

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: BAYCOL PRODUCTS LITIGATION

MDL No. 1431

(MJD/JGL)

This Document Relates to All Actions

Pretrial Order No. 5

**STIPULATION AND PROTECTIVE ORDER
REGARDING CONFIDENTIAL INFORMATION**

WHEREAS pursuant to Fed. R. 26(c), the Court deems it appropriate to limit disclosure of certain confidential information, as set forth below, and the parties to this action, by counsel, have stipulated and agreed to give effect to the stipulations set forth below.

IT IS HEREBY ORDERED THAT:

1. **Discovery Material.** This Order applies to all products of discovery and all information derived therefrom, including, but not limited to, all documents and deposition testimony and any copies, excerpts or summaries thereof, obtained by any party pursuant to the requirements of any court order, requests for production of documents, requests for admissions, interrogatories or subpoena.
2. **Confidential Discovery Material.** Discovery material containing trade secrets, or other confidential or proprietary research, development, manufacturing or commercial or business information may be designated as "Confidential." Without prejudice to the right of a party to object to the production of the following information or of a party to seek production, the information subject to such designation shall include the producing party's:
 - (a) Customer names;

(b) Proprietary licensing, distribution, marketing, design, development, research and manufacturing information regarding products and medicines, whether previously or currently marketed or under development;

(c) Clinical studies;

(d) Information concerning competitors;

(e) Production information;

(f) Personnel records and information;

(g) Financial information not publicly filed with any federal or state regulatory authorities; and

(h) Information submitted to any governmental or regulatory agency, which information is exempt from public disclosure.

3. (a) The parties agree that discovery material will be used only for the litigation of actions under In re: BAYCOL PRODUCTS LITIGATION, MDL No. 1431 ("Litigation"), including any appeals of this litigation, and for any other action brought by or on behalf of a former Baycol user alleging injuries or other damages therefrom, so long as all parties have agreed to be governed by the terms of this Order, or another judicially approved protective order that is the substantial equivalent to this Order. Confidential discovery material will not be disclosed except in accordance with paragraphs 3.b. and 6.

(b) Prior to being given access to confidential discovery material, any person falling within subparagraphs 6(a)(vi) or 6(a)(viii) shall be provided with a copy of this Order and shall execute a copy of the Endorsement of Stipulation and Protective Order, attached as Exhibit A. Counsel providing such access to confidential discovery material shall retain

copies of the Endorsement(s) of Stipulation and Protective Order and shall provide them to counsel producing confidential discovery material as provided below. For testifying experts, a copy of the Endorsement of Stipulation and Protective Order executed by the testifying expert shall be furnished to counsel for the party who produced the confidential discovery material to which the expert has access, either at the time the confidential discovery material is provided to the testifying expert, or at the time the expert's designation is served, whichever is later.

4. Confidential discovery material, if a writing, shall have the following language stamped on the face of the writing, or shall otherwise have such language clearly marked:

**CONFIDENTIAL
SUBJECT TO PROTECTIVE ORDER**

Such stamping or marking will take place prior to production by the producing person, or subsequent to selection by the receiving party for copying but prior to the actual copying if done expeditiously. The stamp shall be affixed in such manner as not to obliterate or obscure any written matter. In the case of deposition testimony, confidentiality designations shall be made within 30 days after the transcript has been received by counsel making the designation, and shall specify the testimony being designated confidential by page and line number(s). Until the expiration of such 30-day period, the entire text of the deposition, including exhibits, shall be treated as confidential under this Order. In the event that the producing person or party inadvertently fails to designate discovery material as confidential in this or any other litigation, it may make such a designation subsequently by notifying all parties to whom such discovery material was produced, in writing as soon as practicable. After receipt of such notification, the parties

to whom production has been made shall treat the designated discovery material as confidential, subject to their right to dispute such designation in accordance with paragraph 7.

5. Confidential discovery material shall be used solely for the purposes of this litigation and for no other purpose without prior written approval from the Court or the prior written consent of the producing person or party. All persons receiving or given access to confidential discovery material in accordance with the terms of this Order consent to the continuing jurisdiction of the Court for the purposes of enforcing this Order and remedying any violations thereof.

6. (a) Confidential discovery material shall not be disclosed to anyone other than the following categories of persons:

(i) The Court (and any appellate court), including court personnel, jurors, and alternate jurors only in the manner provided in paragraph 9 below.

(ii) If produced by Plaintiffs, Defendants' in-house counsel, paralegals and clerical support staff, and outside counsel, including any attorneys employed by or retained by Defendants' outside counsel who are assisting in connection within this litigation, and the paralegal, clerical, secretarial and other staff employed or retained by such outside counsel or retained by the attorneys employed by or retained by Defendants' outside counsel. To the extent a Defendant does not have in-house counsel, it may designate two individuals employed by such Defendant (in addition to outside counsel) to receive Confidential Discovery Materials produced by Plaintiffs.

(iii) If produced by Defendants, the named Plaintiffs to this litigation,

Plaintiffs' attorneys in this litigation, including the paralegal, clerical, secretarial and other staff employed or retained by such counsel, as well as Plaintiffs' attorneys in other filed litigation alleging injuries or damages resulting from the use of Baycol, including their paralegal, clerical, secretarial and other staff employed or retained by such counsel, provided that such counsel have agreed to be governed by the terms of this Order or another protective order that is the substantial equivalent of this Order. (In connection with disclosure to an attorney not bound by this Order or its substantial equivalent, the producing party shall be given 10 days notice of the proposed disclosure in order to determine whether the party to whom disclosure is contemplated is governed by a "substantially equivalent" order. If the producing party does not object within that 10-day period, the disclosure may be made. If the producing party objects, no disclosure shall be made until the matter is resolved by the Court.)

(iv) If produced by any Defendant, outside counsel for any other Defendant, including any attorneys employed by or retained by any other Defendant's outside counsel who are assisting in connection with the this litigation, and the paralegal, clerical, secretarial and other staff employed or retained by such outside counsel.

(v) Court reporters (including persons operating video recording equipment at depositions) and persons preparing transcripts of testimony to the extent necessary to prepare such transcripts.

(vi) Retained experts, advisors and consultants, including persons directly employed by such experts, advisors and consultants, (collectively "Experts") but only to the extent necessary to perform their work in connection with this litigation.

(aa) Prior to a Plaintiff or his/her/their counsel disclosing any confidential discovery material to an expert who is or has been an employee, officer, director, contractor, subcontractor or consultant at any time since January 1, 2000, of any entity that is engaged in the development, marketing or sale of prescription pharmaceuticals (excluding prescription biologics), such Plaintiff(s) or his/her/their counsel shall promptly notify the producing or designating person or party's counsel, including with such notification a copy of the expert's curriculum vitae. Within 5 business days of receiving such notification and curriculum vitae, the producing or designating person or party's counsel shall notify Plaintiff's counsel whether the producing or designating person or party objects to the disclosure of confidential discovery material to the proposed expert. Any such objection shall be made in good faith and on reasonable grounds. If an objection is made and not resolved by the parties, the party objecting to disclosure shall file a motion (or letter to the Court) in support of that objection within 5 business days of the failure to reach resolution. Under no circumstances shall confidential discovery material be disclosed to an expert who is or has been an employee, officer, director, contractor, subcontractor or consultant at any time since January 1, 2000, of any entity that is engaged in the development, marketing or sale of prescription pharmaceuticals (excluding prescription biologics), the objection is withdrawn, the Court permits disclosure, or the producing or designating person or party fails to object to such disclosure or file a motion in support of their objection within the times specified herein (or other schedule agreed among the parties).

(bb) Prior to any Defendant or its counsel disclosing any

confidential discovery material produced by another Defendant to an expert who is or has been an employee, officer, director, contractor, subcontractor or consultant at any time since January 1, 2000, of any entity that is engaged in the development, marketing or sale of prescription pharmaceuticals (excluding prescription biologics), the Defendant wishing to make such disclosure or its counsel shall promptly notify counsel for the producing Defendant, including with such notification a copy of the expert's curriculum vitae. Within 10 business days of receiving such notification and curriculum vitae, counsel for the producing Defendant(s) shall notify the counsel for the Defendant who wishes to make the disclosure whether they object to the disclosure of confidential discovery material to the proposed expert. Any such objection shall be made in good faith and on reasonable grounds. If an objection is made and not resolved by the parties, the party making the objection shall file a motion (or letter to the Court) in support of that objection within 10 business days of the failure to reach resolution. Under no circumstances shall confidential discovery material produced by another Defendant be disclosed to an expert who is or has been an employee, officer, director, contractor, subcontractor or consultant at any time since January 1, 2000, of any entity that is engaged in the development, marketing or sale of prescription pharmaceuticals (excluding prescription biologics), unless and until the parties resolve the matter, the objection is withdrawn, the Court permits disclosure, or the parties who oppose the disclosure fail to object to such disclosure or fail to file a motion in support of their objection within the times specified herein (or other schedule agreed among the parties).

(vii) The persons who authored the confidential discovery material or who

received such confidential discovery material in the ordinary course of business.

(viii) Such persons as the undersigned counsel shall consent to in writing before the proposed disclosure.

(b) All parties and their respective counsel, paralegals and the employees and assistants of all counsel receiving discovery material shall take all steps reasonably necessary to prevent the disclosure of confidential discovery material other than in accordance with the terms of this Order.

(c) Disclosure of confidential discovery material other than in accordance with the terms of this Order may subject the disclosing person to such sanctions and remedies as the Court may deem appropriate, including without limitation, contempt, injunctive relief and damages.

7. (a) If at any time a party wishes for any reason to dispute a designation of discovery material as confidential hereunder, such party shall notify the designating party of such dispute in writing, specifying by exact document numbers the discovery material in dispute and the precise nature of the dispute with regard to each such document or other discovery material. If the parties are unable amicably to resolve the dispute, the proponent of confidentiality may apply by motion to the Court for a ruling as to whether the designated discovery material may, in accordance with this Order, properly be treated as confidential, provided such motion is made within 30 days from the date on which the parties, after good faith attempt, cannot resolve the dispute or such other time period as the parties may agree. The designating party shall have the burden proof on such motion to establish the propriety of its confidentiality designation.

(b) All discovery material designated as confidential under this Order, whether or not such designation is in dispute pursuant to subparagraph 7(a) above, shall retain that designation and be treated as confidential in accordance with the terms hereof unless and until:

(i) the time period for filing a Motion for Protective Order set in paragraph 10(a) has expired without the filing of any such Motion.

(ii) the producing party agrees in writing that the material is no longer confidential and subject to the terms of this Order; or

(iii) ten days after the expiration of the appeal period of an Order of this Court that the matter shall not be entitled to confidential status (or such longer time as ordered by this Court) if the Order on appeal is not subject to a stay.

(c) The parties shall negotiate in good faith before filing any motion relating to this Order.

8. Any non-party who is producing discovery materials in this litigation may subscribe to and obtain the benefits of the terms and protections of this Order by designating as “Confidential” the discovery materials that the non-party is producing as set forth in paragraphs 2 and 4.

9. Any confidential discovery material that is filed with the Court, and any pleading, motion or other paper filed with the Court containing or disclosing any such confidential discovery material shall be filed under seal and shall bear the legend:

"THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION
COVERED BY A PROTECTIVE ORDER OF THE COURT AND IS

SUBMITTED UNDER SEAL PURSUANT TO THAT PROTECTIVE ORDER. THE CONFIDENTIAL CONTENTS OF THIS DOCUMENT MAY NOT BE DISCLOSED WITHOUT EXPRESS ORDER OF THE COURT."

Said confidential discovery material and/or other papers shall be kept under seal until further order of the Court; however, said confidential discovery material and other papers filed under seal shall be available to the Court and counsel of record, and to all other persons entitled to receive the confidential information contained therein under the terms of this Order.

10. (a) Except as provided for herein, nothing in this Order shall prevent or restrict counsel for any party in any way from inspecting, reviewing, using or disclosing any discovery material produced or provided by that party, including discovery material designated as confidential.

(b) Nothing shall prevent disclosure beyond that required under this Order if the producing party consents in writing to such disclosure, or if the Court, after notice to all affected parties, orders such disclosure and that Order is not subject to an appellate stay within 20 days after it is issued.

(c) No disclosure pursuant to this paragraph 10 shall waive any rights or privileges of any party granted by this Order.

11. This Order shall not enlarge or affect the proper scope of discovery in this or any other litigation, nor shall this Order imply that confidential discovery material is properly discoverable, relevant or admissible in this or any of the litigation. Each party reserves the

right to object to any disclosure of information or production of any documents that the producing party designates as confidential discovery material on any other ground it may deem appropriate.

12. The entry of this Order shall be without prejudice to the rights of the parties, or any one of them, or of any non-party to assert or apply for additional or different protection.

13. All parties and counsel for such parties in this litigation shall make a good faith effort to ensure that their experts, employees and agents comply with this Order. In the event of a change in counsel, retiring counsel shall fully instruct new counsel of their responsibilities under this Order.

14. The terms of this Order shall survive and remain in effect after the termination of this litigation. The parties shall take such measures as are necessary and appropriate to prevent the public disclosure of confidential discovery material, through inadvertence or otherwise, after the conclusion of this litigation.

15. Within 30 days of the termination of this litigation (including any appeals) or such other time as the producing party may agree in writing, the parties shall return the confidential discovery material to counsel for the producing party. Outside counsel, however, shall not be required to return any pretrial or trial records regularly maintained by that counsel in the ordinary course of business, which records will continue to be maintained confidential in conformity with this Order.

16. If a receiving party or its counsel or expert is served with a subpoena or other process by any court, administrative or legislative body, or any other person or organization which calls for production of any confidential discovery material produced by

another party, the party to whom the subpoena or other process is directed shall not, to the extent permitted by applicable law, provide or otherwise disclose such documents or information until 10 business days after notifying counsel for the producing party in writing of all of the following: (1) the information and documentation which is requested for production in the subpoena; (2) the date on which compliance with the subpoena is requested; (3) the location at which compliance with the subpoena is requested; (4) the identity of the party serving the subpoena; and (5) the case name, jurisdiction and index, docket, complaint, charge, civil action or other identification number or other designation identifying the litigation, administrative proceeding or other proceeding in which the subpoena has been issued. The party, counsel or expert receiving the subpoena or other process shall cooperate with the producing party in any proceeding relating thereto.

17. Inadvertent production of documents subject to work-product immunity, the attorney-client privilege or other legal privilege protecting information from discovery shall not constitute a waiver of the immunity or privilege, provided that the producing party shall promptly notify the receiving party in writing of such inadvertent production. If reasonably prompt notification is made, such inadvertently produced documents and all copies thereof, as well as all notes or other work product reflecting the contents of such materials, shall be returned to the producing party or destroyed, upon request, and such returned or destroyed material shall be deleted from any litigation-support or other database. No use shall be made of such documents during depositions or at trial, nor shall they be disclosed to anyone who was not given access to them prior to the request to return or destroy them. The party returning such material then may move the Court for an order compelling

production of the material, but such motion shall not assert as a ground for entering such an order the fact or circumstances of the inadvertent production.

18. This Order does not restrict or limit the use of confidential discovery material at any hearing or trial, which is expected to be the subject of a further protective order and/or appropriate court orders. Prior to any hearing or trial at which the use of confidential discovery material is anticipated, the parties shall meet and confer regarding the use of the confidential discovery material. If the parties cannot agree, the parties shall request the Court to rule on such procedures.

19. This Order shall not prevent any persons bound hereby from making use of information or documents without the restrictions of this Order if the information or documents are lawfully in their possession and/or lawfully obtained through discovery in this litigation or in any other litigation alleging injuries or damages resulting from the use of Baycol in which such information was not designated as "Confidential" or subject to a protective order or court order as "Confidential" or subject to confidential treatment, or where there has been a final judgment (including any appeal therefrom) declaring that such information or documents are not confidential.

20. Nothing in this Order shall limit or circumscribe in any manner any rights the parties may have under common law or pursuant to any statute, regulation or ethical canon.

Dated: March 4, 2002

BY THE COURT:

//s//

Michael J. Davis
United States District Court

EXHIBIT A

ENDORSEMENT OF STIPULATION AND PROTECTIVE ORDER

I hereby attest to my Understanding that information or documents designated Confidential are provided to me subject to the Stipulation and Protective Order Regarding Confidential Information dated _____, _____ (the "Protective Order", in the above-captioned litigation; that I have been given a copy of and have read the Protective Order, and that I agree to be bound by its terms. I also understand that my execution of this Endorsement of Stipulation and Protective Order, indicating my agreement to be bound by the Protective Order, is a prerequisite to my review of any information or documents designated as confidential pursuant to the Protective Order.

I further agree that I shall not disclose to others, except in accord with the Protective Order, any confidential discovery material, in any form whatsoever, and that such confidential discovery material and the information contained therein may be used only for the purposes authorized by the Protective Order.

I further agree and attest to my understanding that my obligation to honor the confidentiality of such discovery material and information will continue even after this litigation concludes.

I further agree and attest to my understanding that, if I fail to abide by the terms of the Protective Order, I may be subject to sanctions, including contempt of court, for such failure. I agree to be subject to the jurisdiction of the United States District Court

for the District of Minnesota, for the purposes of any proceedings relating to enforcement of the Protective Order.

I further agree to be bound by and to comply with the terms of the Protective Order as soon as I sign this Agreement, whether or not the Protective Order has yet been entered as an Order of the Court.

Date:

By:

Subscribed and sworn to before me this

___ day of _____, 2002.

Notary Public