

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: BAYCOL PRODUCTS LITIGATION

MDL No. 1431

(MJD)

This Document Relates to All Action

Pretrial Order No. 11

Having considered the written submission of the parties with respect to Plaintiffs' motion for a protective order pursuant to Rule 23(d)(2), the comments of counsel at oral argument on March 18, 2002, the letter of interest submitted by the FDA, and the applicable law, IT IS HEREBY ORDERED:

I. The Drug Safety Department of Bayer Corporation will modify the forms of letter and release used when contacting consumer reporters to collect adverse drug experience data relating to spontaneous consumer reports of adverse events associated with Baycol to reflect more clearly that the information sought is only that pertinent to the adverse drug experience reported by the consumer. A sample consumer letter and release, with the clarifying language indicated in bold face, are attached to this Order.

II. Absent further Court order, counsel for Bayer Corporation will not use or have access to patient medical records collected by Bayer's Drug Safety Department relating to spontaneous consumer reports of adverse events associated with Baycol. In the event that plaintiffs in litigation relating to Baycol obtain through court-supervised discovery and put at issue the contents of consumer medical records collected by Bayer Drug Safety as part of its investigation of Baycol adverse drug experience

reports, counsel for Bayer Corporation may seek and will be permitted access to and use of such medical records. This paragraph shall not prevent the use by counsel for Bayer Corporation of other adverse event reporting data.

III. Professor Roger Haydock¹ is hereby appointed under Rule 53 of the Federal Rules of Civil Procedure as Special Master in the Baycol Products Liability Litigation, MDL No. 1431.

a. The Special Master is hereby directed to ensure that Bayer Corporation complies with this Order to the extent that counsel for Bayer Corporation does not obtain access to the information obtained by Bayer Drug Safety for use in this litigation, without prior Court approval.

b. The Special Master shall have the rights, powers, and duties provided in Rule 53 and may adopt such procedures, as are not inconsistent with the rule or with this or other orders of the Court. Until directed otherwise by the Special Master or the Court, in the event a dispute arises as to the use of information obtained by Bayer Drug Safety, the parties must identify the document or other communication at issue. The Special Master shall make findings of fact and conclusions of law with respect to the matters presented by the parties and shall report expeditiously to the Court pursuant to Rule 53(e) as applicable in nonjury actions.

¹ This Court has appointed Professor Haydock as Special Master in at least ten prior cases that involved complex issues: *80th South Eighth Street Limited v. W. R. Grace & Co. et al.*, Civil No. 3-88-323; *IBM v. Seagate Technology et al.*, Civil No. 3-91-630; *Bossworks, Inc. v. Ionics Inc.*, Civil No. 3-94-1164; *SPX Corp. v. Computer Aided Service*, Civil No. 3-94-565; *Shimek et al. v. Louis Berkman Company*, Civil No. 3-96-768; *CFM Majestic v. Heat-N-Glo*, Civil No. 3-96-929; *Knopik v. Amoco Corporation et al.*, Civil No. 97-1134 (MJD/AJB); *Travelers Express Company, Inc. v. American Express et al.*, Civil No. 3-94-234; *Amtrail, Inc. v. C.O. Lynch Enterprises*, Civil No. 99-814 (MJD/JGL); *Ecolab v. Gardner*, Civil No. 98-2294 (MJD/JGL).

c. The Special Master does not act as an advocate, representative, fiduciary or counsel for any party and has no formal coercive authority to make any binding decisions or recommendation or to compel the making of any agreement or the granting of any concession.

d. The fee for the Special Master shall be \$300.00 per hour. This fee shall be paid to the Special Master upon receipt of the Special Master's invoice. The fee shall be borne by the mutual agreement of the parties. In the event the parties are not able to agree, after due notice and hearing the Court shall allocate responsibility for the payment of the Special Master's fee amongst the parties.

e. Failure to comply with any part of this Order shall subject the parties to appropriate sanctions to include assessment of costs against the delinquent party, dismissal or other relief the Court may deem appropriate.

IV. Plaintiffs' motion for protective order and request for related relief is otherwise DENIED.

DATED:

Michael J. Davis
United States District Court

Dear Ms. _____ :

Thank you for notifying us about the adverse events

which occurred during treatment with Baycol.

To obtain more information concerning the adverse events, Bayer would like to contact your prescribing physician. Please complete the enclosed consent form. This will authorize Bayer to contact the prescribing physician to request medical information about the adverse events. Return the completed form in the enclosed prepaid envelope. Any information you can provide **concerning your adverse experience** will assist us in monitoring the safety of our drugs in the general population.

If you have any questions, please contact Bayer Drug Safety Assurance toll-free at 888-765-3203 (Monday through Friday, 8 am to 5 pm ET).

Thank you.

Enclosures: Patient consent form
Prepaid envelope

Prescribing Physician's:

Name:

Address:

Telephone Number:

I, the undersigned, do hereby give permission for Bayer Corporation to contact my physician to collect further information about the adverse events I experienced during the use of Baycol. I also grant permission for the physician named above to release to **Bayer Corporation** medical information **pertinent to** the adverse events **that I have reported in connection with my use of Baycol.**

Patient's Signature

Date Signed

Please return this completed form in the enclosed prepaid envelope.