
24 17500 *et seq.*; CONNECTICUT – Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. §42-110 *et seq.*;  
25 DELAWARE - Consumer Fraud Act, 6 Del.C. Section 2511, *et seq.*, UDTPA, 6 Del.C. Section 2531, *et seq.*;  
26 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



1       **3.3.** The States have concerns that Bayer failed to adequately warn prescribers and  
2 consumers of potential adverse side effects of Baycol<sup>®</sup>, and, in particular, that such failure  
3 violated the States' Consumer Protection Laws.

4       **3.4.** Bayer denies that it failed to adequately warn prescribers and consumers of  
5 potential adverse side effects of Baycol<sup>®</sup> and denies that it violated any of the States'  
6 Consumer Protection Laws.

7       **3.5.** Bayer enters into this Consent for the purpose of resolving the Signatory  
8 Attorneys' General investigation into Bayer's promotional and marketing practices regarding  
9 Baycol<sup>®</sup>, arriving at a complete and total settlement and resolution of any disagreement as to  
10 the matters addressed in this Consent to avoid unnecessary expense, inconvenience, and  
11 uncertainty, without admitting any violation of law and without admitting any wrongdoing, and  
12 for settlement purposes only.

#### 13                                   **IV. COMPLIANCE PROVISIONS**

14       **4.1.** Bayer shall comply with all applicable laws and regulations relating to the  
15 marketing, sale and promotion of its Products. Bayer shall not make any false, misleading or  
16 deceptive representation regarding any of its Products in violation of all applicable laws and  
17 regulations.

18       **4.2.** Any terms that are not defined above in Section I shall be interpreted to have  
19 the same meaning as they have in the International Conference on Harmonization of Technical  
20 Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidelines for  
21 Industry: Structure and Content of Clinical Study Reports (July 1996), which is annexed as  
22 Exhibit 1.

23       **4.3.** Bayer shall register all Non-Exploratory Phase II, and all Phase III and IV  
24 Bayer-Sponsored Clinical Studies on ClinicalTrials.gov in accordance with the following  
25 requirements:  
26

1           a.       Bayer shall register Non-Exploratory Phase II, and all Phase III and IV  
2 Bayer-Sponsored Clinical Studies on ClinicalTrials.gov at the time such studies are initiated.

3           b.       At the time of registration of a Non-Exploratory Phase II Bayer-  
4 Sponsored Clinical Study, Bayer will post 15 of the 20 data set items established by the World  
5 Health Organization ("WHO"), attached as Exhibit 2, to ClinicalTrials.gov (that is, all data set  
6 items except 10, 13, 17, 19 and 20) and, if there is a change in status, update data set 18 in a  
7 timely manner. Bayer will populate the remaining five WHO data fields either when the  
8 Product reaches Phase III (and a Phase III Bayer-Sponsored Clinical Study is initiated), or  
9 when the Summary of the Clinical Study Report is Posted, whichever occurs first. In the event  
10 that a Non-Exploratory Phase II Bayer-Sponsored Clinical Study of a Bayer Product that is  
11 approved for marketing and is commercially available in the United States is terminated prior  
12 to one or more of its endpoints, Bayer will populate the remaining five WHO data fields no  
13 later than 30 days following termination of the study.

14           c.       At the time of registration of a Phase III or IV Bayer-Sponsored Clinical  
15 Study, Bayer will post all 20 data set items to ClinicalTrials.gov.

16       **4.4.**    Bayer shall Post on ClinicalStudyResults.org Summaries of Clinical Study  
17 Reports ("Summaries of Clinical Study Reports") for all Phase II, III and IV Bayer-Sponsored  
18 Clinical Studies of Bayer Products that are approved for marketing and are commercially  
19 available in the United States. Should a publicly funded website for such postings become  
20 available after the Date of this Consent, Bayer shall also Post on that website as well. Such  
21 summaries shall conform to ICH E3 principles and to the template published in the Federal  
22 Register, Vol. 61, July 17, 1996, Page 37320 *et seq.*

23       **4.5.**    For studies initiated after the date of this Consent, Bayer will also make all  
24 reasonable efforts to encourage the publication of, or in the alternative, secure the right to Post,  
25 Summaries of Clinical Study Reports in which Bayer had significant participation but did not  
26 sponsor.

1       **4.6.** The Summaries of Clinical Study Reports that Bayer Posts shall accurately  
2 reflect the methodology used to conduct the Clinical Study and summaries of the Data obtained  
3 during the Clinical Study. The Summaries of Clinical Study Reports that Bayer Posts shall  
4 include not only the generic and brand names of the Bayer Products, but also a listing of all  
5 aliases under which the Bayer Products may be known at the time of Posting, including the  
6 serial numbers, code names and chemical descriptions.

7       **4.7.** Bayer shall Post the Summaries of Clinical Study Reports in accordance with  
8 the following time requirements:

9           a. With respect to Products approved for marketing and commercially  
10 available in the United States for any indication prior to the Date of this Consent

11                   (1) Studies completed prior to the Date of this Consent: Summaries  
12 of Phase II, III and IV Clinical Study Reports and summaries of any other studies material to a  
13 physician's judgment in relation to prescribing Products in the United States, with a Study  
14 Completion Date that occurred between July 1, 2005, and the Date of this Consent will be  
15 posted within 120 days of the Effective Date of this Consent or within twelve months of the  
16 Study Completion Date, whichever is later.

17                   (2) Studies completed after the Date of Consent: Summaries of  
18 Clinical Study Reports for Phase II, III and IV Clinical Studies and summaries of any other  
19 studies material to a physician's judgment in relation to prescribing Products in the United  
20 States, completed after the Date of this Consent will be Posted within twelve months of the  
21 Study Completion Date

22           b. With respect to Products approved for marketing and commercially  
23 available in the United States for an initial indication after the Date of this Consent, Summaries  
24 of Clinical Study Reports and summaries of any other studies material to a physician's  
25 judgment in relation to prescribing Products in the United States will be posted within twelve  
26 months of the Study Completion Date or first marketing, whichever is later.

1 c. The parties recognize that, in some instances, there may be a delay in  
2 Posting complete Summaries of Clinical Study Reports because Bayer must seek  
3 intellectual-property protection or comply with policies of Peer Reviewed Journals to which  
4 manuscripts have been submitted for publication; and, further, that Bayer may be required to  
5 withhold certain Summaries of Clinical Study Reports to comply with confidentiality  
6 provisions in agreements with other parties.

7 d. In regard to confidentiality agreements, in all future Clinical Studies  
8 Bayer will use reasonable efforts to exclude provisions limiting the publication of Summaries  
9 of Clinical Study Reports. For all past Clinical Studies with such confidentiality agreements,  
10 Bayer will make reasonable efforts to secure the right to Post the Summaries of Clinical Study  
11 Reports.

12 e. The Signatory Attorneys General and Bayer do not intend Bayer's  
13 determination of materiality for posting to be admissible in private litigation or to constitute an  
14 admission by Bayer that the information posted is in fact material to prescribing decisions.

15 **4.8.** Bayer shall clearly and conspicuously state on the Home Page of the Bayer  
16 Website that the Posted information is available at [ClinicalTrials.gov](http://ClinicalTrials.gov) and  
17 [ClinicalStudyResults.org](http://ClinicalStudyResults.org), and shall prominently feature links to those websites on the Home  
18 Page of the Bayer Website.

19 **4.9.** Within two weeks of the Date of this Consent, Bayer shall arrange and pay for  
20 the publication of the advertisement annexed hereto as Exhibit 3 to run in the next available  
21 print and electronic editions (for at least one month on the electronic editions) of each of the  
22 following journals: Journal of the American Medical Association, New England Journal of  
23 Medicine, Annals of Internal Medicine, Journal of the American Board of Family Practice,  
24 Pharmacotherapy, Annals of Pharmacotherapy, and the Journal of Clinical Pharmacology &  
25 Therapeutics. Bayer shall arrange and pay for each of the advertisements to be placed between  
26 the front cover and the first article in each journal. Letters to the editor do not constitute

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

3 **4.10.** Nothing in this Consent shall require Bayer to:

4 a. take an action that is prohibited by the FDCA or any regulation  
5 promulgated thereunder, or by FDA; or

6 b. fail to take an action that is required by the FDCA or any regulation  
7 promulgated thereunder, or by FDA. Any written or oral promotional claim subject to this  
8 Consent which is the same or substantially the same as the language prescribed by FDA shall  
9 not constitute a violation of this Consent.

10 **4.11.** Bayer shall:

11 a. provide a copy of the Compliance Provisions of this Consent Decree to  
12 all current employees having direct responsibility for Posting Clinical Study information; and  
13 will make this Consent Decree accessible on Bayer's intranet site to all current employees  
14 having responsibility for marketing and promoting its Products. ("Relevant Persons");

15 b. obtain certifications from the Relevant Persons that they have received  
16 and/or reviewed a copy of the Compliance Provisions of this Consent, have read them,  
17 understand their responsibilities and duties in accordance therewith, and will abide by the  
18 Compliance Provisions; and

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

22 **V. DISBURSEMENT OF PAYMENTS: PAYMENT TO THE STATES**

23 **5.1.** Within thirty (30) days of the Effective Date of this Consent, Bayer shall pay  
24 \$8,000,000.00 to the States by electronic fund transfer made payable to the Oregon Attorney  
25 General's Office which shall divide and distribute these funds as designated by and in the sole  
26 discretion of the Signatory Attorneys General as part of the consideration for the termination of

1 their respective investigations under the State Consumer Protection Laws regarding the Subject  
2 Matter of this Consent. Said payment shall be used by the States as and for attorneys' fees and  
3 other costs of investigation and litigation, or to be placed in, or applied to, the consumer  
4 protection enforcement fund, consumer education, litigation or local consumer aid fund or  
5 revolving fund, used to defray the costs of the inquiry leading hereto, or for other uses  
6 permitted by state law, at the sole discretion of each Signatory Attorney General.<sup>3</sup>

## 7 VI. GENERAL PROVISIONS

8 6.1. This Consent shall be governed by the laws of the above-named states.

9 6.2. This Consent is entered into by the Parties as their own free and voluntary act  
10 and with full knowledge and understanding of the nature of the proceedings and the obligations  
11 and duties imposed by this Consent.

12 6.3. Nothing in this Consent constitutes any agreement by the Parties concerning the  
13 characterization of the amounts paid pursuant to this Consent for purposes of the Internal  
14 Revenue Code or any state tax laws.

15 6.4. This Consent does not constitute an approval by the Signatory Attorneys  
16 General of any of Bayer's business practices, including its promotional or marketing practices,  
17 and Bayer shall make no representation or claim to the contrary.

18 6.5. This Consent sets forth the entire agreement between the Parties hereto and  
19 supersedes all prior agreements or understandings, whether written or oral, between the Parties  
20 and/or their respective counsel with respect to the subject matter hereof. This Consent may be

21 <sup>3</sup> For ARKANSAS, the money shall be placed in the Arkansas Attorney General's Consumer  
22 Education and Enforcement Fund and held in trust for purposes directly related to Arkansas consumer protection  
23 efforts. For California payment will go to the California Unfair Competition Fund, DELAWARE'S payment will  
24 go to the Consumer Protection Fund. In MASSACHUSETTS, the money shall be deposited into the Local  
25 Consumer Aid Fund pursuant to M.G.L. c. 12, section 11G. In OREGON, the money shall be deposited to the  
26 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.



1 amended by written agreement between the Parties, subject to any further requirements under  
2 an individual Signatory Attorney General's state law.

3       **6.6.** This Consent may be executed in counterparts, and by different signatories on  
4 separate counterparts, each of which shall be deemed to constitute an original counterpart  
5 hereof, and all of which shall together constitute one and the same Consent. One or more  
6 counterparts of this Consent may be delivered by facsimile or electronic transmission with the  
7 intent that it or they shall constitute an original counterpart hereof.

8       **6.7.** This Consent shall become effective on the Effective Date and Bayer's  
9 obligations to Post information and otherwise publish its Clinical Study Reports shall remain in  
10 effect for Ten (10) years following the Effective Date.

## 11                   **VII. REPRESENTATIONS AND WARRANTIES**

12       **7.1.** Bayer acknowledges that it is a proper party to this Consent. Bayer further  
13 warrants and represents that the individual signing this Consent on behalf of Bayer is doing so  
14 in his or her official capacity and is fully authorized by Bayer to enter into this Consent and to  
15 legally bind Bayer to all of the terms and conditions of the Consent.

16       **7.2.** Each of the Parties represents and warrants that it negotiated the terms of this  
17 Consent in good faith.

18       **7.3.** Each of the Signatory Attorneys General warrants and represents that he or she  
19 is signing this Consent in his or her official capacity, and that he or she is fully authorized by  
20 his or her state to enter into this Consent, including but not limited to the authority to grant the  
21 release contained in Paragraphs 8.1-8.3 of this Consent, and to legally bind his or her state to  
22 all of the terms and conditions of this Consent.

23       **7.4.** Bayer acknowledges and agrees that the Signatory Attorneys General have  
24 relied on all of the representations and warranties set forth in this Consent and that, if any  
25 representation is proved false, deceptive, misleading, or inaccurate in any material respect, the  
26

1 Signatory Attorneys General have the right to seek any relief or remedy afforded by law or  
2 equity in their respective states.

### 3 **VIII. RELEASE**

4 **8.1.** Based upon their investigation into Bayer's promotional and marketing  
5 practices regarding Baycol, the Signatory Attorneys General have concluded that this Consent  
6 is the appropriate resolution of any alleged violations of the State Consumer Protection Laws.  
7 The Signatory Attorneys General acknowledge by their execution hereof that this Consent  
8 terminates their investigation under the State Consumer Protection Laws into Bayer's  
9 promotional practices regarding Baycol® prior to the Effective Date of this Consent.

10 **8.2.** In consideration of the Compliance Provisions, payments, undertakings and  
11 acknowledgments provided for in this Consent, and conditioned upon Bayer's full payment of  
12 the amount specified in Paragraph 5.1 and subject to the reservations set forth in Paragraph 8.3  
13 by its execution of this Consent, each Signatory Attorney General, as defined in Section II,  
14 Paragraph 2.20, releases and forever discharges, to the fullest extent permitted by law, Bayer  
15 and all of its past and present officers, directors, shareholders, employees, subsidiaries,  
16 affiliates, predecessors, assigns and successors (hereinafter referred to collectively as the  
17 "Released Parties"), from the following: all civil claims, causes of action, counterclaims, set-  
18 offs, demands, actions, suits, rights, liabilities, damages, restitution, fines, costs and penalties  
19 under the above-cited statutes arising from the Covered Conduct, also defined as the Subject  
20 Matter of this Consent in Section II, Paragraph 2.22, as described in Section III, Paragraph 3.3  
21 of the Consent, that were or could have been asserted against the Released Parties by the  
22 Signatory Attorneys General on or after February 18, 1998. This release does not apply to any  
23 conduct occurring after the Effective Date of this Consent.

24 **8.3.** Notwithstanding any term of this Consent, specifically reserved and excluded  
25 from the Released Claims as to any entity or person, including Released Parties, are any and all  
26 of the following:

1           a.     Any criminal liability that any person or entity, including Released  
2 Parties, has or may have to any or all of the Signatory Attorneys General;

3           b.     Any civil or administrative liability that any person or entity, including  
4 Released Parties, has or may have to any or all of the Signatory Attorneys General, under any  
5 statute, regulation or rule not expressly covered by the release in Paragraph 8.2 above,  
6 including, but not limited to, any and all of the following claims:

7                   (1)     State or federal antitrust violations;

8                   (2)     Reporting practices, including "best price", "average wholesale  
9 price" or "wholesale acquisition cost";

10                  (3)     Medicaid violations, including federal Medicaid drug rebate  
11 statute violations, Medicaid fraud or abuse, and/or kickback violations related to any State's  
12 Medicaid program;

13                  (4)     State false claims violations; and,

14                  (5)     Claims to enforce the terms and conditions of this Consent.

15           c.     Any liability under the above-cited consumer protection laws of any or  
16 all of the Signatory Attorneys General which any person or entity, including Released Parties,  
17 has or may have to individual consumers or State program payors of said Individual States, and  
18 which have not been specifically enumerated as included herein.

19                           **IX.    NO ADMISSION OF LIABILITY**

20           **9.1.**    This Consent does not constitute an admission by Bayer for any purpose, of any  
21 fact or of a violation of any state law, rule, or regulation, nor does this Consent constitute  
22 evidence of any liability, fault, or wrongdoing. Bayer enters into this Consent for the purpose  
23 of resolving the concerns of the Signatory Attorneys General regarding Bayer's promotional  
24 and marketing practices for Baycol®. Bayer does not admit any violation of the State  
25 Consumer Protection Laws, and does not admit any wrongdoing that could have been alleged  
26 by the Signatory Attorneys General.

1       **9.2.** This Consent shall not be construed or used as a waiver or any limitation of any  
2 defense otherwise available to Bayer. This Consent is made without trial or adjudication of  
3 any issue of fact or law or finding of liability of any kind. Nothing in this Consent, including  
4 this paragraph, shall be construed to limit or to restrict Bayer's right to use this Consent to  
5 assert and maintain the defenses of res judicata, collateral estoppel, payment, compromise and  
6 settlement, accord and satisfaction, or any other legal or equitable defenses in any pending or  
7 future legal or administrative action or proceeding.

8                               **X.       DISPUTES REGARDING COMPLIANCE**

9       **10.1.** For the purposes of resolving disputes with respect to compliance with this  
10 Consent, should any of the Signatory Attorneys General have cause to believe that Bayer has  
11 violated a provision of this Consent subsequent to the Effective Date of this Consent, then such  
12 Attorney General shall notify Bayer in writing of the specific objection, identify with  
13 particularity the provisions of this Consent and/or the State Consumer Protection Law that the  
14 practice appears to violate, and give Bayer thirty (30) business days to respond to the  
15 notification; provided, however, that a Signatory Attorney General may take any action where  
16 the Signatory Attorney General concludes that, because of the specific practice, a threat to the  
17 health or safety of the public requires immediate action.

18       **10.2.** Upon giving Bayer thirty (30) business days to respond to the notification  
19 described in Paragraph 10.1 above, the Signatory Attorney General shall be permitted to serve  
20 a document request for relevant, non-privileged, non-work-product records and documents in  
21 the possession, custody or control of Bayer that relate to Bayer's compliance with each  
22 provision of this Consent as to which legally sufficient cause has been shown. In response to  
23 that document request, Bayer will make responsive documents available to the Signatory  
24 Attorneys General.

1                                   **XI.    PENALTIES FOR FAILURE TO COMPLY**

2           **11.1.** The State may assert any claim that Bayer has violated this Consent in a  
3 separate civil action to enforce this Consent, or to seek any other relief afforded by law. In any  
4 such action or proceeding, relevant evidence of conduct that occurred before the Effective Date  
5 shall be admissible on any material issue, including alleged willfulness, intent, knowledge,  
6 contempt or breach, to the extent permitted by law. Bayer does not waive any objection it  
7 may have to the admissibility of any such evidence, as permitted by law.

8                                   **XII.   COMPLIANCE WITH ALL LAWS**

9           **12.1.** Except as expressly provided in this Consent, nothing in this Consent shall be  
10 construed as:

11                   a.       relieving Bayer of its obligation to comply with all applicable state laws,  
12 regulations or rules, or granting permission to engage in any acts or practices prohibited by  
13 such law, regulation or rule; or

14                   b.       limiting or expanding in any way any right the State may otherwise have  
15 to obtain information, documents or testimony from Bayer pursuant to any applicable state  
16 law, regulation or rule, or any right Bayer may otherwise have to oppose any subpoena, civil  
17 investigative demand, motion, or other procedure issued, served, filed, or otherwise employed  
18 by the State pursuant to any such state law, regulation, or rule.

19                                   **XIII. NOTICES UNDER THIS CONSENT**

20           **13.1.** Any notices that must be sent to the State or to Bayer under this Consent shall  
21 be sent by overnight United States mail. The documents shall be sent to the following  
22 addresses:  
23

24 ///

25 ///

26 ///

1 *For the MSWG:*

Suzanne D. Sonneborn

2 Assistant Attorney General, Consumer Protection Division

G Mennen Williams Building, 6<sup>th</sup> Floor

3 525 West Ottawa Street

Post Office Box 30213

4 Lansing, Michigan 48909

Telephone: 517.335.0855

5 Facsimile: 517.335.1935

6 David Anthony Hart

Assistant Attorney General

7 1162 Court Street NE

Salem, Oregon 97301-4096

8 Telephone: 503. 947-4333

Facsimile: 503. 378-5017

9 *For Bayer:*

10 Chief Legal Officer

Bayer Corporation

11 100 Bayer Road

Pittsburgh, Pennsylvania 15205

12 Telephone: 412.777.5774

Facsimile: 412.777.4417

13 and

14 Kristin Graham Koehler, Esquire

15 Sidley Austin LLP

1501 K Street, N.W.

16 Washington, D.C. 20005

Telephone: 202.736.8359

17 Facsimile: 202.736.8711

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1 IT IS SO ADJUDGED AND ORDERED:

2 DATED this 23 day of JAN, 2007.

3  
4 /s/ Kimberly Prochnau  
5 SUPERIOR COURT JUDGE  
6 Commissioner

7 **SIGNATURES**  
8 **FOR BAYER:**

9 By: <u>George J. Lykos</u> 10 George Lykos 11 Chief Legal Officer 12 Bayer Corporation 13 100 Bayer Road 14 Pittsburgh, PA 15205 15 412.777.5774	16 Date: <u>January 17, 2007</u>
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1 Approved as to form:

2 By:

3 Bert W. Markovich  
4 Bert W. Markovich, WSBA #13580  
5 Schwabe, Williamson & Wyatt, P.C.  
6 U.S. Bank Centre  
1420 Fifth Avenue, Suite 3010  
Seattle, WA 98101-2339  
(206) 622-1711

Date:

January 11, 2007



1 **Approved as to form:**

2  
3 By: Kristin Graham Koehler  
4 Kristin Graham Koehler, Partner  
5 Sidley Austin LLP  
6 1501 K Street, N.W.  
7 Washington, D.C. 20005  
8 Telephone: 202.736.8359

Date: January 17, 2007

1 ATTORNEY GENERAL

2  
3  
4 ROBERT A. LIPSON, WSBA #11889  
5 Assistant Attorney General  
6 Consumer Protection Division  
7 800 5<sup>th</sup> Ave., Suite 2000  
8 Seattle, Washington 98104  
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1/19/07  
DATE