

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA**

In re: BAYCOL PRODUCTS LITIGATION)	MDL No. 1431 (MJD/JGL)
)	
)	SPECIAL MASTER
)	RECOMMENDATION
This Document Relates To: All Actions)	AND ORDER NO. 1
)	

Pursuant to Pretrial Order No. 11 ("PTO 11"), this matter was referred by the Court to Special Master Roger Haydock to establish procedures ("a Wall") to assure that counsel do not access or use medical records collected by Bayer Corporation's Drug Safety Department relating to spontaneous consumer reports of adverse events associated with Baycol ("Bayer") in furtherance of this litigation.

At the Special Master's direction and with his assistance, the parties have met and conferred to set procedures that establish and ensure maintenance of the Wall;

ACCORDINGLY, without waiving positions, argument, or defenses taken before Judge Davis and without waiving arguments and objections or defenses related to discovery of the past, present, and future use of medical records, plaintiffs and Bayer hereby agree and stipulate at the recommendation of the Special Master that:

1. Certain guidelines, rules, and procedures are necessary to establish and maintain the Wall.
2. Until further order of Judge Davis, Bayer's counsel, whether in-house, outside, or specially retained, and their firms, partners, associates, employees, contractors, and experts shall not have access to medical records collected by Bayer in investigating spontaneous consumer reports of adverse events associated with Baycol ("protected medical records").

3. The protected medical records are contained in and intermixed with other documents and papers including, but not limited to, adverse event reports, MedWatch reports, and comments or complaints which are the subject of outstanding discovery requests and are not addressed in PTO 11 (“non-Wall information”).
4. In order to facilitate discovery of the non-Wall information, while simultaneously maintaining the Wall, the Special Master shall hire a legal assistant to review the files containing both protected medical records and non-Wall information. The legal assistant’s salary or hourly rate shall be charged to and equally shared by the Plaintiffs and Bayer.
5. Bayer shall provide to the Special Master and the legal assistant a list of files containing spontaneous consumer reports of adverse events, which may contain protected medical records. Bayer also will provide the Special Master, the legal assistant, and plaintiffs' counsel with a list of all Drug Safety personnel who, in the course of their duties, would have access to the spontaneous consumer report files.
6. The legal assistant shall review Bayer’s files to identify protected medical records. Once identified, the protected medical records shall be logged and shall be placed in an envelope marked:

Restricted Access by
Order of Judge Michael J. Davis

The envelope containing the protected medical records shall be sealed.

7. A sign-out sheet will be attached to each envelope containing protected medical records. Any person accessing the protected medical records shall be required to: (a) sign and date the sheet, designate the person's title and affiliation, and note if the medical record is copied, transmitted, or reported to any person outside of Bayer Drug Safety (and if so, identify by name, title, and affiliation the person to whom the medical record was transmitted); and (b) reseal the envelope before returning the protected medical records to the master file.
8. Protected medical records received subsequent to the establishment of the Wall shall be recorded on a separate log maintained by a member of Bayer's Drug Safety staff, whose identity will be provided to the Special Master. The protected medical records will be placed in a sealed envelope and thereafter will be subject to the access provisions set forth in Paragraph 7.

9. Once the legal assistant has segregated the protected medical records, the non-Wall information can be accessed and reviewed by Bayer's counsel in responding to discovery demands and for use in this and other litigation.
10. Once a month, the legal assistant retained by the Special Master will review the log on each envelope containing protected medical records and the log that tracks incoming protected medical records. The legal assistant will compare these logs with the master list of Bayer Drug Safety employees and report access by any person not appearing on the list of employees to the Special Master, who thereafter will provide notice to the parties and resolve any disputes relating thereto.

ORDER

The Special Master, in accord with the directions of Pretrial Order No. 11 and Rule 53 of the Federal Rules of Civil Procedure, orders the parties to establish as soon as practicable and to maintain continuously the Wall as set forth in paragraphs 1 through 10 of this Recommendation and Stipulation.

Nothing in this Order governs the method, manner, and means by which the parties may discover or object to discovery related to who has accessed, will access, has used, or will use medical records and non-Wall information; and nothing in this order acts as a waiver of any positions, arguments, defenses, or objections that were raised before Judge Davis which resulted in or led to the issuance of PTO 11.

Dated: May 11, 2002

_____/s/_____
Roger Haydock
Special Master, MDL No. 1431