

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA**

Case No. 1:08-MD-01928-MIDDLEBROOKS/JOHNSON

IN RE TRASYLOL PRODUCTS LIABILITY
LITIGATION – MDL-1928

This Document Relates to All Actions

PRETRIAL ORDER NO. 4 RELATING TO CASE MANAGEMENT

In accordance with Local Rule 16.1B, the Parties respectfully request that the Court enter the following Case Management Order.

CASE MANAGEMENT AND SCHEDULING ORDER NO. 1

Any other actions filed, whether filed directly in the United States District Court for the Southern District of Florida or in any other United States District Court (whether by original filing or removal), that are related to this litigation (that is, civil actions seeking damages arising from the use of Trasylol) are hereby consolidated into one action (the “Consolidated Action”) for all pre-trial purposes, pursuant to Rule 42 of the Federal Rules of Civil Procedure and MDL Transfer Order dated April 7, 2008, under 28 U.S.C. § 1407.

This Order shall govern all cases (1) transferred to this Court by the Judicial Panel on Multidistrict Litigation, pursuant to its Orders of April 7, 2008 and May 5, 2008; (2) any tag-along actions subsequently transferred to this Court by the Judicial Panel on Multidistrict Litigation; and (3) all related cases originally filed in this Court or transferred or removed to this Court. This Order applies to all Plaintiffs in federal actions, and to Defendants Bayer Corporation; Bayer HealthCare Pharmaceuticals Inc. (hereinafter “BHCP”), as successor to Bayer Pharmaceuticals Corporation; Bayer HealthCare LLC; Bayer AG; and Bayer HealthCare AG (hereinafter “BHCAG”) in the federal actions in which each such defendant was properly served.

All subsequent Orders of this Court with the designation “All Actions” entered in MDL-

1928 shall likewise apply to all cases that are, or become, part of this MDL, regardless of whether that case was part of MDL-1928 when the Order was entered.

I. CAPTION.

All Orders, pleadings, motions and other documents served or filed in this Consolidated Action shall have the following caption:

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA**

Case No. 1:08-MD-01928-MIDDLEBROOKS/JOHNSON

IN RE TRASYLOL PRODUCTS LIABILITY
LITIGATION – MDL-1928

This Document Relates to All Actions

[OR

THIS DOCUMENT RELATES TO:

SESSUMS v. BAYER A.G., et al.,
Case No. 08-civ-80388]

The original of this Order shall be filed by the Clerk in each of the Trasylol Products Liability actions pending in this Court and a copy thereof shall be filed in each subsequently filed or transferred action, which is related to and consolidated with this action for pretrial purposes. The Clerk of Court will maintain docket and case files under this caption, and pursuant to the procedures set forth in Section IV, below.

II. STATUS CONFERENCES.

Prior to the case management conference held on May 16, 2008, the Parties through their respective counsel or representatives conferred on the issues addressed herein. A further status conference shall take place on _____, 2008 at ____ .m.

To minimize costs and facilitate manageable conferences, all Parties are not required to

attend but shall be represented at status conferences by Lead and/or Liaison Counsel. A Party will not, by designating an attorney to represent its interests at a status conference, be precluded from other representation during the litigation and attendance at the conference will not waive objections to jurisdiction, venue or service.

Future status conferences shall be held as directed by the Court. To aid the Court and the Parties in preparing for future conferences, Lead and/or Liaison Counsel for the Parties shall meet and confer at least ten (10) days prior to each future status conference to attempt to agree upon a proposed agenda for the conference. Not less than three (3) business days prior to the conference, the Parties shall submit a joint agenda that reports on the number of cases in the MDL and the number tagged for transfer, that lists all motions that have been fully briefed, and that identifies any issue that either or both Parties wish to raise with the Court. The Parties may submit at the same time separate statements of their positions on said issues. If the Parties agree that they would like the Court to take any action, the joint agenda shall so state. The agenda is intended to inform the Court of matters that the Parties desire to raise at the status conference, and the Court may amend or augment the agenda as it deems appropriate.

III. ADMISSION AND ORGANIZATION OF COUNSEL.

A) Admission of Counsel. Attorneys admitted to practice and in good standing of the bar of any United States District Court will be admitted to practice in this litigation upon the filing of a Notice of Appearance in (1) the Master File and (2) the particular action(s) in which they seek to appear. The requirements of Rule 4 of the Special Rules Governing the Admission and Practice of Attorneys (contained in the Local Rules of the United States District Court for the Southern District of Florida) are waived. Attorneys, upon filing of a Notice of Appearance, will be permitted to electronically receive Notices of Electronic Filing provided the Notice of Appearance includes a request to receive such Notices and provides an e-mail address for the Attorney. Attorneys admitted to practice in this litigation pursuant to this Section are authorized to file documents conventionally as this District does not currently have any mechanism allowing for electronic filing by attorneys located outside of the Southern District of Florida.

B) **Appointment of Plaintiffs' Steering Committee/Lead/Liaison Counsel.**

1) **Plaintiffs' Steering Committee**

Co-Lead Counsel

James R. Ronca
Anapol, Schwartz, Weiss, Cohan, Feldman & Smalley, PC
1710 Spruce Street
Philadelphia, PA 19103

Scott Love
Fleming & Associates, LLP
1330 Post Oak Blvd., Suite 3030
Houston, TX 77056

Liaison Counsel to the District Court for the Southern District of Florida

Theodore Babbitt
Joseph Osborne
Babbitt, Johnson, Osborne & LeClainche, P.A.
1450 Centrepark Blvd., Suite 100
West Palm Beach, FL 33401

Committee Members

Doug Monsour
The Monsour Law Firm
P.O. Box 4209
Longview, TX 75606

Brian Barr
Levin, Papantonio, Thomas, Mitchell, Echsner & Proctor, P.A.
P.O. Box 12308
Pensacola, FL 32501

Brian Turner
Cory, Watson, Crowder & DeGaris, PC
2131 Magnolia Avenue
Birmingham, AL 35205

Marc Jay Bern
Napoli, Bern, Ripka, LLP
115 Broadway, 12th Floor
New York, NY 10006

Fred Thompson
Motley Rice LLC
P.O. Box 1792
Mt. Pleasant, SC 29405

Neil Overholtz
Alystock, Witkin, Kreis & Overholtz, PLLC

803 North Palafox Street
Pensacola, FL 32501

Joey Danis
Carey and Danis, LLC
8235 Forsyth Blvd., Suite 1100
St. Louis, MO 63105

David Matthews
Matthews & Associates
2905 Sackett Street
Houston, TX 77098

Federal-State Liaison

Neal Moskow
Ury & Moskow, LLC
883 Black Rock Turnpike
Fairfield, CT 06825

Appointment of Lead and Liaison Counsel is subject to the approval of the Court. Lead Counsel should be prepared to discuss any additional needs for an organizational structure at the status conference.

C) Responsibilities of Plaintiffs' Steering Committee/Lead/Liaison Counsel.

1) Plaintiffs' Steering Committee will coordinate this litigation on behalf of all Plaintiffs, and will have the authority to bind and/or act on behalf of all Plaintiffs. Plaintiffs' Lead and Liaison Counsel will be responsible for dealing with Defense counsel on a day-to-day basis, and will have the authority to bind and/or act on behalf of all Plaintiffs. The responsibilities of Plaintiffs' Steering Committee, by themselves or through their designees, shall include, but not be limited to, the following:

(a) Discovery:

(i) Initiate, coordinate, and conduct all pretrial discovery, consistent with this Order and any subsequent Orders of this Court, on behalf of all Plaintiffs who file civil actions that are consolidated with the instant action, MDL-1928.

(ii) Cause to be issued in the name of all Plaintiffs the

necessary pretrial discovery requests, motions, and subpoenas. Similar requests, notices, and subpoenas may be caused to be issued by Plaintiffs' Lead Counsel upon written request by an individual attorney in order to assist him/her in the preparation of his/her case.

(iii) Conduct all discovery in a coordinated and consolidated manner on behalf of and for the benefit of all Plaintiffs.

(iv) Coordinate the taking of discovery with the discovery being conducted in parallel state court cases in order to avoid unnecessary duplication and burden on the Parties.

(b) Hearings and Meetings:

(i) Call meetings of counsel for Plaintiffs for any appropriate purpose.

(ii) If any evidentiary hearings are held in this MDL, examine witnesses and introduce evidence on behalf of Plaintiffs.

(iii) Act as spokesperson for all Plaintiffs at pretrial proceedings and in response to any inquiries by the Court, subject to the right of any Plaintiff's counsel to present non-repetitive individual or different positions.

(c) Miscellaneous:

(i) Submit and argue any motions presented to the Court on behalf of Plaintiffs as well as oppose, when necessary, any motions submitted by the Defendants or other Parties which involve matters within the responsibility of Plaintiffs' Steering Committee.

(ii) Negotiate and enter into stipulations with Defendants

regarding this litigation. All stipulations entered into by Plaintiffs' Steering Committee and/or Lead Counsel, except for administrative details such as scheduling, must be submitted for Court approval and will not be binding until the Court has ratified the stipulation. Any attorney not in agreement with a non-administrative stipulation shall file with the Court a written objection thereto within five (5) days after the stipulation has been filed with the Court for approval. Failure to object within the term allowed shall be deemed a waiver and the stipulations will be automatically binding on that Party.

(iii) Maintain adequate files of all pretrial matters and have them available, under reasonable terms and conditions, for examination by Plaintiffs' attorneys.

(iv) Prepare periodic status reports summarizing Plaintiffs' Steering Committee's work and progress. Copies of these reports shall be promptly distributed to other Plaintiffs' attorneys.

(v) Perform any tasks necessary and proper for Plaintiffs' Steering Committee to accomplish its responsibilities as defined by the Court's Orders.

(d) Maintain and make available to all co-counsel at reasonable hours a complete file of all documents served by or upon each Party;

(e) Receive and distribute to Plaintiffs documents produced by Defendants and third parties; Defendants shall be required to produce documents only to Plaintiffs' Liaison Counsel, except for case-specific documents which shall only be produced by Defendants to counsel of record for the individual plaintiff. Plaintiffs' Liaison Counsel may provide

copies of documents produced by a defendant only to any plaintiff in these consolidated proceedings (i) who has filed an individual action against the specific defendant by which the document production is made, and served such defendant with process in the individual action, and (ii) who is subject to the Protective Order for confidential information that is appended hereto as Exhibit A.

(f) Perform such other functions as may be expressly authorized or required by further Orders of the Court.

2) Plaintiffs' Lead and Liaison Counsel shall be responsible for the following administrative duties:

- (a) Maintain and distribute to co-counsel an up-to-date service list;
- (b) Coordinate service and filing;
- (c) Serve as the recipient of all Court Orders;
- (d) Receive and distribute pleadings, Orders, stipulations and motions designated in the caption as related to All Actions by overnight courier service, email, or fax, unless such service has been waived, in writing, by a receiving counsel; and
- (e) Carry out such other duties as the Court may order.

D) Defendants' Lead and Liaison Counsel.

Lead Counsel for Defendants are:

Philip S. Beck
Steven E. Derringer
Bartlit Beck Herman Palenchar & Scott LLP
Courthouse Place
54 West Hubbard Place Suite 300
Chicago, IL 60610

Eugene A. Schoon
Sidley Austin LLP

One South Dearborn
Chicago, IL 60603
Richard K. Dandrea
Eckert Seamans Cherin & Mellott, LLC
600 Grant Street, 44th Floor
Pittsburgh, PA 15219
Susan Artinian
Dykema Gossett PLLC
400 Renaissance Center
Detroit, MI 48243

Liaison Counsel for Defendants is:

Patricia E. Lowry
Squire, Sanders & Dempsey L.L.P.
1900 Phillips Point West
777 South Flagler Drive
West Palm Beach, FL 33401

E) Privileges Preserved. No communications among Plaintiffs' Counsel or among Defendants' Counsel shall be taken as a waiver of any privilege or protection to which they would otherwise be entitled.

IV. MASTER TRASYLOL DOCKET AND FILE.

The clerk will maintain a master docket and case file. All Orders, pleadings, motions and other documents will, when filed and docketed in the master case file, be deemed filed and docketed in each individual case to the extent applicable. The Court will maintain a separate docket for each case removed or transferred to this Court. Each such case will be assigned a new case number in this Court.

When filing documents relating to "ALL ACTIONS" with the Court, the Parties will comply with the Court's requirements as to electronic filing and the documents shall be filed on the ECF system under the master file, or, if electronic filing is not possible, a signed original shall be sent to the Clerk for filing in the master file. When filing documents relating to a particular case or cases, the documents shall be filed on the ECF system under both the master file and the particular case, or, if electronic filing is not possible, one signed original shall be sent for the master file and an additional copy for each particular case to which the matter related.

V. PLEADING ISSUES.

A) Master Complaint. On or before June 15, 2008, Plaintiffs shall file in this Court, and serve upon each named defendant in the manner set forth in this Order, a Master Complaint, naming as defendants Bayer Corporation, BHCP and BHCAG. The Master Complaint shall contain allegations that would be suitable for adoption by reference in individual cases. The Master Complaint shall not constitute the inception of a new “case or controversy” in this district and shall not supersede or render moot the pending separate actions that were transferred to this district for pretrial proceedings by the Judicial Panel on Multidistrict Litigation. The filing and service of the Master Complaint does not toll any applicable statute of limitations as to any individual plaintiff, and does not relieve any individual plaintiff of the requirement to perfect service of process of his or her Short Form Complaint. The counts of the Master Complaint are not deemed automatically included in any particular case.

B) Master Answer and Rule 12 Motion. Within sixty (60) days after the filing of the Master Complaint, each defendant named in the Master Complaint shall file a Master Answer or a motion pursuant to Fed. R. Civ. P. 12 in response to the Master Complaint. The filing by a defendant of a Master Answer does not preclude the filing of motions pursuant to Fed. R. Civ. P. 12 or other motions in any particular case at other times, as appropriate.

C) Short-Form Complaints. All cases filed in this MDL proceeding after the date of the filing of the Master Complaint shall be instituted by the filing of a Short-Form Complaint. The Short-Form Complaint shall indicate those counts from the Master Complaint that are being asserted in the individual case.

D) Answers to Short-Form Complaints Not Required. Defendants are not required to file answers to Short-Form Complaints. An entry of appearance shall constitute a denial of all allegations in the Short-Form Complaint and an assertion of all defenses that are included in the defendant’s Master Answer. This paragraph does not preclude the filing of motions pursuant to Rule 12 or other motions in any particular case at other times, as appropriate.

VI. SERVICE OF PROCESS.

A) Waiver of Service of Process. To eliminate disputes over service of process, to reduce the expense of such service, and, in the case of BHCAG, to avoid the need for translation of complaints into German and to avoid the need to follow the procedures for service on German companies under applicable treaties and conventions, Defendants Bayer Corporation, BHCP and BHCAG have agreed to waive the normal legal requirements for service of process in the Consolidated Action. Instead, Bayer Corporation, BHCP and BHCAG have agreed to accept service of process for Trasylol products liability cases filed in federal court or removed to federal court through service, by registered mail, return receipt requested, upon the following:

For Bayer Corporation and BHCP:

Douglas A. Pearson, Esq.
100 Bayer Road, Building 14
Pittsburgh, PA 15205-9741

For BHCAG:

Alexander Bey, Esq.
General Counsel
Bayer HealthCare AG
Law and Patents Department
51368 Leverkusen
GERMANY

A copy of each notice transmitted to any defendant in the foregoing manner shall be provided to Lead and Liaison Counsel for Defendants. Service will be effective only if addressed as above. General mailing to any defendant will not be sufficient to effect service. Service will be effective ten (10) days after mailing in accordance with this Section. The foregoing procedure shall apply to Trasylol products liability cases filed in or removed to federal court only and not to any other litigation. Defendants reserve all other rights available to them under federal or state law and under applicable treaties and conventions.

Subject to Section VII.A. of this Order, Bayer Corporation's and BHCP's responsive pleadings or motions pursuant to Fed. R. Civ. P. 12 to any original process served pursuant to

and in accordance with this Section shall be due sixty (60) days after service and BHCAG's responsive pleadings or motions pursuant to Fed. R. Civ. P. 12 to any original process served pursuant to and in accordance with this Section shall be due ninety (90) days after service in accordance with this Section.

B) Orders. A copy of each Order designated in the caption as related to All Actions will be provided to Defendants' Lead and Liaison Counsel, and to the Plaintiffs' Lead and Liaison Counsel.

C) Pleadings, Motions, and Other Documents Related to All Actions. Plaintiffs' Lead and Liaison Counsel and Defendants' Lead and Liaison Counsel shall be provided with one copy of each document designated in the caption as related to All Actions served and/or filed by a Party, including any and all attachments, to be delivered by electronic mail. Pursuant to Fed. R. Civ. P. 5, service on Plaintiffs' Lead and Liaison Counsel constitutes service on other Plaintiffs' attorneys and Plaintiffs in this action and service on Defendants' Lead and Liaison Counsel constitutes service on other Defendants' attorneys.

D) Pleadings, Motions and Other Documents Related Only to Specific Actions. Pleadings, motions and other documents related only to specific actions served and/or filed by a Party, including any and all attachments, are to be delivered by electronic mail and shall be served on counsel of record for that action.

VII. PLEADINGS AND MOTIONS.

A) Pleadings. Deadlines for answers or responses to the Complaints in all actions are hereby suspended until further order of this Court.

B) Amendments. The deadline for motions to amend pleadings or to add Parties is ninety (90) days from the date of this Order, or forty-five (45) days after transfer to MDL-1928, whichever is later. It shall not be necessary to seek leave of court to amend pleadings or add parties if done within the time frames referenced in this Section.

C) Separate Complaints. In an effort to avoid administrative complications and inefficiencies, unrelated claimants shall be required to file separate complaints.

D) Motions. Except for emergencies or unless otherwise agreed by the Parties, motions shall not be brought for hearing at any time other than a regularly scheduled status conference. In order to be heard at a regularly scheduled status conference, a motion must be filed and served at least twenty (20) days before said conference. Any motion filed and served less than twenty (20) days before a status conference shall be heard not at the upcoming status conference but at the status conference thereafter.

VIII. WRITTEN DISCOVERY.

A) Required Disclosures by Plaintiffs.

1) Within ninety (90) days of the date of this Order (but no later than August 21, 2008) or within sixty (60) days of the date on which an action is commenced, whichever is later, a plaintiff who is subject to this Order shall serve Defendants in the action brought by such person with:

(a) A completed Fact Sheet (the form of which is being negotiated by the Parties). The Fact Sheet shall include a completed Affidavit attesting that the information contained therein is true and correct to the best of the plaintiff's knowledge, information and belief formed after due diligence and reasonable inquiry.

(b) Authorizations for the release of records. Plaintiffs shall provide addressed authorizations for each health care provider identified in Plaintiff's Fact Sheet.

(i) Plaintiffs shall serve undated authorizations.

(ii) Plaintiffs' service of authorizations constitutes permission for Defendants to date (and where applicable, re-date)

authorizations before sending to healthcare providers.

(c) Copies of all documents subject to the requests for production contained in the Fact Sheet which are in the possession of Plaintiffs or their counsel.

(d) In addition to the addressed authorizations described above, Plaintiff's counsel shall also maintain in their file unaddressed, executed authorizations. Plaintiff's counsel shall provide executed authorizations to Defendants' counsel within fourteen (14) days of a request for authorizations. Defendants' use of authorizations provided by Plaintiffs pursuant to Section VIII.A.1(b) above and this Section VIII.A.1(d) shall be subject to the provisions of Section VIII.B below.

2) *Fact Sheets as Interrogatories and Requests for Productions.* The Plaintiffs' Fact Sheets which Plaintiffs are required to answer are a convenient form of propounding interrogatories and requests for production of documents. The completed fact sheets shall be considered interrogatory answers pursuant to Fed. R. Civ. P. 33 and as responses to requests for production pursuant to Fed. R. Civ. P. 34 and will be governed by the standards applicable to written discovery under Fed. R. Civ. P. 26 through 37. The questions and requests for production contained in the Fact Sheet are non-objectionable and shall be answered without objection. This section does not prohibit a plaintiff from withholding or redacting information based upon a recognized privilege. If a plaintiff withholds or redacts any information on the basis of privilege, he or she shall provide Defendants with a privilege log pursuant to Section VIII.F.7 below. In the event that a dispute arises concerning the completeness or adequacy of a plaintiff's response to any request contained in the Fact Sheet, this Section shall not prohibit the plaintiff from asserting that his or her response is adequate.

B) Defendants' Discovery of Documents from Third Parties.

1) *Defendants' Procedure to Obtain Records from Third Parties.* Defendants may request Plaintiffs' medical records, employment records, disability and workers compensation records, social security records, insurance records, educational records and/or tax records (in appropriate cases) from third parties through a record copy service. Unless Plaintiff has waived this review period, information specifying each such request will be provided to Plaintiff's counsel who will have twenty (20) days from the date of receipt of such information in which to notify Defendants' counsel and the record copy service of any objection to production of the records to Defendants. If no such objection is made, production from the record copy service to Defendants shall occur forthwith. If an objection is made, counsel shall confer concerning that objection, and if the objection cannot be resolved, Plaintiffs shall file a motion for a protective order to preclude the discovery of all or part of the records requested. That motion shall be filed no later than ten (10) days after the parties have conferred or reasonable attempts at conferring have failed. If said motion is filed, the record copy service will not produce to Defendants a copy of the records subject to the request to which an objection has been made until such time as the motion is resolved. If no such motion is filed within the time provided herein, the record copy service shall produce the records to Defendants. Plaintiffs may obtain their own copy of the same from the record copy service upon payment of the reasonable costs of copying such documents.

2) *Defendants' Use of Authorizations.* Defendants may not use authorizations except in accordance with this Order. The Parties may subpoena records from any third party pursuant to the Federal Rules of Civil Procedure. Any Party may waive the notice of subpoena provisions of the Federal Rules, either in the Fact Sheet or otherwise in writing. If there is such a waiver, the subpoena may be served without the time period allowed for objections.

C) Document Production by Defendants.

1) With respect to each of the document productions by BHCP and BHCAG described below in Sections VIII.C.2-7, the producing defendant shall provide Plaintiffs with a statement confirming that the production was undertaken in a manner consistent with a producing party's obligations under Fed. R. Civ. P. 26 and 34, and that the producing defendant's description of the production and the components thereof is true and correct to the best of the producing defendant's knowledge, information and belief.

2) By May 15, 2008, BHCP shall complete the production to Plaintiffs of the following non-privileged, discoverable Trasylol-related documents:

(a) Hard copy (paper) and Electronically Stored Information ("ESI") of 28 present or former employees who have or had Trasylol-related responsibilities. BHCP has provided Plaintiffs with a list of the names and titles of these 28 employees. Present and former employees' hard-copy (paper) documents and ESI productions will be made, as applicable, and available, from paper files maintained by the individual, the hard drive of the individual's personal computer, the individual's Lotus Notes e-mail file, the individual's home share file on file share servers and other media (CDs or DVDs) on which the individual has stored ESI (hereinafter "Personal File Materials"); for each of the 28 present or former employees referred to herein, BHCP shall within sixty (60) days after the entry of this Order provide to plaintiffs (i) the individual's resume (if available) or (if the resume is not available) a description of the individual's job title and departmental associations; (ii) the time period of the individual's Trasylol-related responsibilities; and (iii) the individual's employer if the person is currently employed by a defendant and, if not, the individual's last known address.

(b) Hard copy (paper) documents or ESI from the following databases

and files:

- (i) Trasylol portion of the Goldmine database;
- (ii) Trasylol portion of the Faxback database;
- (iii) Investigational New Drug Application, New Drug Application and Supplemental New Drug Applications for Trasylol;
- (iv) Regulatory Affairs department correspondence/contact files regarding communications and contacts with the FDA concerning Trasylol;
- (v) Trasylol Resource Center database;
- (vi) www.trasylol.com website;
- (vii) Promotional and marketing materials for Trasylol.

3) Within sixty (60) days after the entry of this Order, BHCP shall produce to Plaintiffs (a) published and unpublished reports of Trasylol preclinical, clinical and epidemiological studies; (b) document retention policies that relate to Trasylol-related documents; and (c) organizational charts.

4) Upon completion of and to supplement the production of documents described above in Section VIII.C.2, BHCP will produce on a rolling basis at forty-five (45) day intervals, the 2007 Lotus Notes e-mail files not previously produced up to November 30, 2007 for those present or former employees referred to in Section VIII.C.2 who were still employed in 2007. These 2007 Lotus Notes e-mail files shall hereinafter be considered part of the individual's Personal File Materials for purposes of this Order.

5) On a rolling basis following completion of the production of documents described above in Section VIII.C.4 , and continuing at intervals of forty-five (45) days

thereafter, BHCAG shall produce to Plaintiffs the following non-privileged, discoverable Trasylol-related documents:

- (a) hard-copy (paper) documents and ESI of twenty-eight (28) present or former employees who have or had Trasylol-related responsibilities. Plaintiffs have been provided with a list of the names and titles of the twenty-eight (28) employees referred to above. Present and former employees' hard copy (paper) documents and ESI productions will be made, as applicable, and available, from their Personal File Materials;
 - (a) The Trasylol portion of the BHCAG regulatory affairs tracking database;
 - (b) The Trasylol portion of BHCAG's global regulatory affairs labeling database, including data regarding Trasylol company core data sheets;
 - (c) Trasylol periodic safety update reports ("PSURs") and other Trasylol safety update reports;
 - (d) Trasylol-related meeting minutes of, and presentations to, the International Product Development Committee and successor committees;
 - (e) Trasylol Adverse Event Data from the Clintrace database; and
 - (f) Trasylol investigator's brochures.
- 6) Upon completion of and to supplement the production of documents described above in Section VIII.C.5, BHCAG will produce on a rolling basis at forty-five (45) day intervals, the 2007 Lotus Notes e-mail files not previously produced up to November 30, 2007 for those present or former employees referred to in Section VIII.C.5 who were still employed in 2007. These 2007 Lotus Notes e-mail files shall hereinafter be considered part of the individual's Personal File Materials for purposes of

this Order.

7) As promptly as reasonably possible after the completion of the production provided for in VIII.C.6, BHCAG will produce on a rolling basis at forty-five (45) day intervals, to the extent discoverable and non-privileged, its group share files related to Trasylol.

8) Following the completion of the production of the documents described above in Section VIII.C.7, BHCP will produce to Plaintiffs the following non-privileged, discoverable Trasylol-related documents on a rolling basis at forty-five (45) day intervals:

- (a) The Trasylol portion of the Q&A adverse event database;
- (b) The hard copy files of Trasylol-related adverse event reports maintained by BHCP's drug safety department;
- (c) Trasylol-related materials used for training of sales representatives;
- (d) Trasylol package inserts;
- (e) Trasylol Resource Center Discussion database;
- (f) The Trasylol portion of the Scientific Affairs Resource Center database;
- (g) Trasylol Dear Healthcare Provider Letters;
- (h) Exemplars of Trasylol advertisements;
- (i) Records of sales calls made to physicians who prescribed or administered Trasylol to plaintiffs;
- (j) Tangible items regarding Trasylol, if any, provided to physicians who prescribed or administered Trasylol to plaintiffs;
- (k) Exemplars of Trasylol-related items that included warnings that

sales representatives provided to physicians;

(l) Exemplars of Trasylol-related materials, if any, provided to physicians for use in speeches;

(m) Documents recording budgets for the promotion, advertisements, or marketing of Trasylol;

(n) Documents reflecting the number of patients to whom Trasylol has been administered;

(o) Documents related to patents or patent applications for Trasylol, if any; and

(p) Relevant portions of minutes of meetings of Bayer Corporation's, BHCP's and BPC's board of directors, if any.

9) Within a reasonable time after receipt of identifying information from a plaintiff as part of Fact Sheet responses, BHCP will produce to that plaintiff discoverable, Trasylol-related documents from the files of any Bayer sales representative who had contacts with the physician(s) who prescribed or administered Trasylol to that plaintiff or plaintiff's decedent.

D) In light of the broad scope and extraordinarily voluminous nature of the above-described document production by BHCP and BHCAG, the parties acknowledge their joint interest in avoiding the substantial expansion of the defendants' document production in the Trasylol cases. Nevertheless, Plaintiffs retain the right to serve upon Defendants focused, limited requests for the production of additional documents, including the Personal File Materials of additional Bayer personnel as well as documents from non-employee-specific sources. Except for the sources of documents specifically set forth in Sections VIII.C.2-9, Defendants may object to the production of documents that may be requested by Plaintiffs.

E) Defendants agree that, in the event that Defendants produce any documents or

materials in another Trasylol products liability lawsuit and those documents or materials have not been produced in these coordinated proceedings, Defendants will produce such documents or materials in these proceedings subject to any and all objections to production on the grounds of relevance and/or any applicable privilege or work product protection.

F) Document Production Protocol.

1) The Parties will produce paper and electronic documents in single-page Tagged Image File Format (".tiff format"). Document productions will be accompanied by a load file in iPro format. The load file will provide the Bates number attachment range for email or other documents containing attachments. For documents that do not contain redactions, the producing Party will produce an extracted text file for electronic documents and an Optical Character Recognition ("OCR") text file for imaged paper documents. For documents that contain redactions, the producing Party will provide an OCR text file for unredacted portions of such documents.

2) Each page of a produced document will contain a legible, unique identification number ("Bates number") and confidentiality notice, where applicable, which will be placed on the page image in a manner that does not conceal or interfere with any information contained on the page. No other stamp or information will be placed on a document other than Bates number, confidentiality notice, and any redactions. This provision does not apply to databases produced in native electronic format.

3) Document productions will be made on CD, DVD, or hard drive. If a production is provided on a hard drive, the receiving Party will return the hard drive to the producing Party within a reasonable time after receipt and downloading of the information and document images contained thereon.

4) Objective coding and Metadata.

(a) Defendants will provide objective coding information as described

below with each production. Defendants may review and, where necessary, revise or redact objective coding if it contains privileged or work product information.

(b) Defendants will provide the following coding information for electronic documents:

- (i) custodian or source
- (ii) starting and ending production number
- (iii) electronic document type (e.g. word processing, email, spreadsheet, etc.)
- (iv) date (date-sent for e-mail; date-created and date-last-modified for non-email electronic documents)
- (v) title (subject line for e-mail; file name or title on face of document for non-email electronic documents)
- (vi) author(s)
- (vii) recipient(s) (for email)
- (viii) cc(s) (for email)
- (ix) bcc(s) (for email)

(c) Defendants will provide the following coding information for paper documents if Defendants have created such information for their own use with respect to this litigation:

- (i) custodian or source
- (ii) starting and ending production number
- (iii) document type (e.g. report, email, letter, article, etc.)

- (iv) date (if determinable from face of document)
- (v) title (if determinable from face of document)
- (vi) author(s)
- (vii) recipient(s)
- (viii) cc(s)
- (ix) bcc(s)

(d) To the extent that Plaintiffs produce electronic documents and/or create coding information for paper documents for Plaintiffs' own use, Plaintiffs will provide objective coding in the format as set forth in paragraphs (b) and (c) above. Plaintiffs may review and, where necessary, revise or redact objective coding if it contains privileged or work product information.

(e) With respect to objective coding information provided for paper documents, the Parties will make reasonable efforts to provide accurate information with respect to subparagraphs (c)(iii) through (c)(ix), but the Parties do not certify the reliability, accuracy, or completeness of objective coding as to any particular paper document. Objective coding of paper documents is not evidence and may not be used by any Party for any purpose other than discovery and document management in this litigation.

(f) Objective coding information for electronic documents, as set forth in subparagraphs (b)(iii) through (b)(ix), will be derived from metadata associated with the document. However, the Parties understand that metadata differs between types of electronic documents and that particular electronic documents may not contain metadata for all of the fields described in subparagraphs (b)(iii) through (b)(ix). Other than information

described in subparagraphs (b)(iii) through (b)(ix), Defendants are not required to provide other metadata that may be associated with an electronic document.

5) Redaction of Documents

(a) Defendants may redact documents that contain (i) information relating to Bayer products other than Trasylol or similar Bayer products investigated or developed to reduce blood loss or blood transfusion requirements in any surgery; (ii) information that is subject to a claim of privilege; (iii) information specifying the chemical structure or composition of or the manufacturing, production or quality control processes for Trasylol; (iv) information that is private, such as social security numbers, dates of birth, or names/addresses of patients involved in clinical studies; and (v) information which Defendants are not permitted to disclose under FDA regulations, specifically including any information that identifies a patient who is the subject of an adverse event report or that identifies any reporter of an adverse event other than Defendants' employees.

(b) In addition to the coding information described above, Defendants will provide for each redacted document an additional coding field which describes the reason(s) for any redaction on the document, e.g. "other product," "privacy," "privilege."

(c) Plaintiffs retain the right to move to compel production of redacted information, and Defendants retain the right to object. Any failure to redact information described above does not waive any right to claims of privilege or privacy, or any objection including relevancy, as to the specific document or any other document that is or will be produced.

6) *Databases.* Prior to production of any database not already identified for production in this CMO, the Parties will meet and confer regarding the discoverability and feasibility of any request for production of a database including the form and content of any such production. Defendants will make reasonable effort to produce Trasylol-related data from electronic databases that operate with generally available software in native database format (including data and schema) where practical and feasible. Where such production is not practical or feasible, the Parties will confer upon an appropriate form of production. The Court's assistance regarding the discoverability, form, and scope of production of data may only be sought after the Parties have failed to reach agreement after good faith discussion.

7) *Privilege Logs.* The Parties will produce privilege logs in Excel format or a similar electronic format that follows text searching and organization of data. A Party will produce a privilege log within ninety (90) days after its first production of documents for which privilege is asserted to apply, and within the same time period following any subsequent or rolling productions.

(a) Consistent with Fed. R. Civ. P. 26(b)(5), the Parties' privilege logs shall include the following information:

- (i) custodian or source
- (ii) date
- (iii) author(s)
- (iv) for documents produced, but redacted on the ground of privilege, the starting and ending production number;
- (v) recipient(s) (for email and hard-copy communications such as letter and internal memoranda)
- (vi) cc(s) (for email and hard-copy communications such as

letter and internal memoranda)

(vii) bcc(s) (for email and hard-copy communications such as letter and internal memoranda)

(viii) specification of the privilege claimed

(ix) a description of the document and the basis for the privilege claim.

G) Inadvertent Production of Documents.

1) Inadvertent production of documents (hereinafter “Inadvertently Produced 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 notify the receiving Party in writing within fourteen (14) days of discovery of the inadvertent production. If such notification is made, such Inadvertently Produced Documents and all copies thereof shall, upon request, be returned to the producing Party, all notes or other work product of the receiving Party reflecting the contents of such materials shall be destroyed, and such returned or destroyed material shall be deleted from any litigation-support or other database. If the receiving Party elects to file a motion pursuant Section VIII.G.3 below, the receiving Party, subject to the requirements of Section VIII.G.2 below, may retain possession of the Inadvertently Produced Documents as well as any notes or other work product of the receiving Party reflecting the contents of such materials pending the resolution by the court of the Section VIII.G.3 motion. If the receiving Party’s Section VIII.G.3 motion is denied, the receiving Party shall promptly comply with the immediately preceding provisions of this Section VIII.G.1.

2) No use shall be made of such Inadvertently Produced Documents, including 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.

3) The Party receiving such Inadvertently Produced Documents may, after receipt of the producing Party's notice of inadvertent production, move the Court to dispute the claim of privilege or immunity, but the motion shall not assert as a ground therefore the fact or circumstances of the inadvertent production.

H) Costs of Production. While each Party expressly reserves its right to seek costs relating to this litigation, including the costs of producing documents and reasonably accessible electronic documents, initially each Party will bear the costs to process, review and produce its own documents and reasonably accessible ESI.

I) Protective Order for Confidential Information. The Parties have submitted a joint proposed Protective Order (Exhibit A) to regulate the use, disclosure or dissemination of confidential documents or information of the Parties or third parties that may be produced during this litigation. The Court will enter the Protective Order to supplement the terms of this Case Management Order.

IX. DEPOSITIONS OF DEFENDANTS' PERSONNEL.

A) Plaintiffs may not issue notices for the depositions of present or former employees of Defendant BHCP or, if appropriate, of other U.S. Bayer entities until after (1) July 1, 2008 and (2) production of the individual's Personal File Materials pursuant to the procedures described above. Defendant BHCP shall provide a formal written notice (email acceptable) advising Plaintiffs when the Personal File Materials of any such current or former employee have been produced. Plaintiffs may not take the deposition of any such individual until at least forty-five (45) days after the deposition notice has been served on the deponent, absent agreement of the parties or upon order of the Court.

B) Plaintiffs may not issue notices for the depositions of present or former employees of BHCAG, or if appropriate, other German Bayer entities until after (1) October 1, 2008 and (2) production of the individual's Personal File Materials pursuant to the procedures described

above. Defendant BHCAG shall provide a formal written notice (email acceptable) advising Plaintiffs when the Personal File Materials of a current or former employee have been produced. Plaintiffs may not take the deposition of any such individual until at least sixty (60) days after the deposition notice has been served on the deponent, absent agreement of the parties or upon order of the Court. In order to reduce the cost and burden of conducting depositions of persons living abroad, the parties agree to coordinate depositions of present or former employees of BHCAG and, if appropriate, other German Bayer entities, at a centralized location in Europe and during a single, consecutive period of time.

C) In the event Defendants object to any deposition notice referred to above in Sections IX.A and IX.B, Defendants must notify Plaintiffs of such objection within twenty (20) days following receipt of said deposition notice.

D) In the event that Plaintiffs depose present or former employees of BHCP, other U.S. Bayer entities, BHCAG, or other German Bayer entities prior to the completion of Defendants' document production (such production being defined above in Sections VIII.C-E), the individual may not be re-deposed on the grounds of discovery of relevant information contained in later-produced documents, absent agreement of the parties or good cause. The party seeking to re-open the deposition of the witness shall bear the burden of demonstrating good cause. If, however, Defendants produce additional Personal File Materials that are dated within the specified temporal scope of the Defendants' production thereof after Defendants have provided the formal written notice pursuant to Sections IX.A or IX.B above that the custodian's Personal File Materials have been produced, such additional production shall constitute prima facie evidence of good cause to re-open the deposition of that custodian for the limited purpose of examining the custodian on his or her newly produced Personal File Materials. Defendants shall have the opportunity to contest the re-opening of any such deposition but bear the burden to demonstrate why the deposition should not be re-opened.

E) The Parties and the Court endorse the cross-noticing of depositions in this MDL

and in state court Trasylol actions to avoid multiple depositions of fact and expert witnesses. If a Party in this Consolidated Action cross-notices a deposition in these cases, it shall provide the notice to Lead Counsel, Liaison Counsel and the Federal-State Liaison by e-mail or facsimile as soon as possible. If a Party in this Consolidated Action objects to that cross-notice, the Party issuing the cross notice shall within two (2) business days after service thereof, notify the Court of the dispute by letter e-mailed, delivered or faxed to the Court and Lead Counsel, Liaison Counsel and the Federal-State Liaison. That letter shall ask the Court to convene a conference call to dispose of the dispute as soon as it can be scheduled. The burden shall be on the Party in this Consolidated Action objecting to the cross notice to demonstrate that the cross notice should be quashed. In no event shall witnesses be deposed on multiple occasions in connection with this proceeding without leave of Court and for good cause shown or by agreement of the parties, except that depositions of healthcare providers may be taken separately for each patient by or for whom a claim is asserted.

X. DEPOSITIONS OF PLAINTIFFS AND OTHER CASE-SPECIFIC WITNESSES.

Defendants may not issue notices for the deposition of Plaintiffs, Plaintiffs' healthcare providers or other case-specific witnesses until after July 1, 2008.

XI. COMPLETION OF FACT DISCOVERY.

A) All fact discovery shall be completed by July 15, 2009, except for case-specific fact witnesses for cases filed after July 15, 2008. Completion of case-specific fact discovery in any such later-filed case shall be completed within twelve (12) months of the date of initial service of the complaint upon a defendant.

B) In addition to the written discovery contemplated by the above paragraphs of this Order, the Parties shall have the right to serve supplemental written discovery limited to information not previously disclosed in discovery. All such written discovery shall be submitted in sufficient time to afford to the responding Party the period provided by the Federal Rules of Civil Procedure within which to serve its response prior to the fact discovery deadline of July 15,

2009.

C) The schedule for expert witness discovery, *Daubert*, and dispositive motions shall be addressed in subsequent Orders.

XII. OTHER COMPOUNDS.

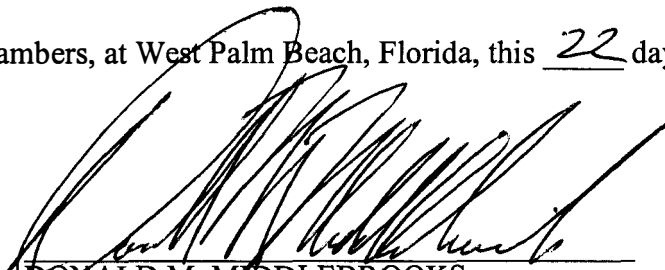
None of the defendants shall be required to produce documents or information relating to: (i) the chemical structure or composition of, (ii) the manufacturing, production or quality control processes for, (iii) the results of pre-clinical and/or clinical tests and studies of, (iv) financial information regarding developmental expenditures, budgets, and other projections of future developmental expenses, or (v) information specifying preclinical and/or clinical developmental plans regarding compounds developed by Bayer, other than Trasylol (aprotinin), that may reduce blood loss and the need for blood transfusions. To the extent documents containing information relating to other compounds also include non-privileged, discoverable information relating to Trasylol, such Trasylol-related information will be provided to Plaintiffs.

XIII. OTHER ISSUES.

A) List of Affiliated Companies and Counsel. No less than twenty-one (21) days before the initial scheduling conference, the Parties are to submit a list of affiliated companies and counsel.

B) Waiver of Fed. R. Civ. P. 26(a)(1). Parties will not be required to serve Fed. R. Civ. P. 26(a)(1) initial disclosures.

DONE AND ORDERED in Chambers, at West Palm Beach, Florida, this 22 day of May, 2008.



RONALD M. MIDDLEBROOKS
UNITED STATES DISTRICT COURT JUDGE

Copies to all counsel of record

EXHIBIT A

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA**

Case No. 1:08-MD-01928-MIDDLEBROOKS/JOHNSON

IN RE TRASYLOL PRODUCTS
LIABILITY LITIGATION – MDL-1928

This Document Relates to All Actions

WHEREAS pursuant to Fed. R. Civ. P. 26(c), the Court deems it appropriate to limit disclosure of certain confidential information, as set forth below, IT IS HEREBY ORDERED THAT:

PROTECTIVE ORDER

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) Unpublished clinical studies and related documents;

- (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 or not contained within any publicly available quarterly or annual reports;
- (h) Private medical information that identifies a person unless such identifying information is redacted;
- (i) Information submitted to any governmental or regulatory agency, which information is exempt from public disclosure

3. **Requests to Designate Other Materials as Confidential.** If any party believes a document not falling within the scope of Paragraph 2 should nevertheless be considered confidential, the parties shall meet and confer, and absent an agreement the party seeking confidential treatment may apply to the Court for an Order designating such document as confidential. Such application shall only be granted for good cause shown.

4. **Use of Confidential Discovery Material.**

(a) Confidential discovery material may be used only for the litigation of cases in this MDL, including post-MDL proceedings in transferor courts (hereinafter referred to collectively as “this litigation”) and for any other action brought by or on behalf of a former Trasylol user alleging injuries or other damages therefrom (“Other Trasylol Lawsuits”), so long as all parties are bound by and subject to another judicially approved protective order that is identical to or the substantial equivalent to this Order. Confidential discovery material will not be disclosed except in accordance with paragraphs 4(b), 7, and 10.

(b) Prior to being given access to confidential discovery material, any person falling within subparagraphs 7(a)(vi) or 7(a)(viii) shall be provided with a copy of this Order and shall execute a copy of the Endorsement of Protective Order, attached as

Exhibit A. Counsel providing such access to confidential discovery material shall retain copies of the Endorsement(s) of Protective Order and shall provide them to counsel producing confidential discovery materials as provided below. For testifying experts, a copy of the Endorsement of 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 material is given to the testifying expert, or at the time the expert's designation is served, whichever is later.

5. **Designation of Confidential Discovery Material.** Confidential discovery material, if in 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 relating to documents designated as confidential, the portion of the transcript in which confidential writings are offered, identified or discussed shall also be designated as confidential. Any additional 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 8.

6. **Consent to Jurisdiction.** 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.

7. **Disclosure of Confidential Discovery Material.**

(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 subject to the requirements of Section 10 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 each Defendant (in addition to outside counsel) to receive Confidential Discovery Materials produced by Plaintiffs.

iii. If produced by any Defendant, a Plaintiff in this litigation, Plaintiffs' attorneys in this litigation, including the paralegal, clerical, secretarial and other staff employed or retained by such counsel. Additionally, confidential discovery material produced by any defendant in this MDL may be disclosed to the named plaintiff(s) in Other Trasylol Lawsuits, and their counsel of record, including paralegal, clerical, secretarial and other staff employed or retained by such other plaintiffs' counsel of record if a protective order identical to or the substantial equivalent to this order has been entered in such Other Trasylol Lawsuits.

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 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 or Other Trasylol Lawsuits in which a protective order that is identical to or the substantial equivalent of this order has been entered.

vii. The persons who authored the confidential discovery material or who received such confidential discovery material in the ordinary course of business.

viii. Such other persons as the counsel for the producing party 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) Each person who is permitted to see confidential documents shall first be shown a copy of this Order and shall further be advised of the obligation to honor the confidentiality designation.

(d) 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.

8. Disputes concerning designation of Confidential Discovery Material.

(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 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 of 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 8(a) above, shall retain that designation and be treated as confidential in accordance with the terms hereof unless and until:

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

ii. twenty 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.

9. Designation by Non-Parties. 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 pursuant to the terms of this Order as

“Confidential” the discovery materials that the non-party is producing.

10. **Filing Under Seal.**

(a) **General Restrictions.** Confidential discovery material may be filed under seal only upon entry of a further Court Order granting a motion to seal particular document(s), or portions thereof. To seek authorization to file confidential discovery materials under seal, the parties must follow Local Rule 5.4(B) which sets forth this Court’s procedure for filing any document under seal.

(b) **Filing a Document Containing Material Designated as Confidential by Another Party.** The party asserting confidentiality bears the burden of obtaining a Court Order to file documents under seal. A party who intends to file a document containing information designated by another party as confidential shall provide written notice to the party asserting confidentiality. The notice shall specify the discovery material designated as confidential which the party intends to file or include in the contemplated filing. Within ten (10) days after receipt of such notice, the party asserting confidentiality shall file a motion to seal pursuant to Local Rule 5.4(B) or withdraw the confidentiality designation. If the party asserting confidentiality files a motion to seal, the party proposing to file the confidential discovery material may proceed with the contemplated filing only after, and in a manner consistent with, the Court’s ruling upon the motion to seal.

11. **Disclosure of Discovery Material.**

(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 materials designated as confidential.

(b) Nothing shall prevent disclosure beyond that permitted 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 shall waive any rights or privileges of any party granted by this Order.

12. **No Effect on Other Obligations.** 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 other 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. Neither the entry of this Order, nor the designation of any discovery material as confidential, nor the failure to make such designation, shall constitute evidence with respect to any issue in this or any other litigation.

13. **No Prejudice to Other Protections.** 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.

14. **Obligation of Good Faith.** 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.

15. **Modifications/Continuing Effect.** By written agreement of the parties, or upon motion and order of the Court, the terms of this Protective Order may be amended or modified. This Protective Order shall continue in force until amended or superseded by express order of the Court, and shall survive any final judgment or settlement in this litigation. This Protective Order shall also continue in effect as to the parties and counsel in any case following remand to the transferor district for trial or other disposition. The parties shall take such reasonable 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.

16. **Return of Confidential Discovery Material.** Within 45 days of the termination of a case in 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 in that case. However, if counsel for Plaintiff in this Litigation has other cases pending brought by or on behalf of a former Trasylol user alleging injuries or other damages therefrom, counsel for Plaintiff will be able to keep the confidential discovery material until such time as all litigation plaintiffs' counsel has pending brought by or on behalf of a former Trasylol user alleging injuries or other damages therefrom, has been terminated. 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.

17. **Responses to Subpoenas or Other Process.** 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 document 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 to

the extent reasonably possible, with the producing party in any proceeding relating thereto.

18. **Use of Confidential Discovery Material at Hearings or Trial.** 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. **Discovery Material Not Subject to Confidentiality.** 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 Trasylol in which such information was not designated as “Confidential” or subject to a protective order or confidential treatment, or where there has been a final judgment (including any appeal therefrom) declaring that such information or documents are not confidential.

20. **Rights of Parties.** 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.

21. **Attorneys’ Fees.** In any application to the Court referred to or permitted by this Order, the Court may exercise discretion in determining whether the prevailing party in such a dispute may recover costs, including reasonable attorneys’ fees, incurred by it and, if so, the amount to be awarded.

22. **Discovery Material Protected under German Law.** Bayer AG and Bayer HealthCare AG (and any other Bayer entity organized under the laws of Germany that may become a party to this litigation) may designate as CONFIDENTIAL those

documents (including electronic or paper form) containing “personal data,” within the meaning of the German Federal Data Protection Act, the confidentiality of which is protected under German law. “Personal data” consists of any and all data which concerns an identified person or a person who is identifiable with recourse to additional information available to the data processor (*e.g.*, reference to an individual by his/her title or position within the company whose identity is specified in other available sources of information). In particular, this applies to the following documents:

- (a) any correspondence (electronic or on paper) which identifies or through recourse to other sources of information available to the data processor allows identification of its author(s)/sender(s) and/or its addressees/recipients, *i.e.*, for example, all email correspondence, letters and faxes (including transmission reports);
- (b) any document such as memoranda, notes, and presentations if they identify or allow identification of its author/sender and/or its addressee/recipient through recourse to other information available to the data processor;
- (c) minutes of internal or external meetings as far as they include information about which individual(s) did or did not attend the meeting;
- (d) personnel records and information; and
- (e) any document containing private medical information.

DONE AND ORDERED in Chambers, at West Palm Beach, Florida, this _____ day of May, 2008.

DONALD M. MIDDLEBROOKS
UNITED STATES DISTRICT COURT JUDGE

Copies to all counsel of record

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA**

Case No. 1:08-MD-01928-MIDDLEBROOKS/JOHNSON

IN RE TRASYLOL PRODUCTS
LIABILITY LITIGATION – MDL-1928

This Document Relates to All Actions

ENDORSEMENT OF PROTECTIVE ORDER

I hereby attest to my understanding that information or documents designated Confidential are provided to me subject to the Protective Order regarding confidential information produced in discovery, entered _____, _____ (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 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 further 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 Southern District of Florida, 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 Court.

Date:

By: _____

STATE OF _____
COUNTY OF _____

Subscribed and sworn to before me this ____ day of _____, 2008.

NOTARY PUBLIC

Print Name _____
Commission Expires: _____
Commission No. _____