

# BAYCOL

MASTER FILE NO. 0247408

IN RE: TEXAS SECOND REGION  
BAYCOL LITIGATION

§ IN THE DISTRICT COURT OF  
§  
§ HARRIS COUNTY, TEXAS  
§  
§ 295TH JUDICIAL DISTRICT

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## PLAINTIFFS' MASTER INTERROGATORIES TO BAYER CORPORATION AND BAYER AG

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Pursuant to Texas Rule of Civil Procedure 197, Plaintiffs serve their Master Interrogatories on Bayer Corporation and Bayer AG. Bayer Corporation and Bayer AG shall answer the following interrogatories separately and fully in writing under oath.

### Definitions

In answering the following Interrogatories, please be advised that the following terms have the following respective meanings:

“**You**,” “**your**” or “**Defendant**” refers to the defendant as well as its agents and representatives, including investigators, predecessors, subsidiaries, divisions, and affiliates.

“**Your Answer**” and “**Defendant’s Answer**” refers to the latest answer filed by Defendant.

“**Document**” shall be construed as broadly as possible to include, without limitation, all originals and all non-identical copies of all written, typed, recorded or graphic matter, as well as all attachments, agenda, and appendices thereto, of any nature or description whatsoever, wherever located, and in whatever form or condition, including, but not limited to all letters, correspondence, telegrams, telexes, memoranda, notes, marginal notations, summaries or other records of either personal or telephonic conversations, summaries or other records of meetings or conferences, summaries or other records of negotiations, or discussions of any kind, diaries, diary entries, calendars, appointment books, time records, visitor records, work records, telephone bills, and records, expense records, travel and entertainment records, inspections, estimates, reports, journals, journal entries, ledgers, ledger entries, worksheets, workpapers,

accounting records, bank records, bank statements, canceled checks, check stubs, check books, deposit receipts, employee records, payroll records, drafts, invoices, fee statements, books, articles, magazines, circulars, trade letters, press clippings, surveys, statistical data, graphs, maps, charts, transcripts, transcripts of hearings, transcripts of testimony, microfilm, microfiche, voice recordings, video recordings, tape or disc recordings, film, photographs, punch cards, programs, statistical data, electronic recordings, e-mails and any other data compilations for which information can be obtained or translated and all other “documents and things” under Rule 192.3(b) of the TEXAS RULES OF CIVIL PROCEDURE.

1. “**Person**” refers to any individual, association, partnership, firm, corporation, or other entity.
2. “**Medical services**” includes, but is not limited to, medical, psychiatric, psychological and/or emotional examination, testing, diagnosis and/or treatment of any sort.
3. “**Incident**” refers to the first date on which you claim to have experienced any symptoms which you allege were caused by the ingestion of Baycol for which you are claiming damages in this lawsuit.
4. “**Medicine**” or “**Baycol**” refers to the drug cerivastatin sodium.
5. “**Identify,**” with respect to a person, means to state that person’s full name, present or last known residence or business address, and title or position.
6. “**Identify,**” with respect to referring to any business or legal entity (which includes, without limitation, corporations, partnerships, associations, d/b/a’s and enterprises), means to give, to the extent known, the entity’s full name. Once a person has been identified in accordance with this subparagraph, only the name of that person need be listed in response to subsequent discovery requesting the identification of that person means to state its full name and present or last known address.
7. “**Identify,**” with respect to a document, means to state the following information, where applicable:
  - (a) The type of document, *e.g.*, letter, memorandum, note, invoice;
  - (b) The date on which the document was prepared;
  - (c) The document’s author or the person who prepared or compiled it;

- (d) The person(s) to whom the document was addressed and sent;
- (e) The document's present location and custodian, or, if it is no longer available, the date and reason it became unavailable.

11. The term "**communication**" means the transmittal of information (in the form of facts, ideas, inquiries or otherwise). This includes both written and non-written records of oral communications.

12. The terms "**and**," "**or**" and "**and/or**" shall be construed either disjunctively or conjunctively as necessary to bring within the scope of the discovery request all responses that might otherwise be construed to be outside the scope.

13. The term "**relating to**" includes referring to, relating to, embodying, connected with, commenting on, responding to, showing, describing, analyzing, reflecting, evidencing or constituting.

14. The term "**on-going studies**" shall mean any toxicological, clinical, or epidemiological research pertaining to the potential health consequences of using Baycol, alone or in combination with any other substances, and which research has not yet been concluded.

15. The term "**Manufacturing/Marketing period**" shall mean a period described as beginning with the earlier of the date that you instituted or sponsored the first scientific study, the date you submitted the investigation new drug application, the date you submitted the new drug application and ending with August 8, 2001.

## **Instructions**

1. Should you fail to answer any Interrogatory, you are requested to provide an explanation for the reason, if any, that no answer is being given.

2. As to any Interrogatory that you refuse to answer in whole or in part, for any reason, state the grounds for your refusal to answer. When you believe that a complete answer to a particular Interrogatory or part thereof is not possible, answer such Interrogatory to the extent possible and furnish a statement explaining the reason for your inability to answer further.

3. These Interrogatories shall be deemed continuing in nature pursuant to Rule 193.5 of the TEXAS RULES OF CIVIL PROCEDURE, so as to require you to serve supplemental answers upon the attorneys of record for Defendant if you later obtain information upon the basis of which: i) you know that an answer was incorrect when made; or ii) you know that an answer, though correct when made, is no longer true, and the circumstances are such that a failure to amend your answer is in substance a knowing concealment.

4. To the extent that the information sought in any Interrogatory is incorporated or contained in a document, please specifically identify the document.

5. When an interrogatory ask you to “identify” communications, please state the time and place of the communication, the person involved in the communication and the details of what was communicated. If the communication was in writing, you may attach the writing in lieu of providing a written description of the communication or you may provide a specific reference to Bates number(s) of documents previously provided.

## **INTERROGATORIES**

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### **INTERROGATORY NO. 1**

Please identify each individual you anticipate calling to testify in the trial of this cause either by deposition or in person.

**ANSWER:**

### **INTERROGATORY NO. 2**

Please identify (full name, current address, and current telephone number) all consulting experts whose mental impressions or opinions have been reviewed by a testifying expert. For each individual identified, please state the expert's qualifications to consult as an expert, the subject matter on which the expert has or will be consulted, the substance of the opinions or impressions of the expert which have been reviewed by a testifying expert, and the name of each testifying expert who has reviewed the opinions and impressions of this expert.

**ANSWER:**

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### **INTERROGATORY NO. 3**

For the Manufacturing/Marketing period, please identify all detailmen or sales representatives who were responsible for providing information or assistance concerning Baycol to physicians or pharmacies in Texas.

**ANSWER:**

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### **INTERROGATORY NO. 4**

Did you ever conduct any animal and/or clinical studies that examined the potential for Baycol used by itself, or in combination with any other substance, to cause (a) rhabdomyolysis; and/or (b) myopathy; and/or (c) myositis; and/or (d) elevated CK's; and/or (e) kidney damage; and/or (f) any other potential harm to users of Baycol. If so, please summarize the findings.

- a. Describe the studies.
- b. When were the studies conducted?
- c. Did any of those studies indicate that the use of Baycol, used by itself or in combination with any other substance, could potentially cause any of the injuries or health problems described above?
- d. If any testing revealed possible injury to humans from the use of Baycol, please describe in narrative form what specific steps were taken in response to each study to inform the FDA about potential harmful effects of the use of Baycol; and when those steps were taken.
- e. If any testing revealed possible injury to humans from the use of Baycol, please describe in narrative form what specific steps were taken in response to each study to inform physicians, including the plaintiff's treating physician, about potential harmful effects of the use of Baycol, and when those steps were taken.
- f. If any testing revealed possible injury to humans from the use of Baycol, please describe in narrative form what specific steps were taken in response to each study to inform detail people or sale representatives about potential harmful effects of the use of Baycol, and when those steps were taken.
- g. If any testing revealed possible injury to humans from the use of Baycol, please describe in narrative form what specific steps were taken to inform the general public and prospective users of Baycol about potential harmful effects of the use of Baycol, and when those steps were taken.
- h. If any testing revealed possible injury to humans from the use of Baycol, please describe in narrative form what specific steps were taken to inform any companies in the business of manufacturing gemfibrozil about potential harmful effects of the use of Baycol, and when those steps were taken.
- i. If any testing revealed possible injury to humans from the use of Baycol, please describe in narrative form what specific steps were taken to inform any companies engaged in co-marketing of Baycol about potential harmful effects of the use of Baycol, and when those steps were taken.

**ANSWER:**

**INTERROGATORY NO. 5**

When did you first determine that Baycol had a higher representation of (a) rhabdomyoysis; and/or (b) myopathy; and/or (c) myositis; and/or (d) elevated CK's than other statins?

**ANSWER:**

**INTERROGATORY NO. 6**

When did you first determine that Baycol in combination with generic gemfibrozil (or Lopid) had a higher representation of (a) rhabdomyoysis; and/or (b) myopathy; and/or (c) myositis; and/or (d) elevated CK's than other statins?

**ANSWER:**

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**INTERROGATORY NO. 7**

What was your first source of information that Baycol had a higher representation of (a) rhabdomyolysis; and/or (b) myopathy; and/or (c) myositis; and/or (d) elevated CK's than other statins.

**ANSWER:**

**I. INTERROGATORY NO. 8**

What was your first source of information that Baycol in combination with generic gemfibrozil (or Lopid) had a higher representation of (a) rhabdomyolysis; and/or (b) myopathy; and/or (c) myositis; and/or (d) elevated CK's than other statins.

**ANSWER:**

**INTERROGATORY NO. 9**

Please describe the efforts made by you to stop or reduce co-prescription of Baycol and generic gemfibrozil (or Lopid), and state when and by whom and in what manner you made each such effort.

**ANSWER:**

**INTERROGATORY NO. 10**

Please identify the efforts by you to determine whether physicians were following the Baycol package insert with regard to co-prescription of Baycol and generic gemfibrozil (or Lopid) and/or dosing.

**ANSWER:**

**INTERROGATORY NO. 11**

Please identify all individuals who had involvement in making substantive decisions regarding the preparation of, or changes to, the package inserts for Baycol.

**ANSWER:**

**INTERROGATORY NO. 12**

For the time period January 1, 1997 to August 8, 2001, please identify the individuals involved with training sales representatives or detailmen concerning the appropriate use of Baycol.

**ANSWER:**

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**INTERROGATORY NO. 13**

For the Manufacturing/Marketing period, please identify the individuals who were involved in communicating with physicians in Texas concerning the appropriate use of Baycol and any potential health hazards associated with the use of Baycol.

**ANSWER:**

**INTERROGATORY NO. 14**

For the Manufacturing/Marketing period, please identify the individuals who were involved with marketing or promoting Baycol in Texas.

**ANSWER:**

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**INTERROGATORY NO. 15**

Please identify your "Opinion Leaders" for Baycol for the years 2002, 2001, 2000, 1999, and 1998.

**ANSWER:**

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**INTERROGATORY NO. 16**

Please list all "ongoing studies" concerning the potential for Baycol used by itself, or in combination with any other substance, to cause (a) rhabdomyolysis; and/or (b) myopathy; and/or (c) myositis; and/or (d) elevated CK's.

**ANSWER:**

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**INTERROGATORY NO. 17**

Please identify the advertising, public relations or communications professionals (whether employed inside or outside of the company) who were consulted concerning the following issues:

- a. The content of package inserts used for Baycol;
- b. The content of any promotional material for Baycol directed at physicians;
- c. The content of any promotional material for Baycol directed at the ultimate users of the drugs;
- d. The decision to remove Baycol from the market and the contents of the communications concerning such decision;
- e. The preparation of any witness testimony concerning the safety of Baycol;
- f. The publication or promotion of any books or articles concerning statins;
- g. The development or implementation of "grass roots" efforts to assist in marketing Baycol against criticism, including the effort to develop and train a network of spokes people.
- h. The performance of any "focus group" research regarding the promotion or use of Baycol.

**ANSWER:**

**INTERROGATORY NO. 18**

Please identify the individuals and/or entities, including but not limited to lobbyist, who communicated with the FDA, the legislative branch, and/or the executive branch of the United States Government on Bayer's behalf regarding the approval of Baycol or continued use of Baycol after its approval.

**ANSWER:**

**INTERROGATORY NO. 19**

Please identify any individual or company with whom you collaborated or cooperated in any way for the purpose of publishing a medical or scientific article pertaining to Baycol.

**ANSWER:**

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**INTERROGATORY NO. 20**

Please list and describe the databases that your company used to contain, compile or process information pertaining to communications from any source related to adverse health affects potentially associated with the use of Baycol.

**ANSWER:**

**INTERROGATORY NO. 21**

Please specify the date and amount of each financial contribution, grant, donation or other financial payment to each of the following:

- a. Any member of the FDA Advisory Panel for Baycol;
- b. National Lipid Association

**ANSWER:**

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**INTERROGATORY NO. 22**

Please list each research group, support group, or institution (public or private) to which your company has given any money to perform any cholesterol related research. Please specify the date and amount of each contribution.

**ANSWER:**

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**INTERROGATORY NO. 23**

Please list all entities with whom you have ever had an agreement concerning the marketing of Baycol in Texas, to be used by itself or in combination with any other substance.

**ANSWER:**

**INTERROGATORY NO. 24**

Please identify the entity(ties) that you believe manufactured the drug which was ultimately sold to Plaintiff.

**ANSWER:**

**INTERROGATORY NO. 25**

What is the legal relationship between Bayer Corporation and the following:

- a. Bayer AG
- b. SmithKline Beecham
- c. GlaxoSmithKline

**ANSWER:**