

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

IN RE: GADOLINIUM BASED  
CONTRAST AGENTS PRODUCTS  
LIABILITY LITIGATION

Case No. 1:08 GD 50000

MDL No. 1909

Honorable Dan Aaron Polster

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THIS DOCUMENT APPLIES TO ALL  
CASES:  
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**CASE MANAGEMENT ORDER NO. 6:  
PROTECTIVE ORDER**

**I. Scope of Order**

1. Disclosure and discovery activity in this proceeding may involve production of confidential, proprietary, and/or private information for which special protection from public disclosure and from use for any purpose other than prosecuting this litigation would be warranted. Accordingly, the parties hereby stipulate to and petition the Court to enter the following Stipulated Protective Order (“Protective Order” or “Order”).

2. This Protective Order shall govern all hard copy and electronic materials, the information contained therein, and all other information produced or disclosed during this proceeding, including all copies, excerpts, summaries, or compilations thereof, whether revealed in a document, deposition, other testimony, discovery response or otherwise, by any Party to this proceeding (the “Producing Party”) to any other party or parties (the “Receiving Party”). This Protective Order is binding upon all the Parties to this proceeding, including their respective corporate parents, subsidiaries and affiliates and their respective attorneys,

principals, agents, experts, consultants, representatives, directors, officers, and employees, and others as set forth in this Protective Order.

3. Third parties who so elect may avail themselves of, and agree to be bound by, the terms and conditions of this Protective Order and thereby become a Producing Party for purposes of this Protective Order.

4. The entry of this Protective Order does not preclude any party from seeking a further order of this Court pursuant to Federal Rule of Civil Procedure 26(c).

5. Nothing herein shall be construed to affect in any manner the admissibility at trial or any other court proceeding of any document, testimony, or other evidence.

6. This Protective Order does not confer blanket protection on all disclosures or responses to discovery and the protection it affords extends only to the specific information or items that are entitled to protection under the applicable legal principles for treatment as confidential.

## **II. Definitions**

7. Party. “Party” means any of the parties in this Litigation at the time this Protective Order is entered, including officers and directors of such parties. If additional parties are added other than parents, subsidiaries or affiliates of current parties to this Litigation, then their ability to receive Confidential Information and/or Highly Confidential Information as set forth in this Protective Order will be subject to them being bound, by agreement or Court Order, to this Protective Order.

8. Discovery Material. “Discovery Material” means any information, document, or tangible thing, response to discovery requests, deposition testimony or transcript, and any other similar materials, or portions thereof. To the extent that matter stored or recorded in the form

of electronic or magnetic media (including information, files, databases, or programs stored on any digital or analog machine-readable device, computers, Internet sites, discs, networks, or tapes) (“Computerized Material”) is produced by any Party in such form, the Producing Party may designate such matters as confidential by a designation of “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” on the media. Whenever any Party to whom Computerized Material designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL is produced reduces such material to hardcopy form, that Party shall mark the hardcopy form with the corresponding “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” designation.

9. Competitor. Competitor as that term is used in this Protective Order shall mean any company, other than the Producing Party, that is engaged in the design and manufacture of any gadolinium based contrast agent used in connection with the administration of the diagnostic tests known as MRI and/or MRA. With respect to Novation only, “competitor” shall also be deemed to include an entity that contracts for the distribution of and/or distributes any gadolinium based contrast agent used in connection with the administration of the diagnostic tests known as MRI and/or MRA.

10. Confidential Information. “Confidential Information” is defined herein as information that the Producing Party in good faith believes constitutes, reflects, discloses, or contains information subject to protection under F.R.C.P. 26, including information required to be treated as confidential pursuant to foreign law, such as “personal data” as defined in data privacy laws and/or regulations of foreign countries, whether it is a document, information contained in a document, information revealed during a deposition or other testimony, information revealed in an interrogatory response, or information otherwise revealed. In designating discovery materials as Confidential Information, the Producing Party shall do so in

good faith consistent with the provisions of this Protective Order and rulings of the Court. Nothing herein shall be construed to allow for global designations of all documents as “Confidential.”

11. Highly Confidential Information. “Highly Confidential Information” is defined herein as Confidential Information which, if disclosed to a Competitor, could result in possible antitrust violations or substantial business harm. In designating discovery materials as Highly Confidential Information, the Producing Party shall do so in good faith consistent with the provisions of this Protective Order and rulings of the Court. Nothing herein shall be construed to allow for global designations of all documents as “Highly Confidential.”

12. Receiving Party. “Receiving Party” means a Party to this Litigation, and all employees, agents and directors (other than Counsel) of the Party that receives Discovery Material from a Producing Party.

13. Producing Party. “Producing Party” means a Party to this Litigation, and all directors, employees and agents (other than Counsel) of the Party or any third party that produces or otherwise makes available Discovery Material to a Receiving Party, subject to paragraph 3.

14. Protected Material. “Protected Material” means any Discovery Material, and any copies, abstracts, summaries, or information derived from such Discovery Material, and any notes or other records regarding the contents of such Discovery Material, that is designated as “Confidential” Or “Highly Confidential” in accordance with this Protective Order.

15. Outside Counsel. “Outside Counsel” means any law firm or attorney who represents BAYER HEALTHCARE PHARMACEUTICALS INC., BAYER SCHERING PHARMA AG, BRACCO DIAGNOSTICS INC., BRACCO RESEARCH USA INC.,

GENERAL ELECTRIC COMPANY, GE HEALTHCARE INC., GE HEALTHCARE BIO-SCIENCES CORP., GE HEALTHCARE AS, MALLINCKRODT INC., NOVATION LLC, or parents, subsidiaries or affiliates of these companies and who is not an employee for any of the companies; counsel of record for Plaintiffs; and their respective support staff, including secretarial and other assistants who are not employed by a Party and to whom it is necessary to disclose Protected Material for the purpose of this Litigation.

16. In-House Counsel. “In-House Counsel” means attorney employees of BAYER HEALTHCARE PHARMACEUTICALS INC., BAYER SCHERING PHARMA AG, BRACCO DIAGNOSTICS INC., BRACCO RESEARCH USA INC., GENERAL ELECTRIC COMPANY, GE HEALTHCARE INC., GE HEALTHCARE BIO-SCIENCES CORP., GE HEALTHCARE AS, MALLINCKRODT INC., or NOVATION LLC or parents, subsidiaries or affiliates of these companies and their insurers.

17. Counsel. “Counsel,” without another qualifier, means Outside Counsel and In-House Counsel.

18. Independent Expert. “Independent Expert” means an expert and/or independent consultant formally retained, and/or employed to advise or to assist Counsel in the preparation and/or trial of this Litigation, and their secretarial staff who are not employed by a Party to whom it is necessary to disclose Confidential Information or Highly Confidential Information for the purpose of this Litigation.

19. This Litigation. “This Litigation” means all actions relating to Gadolinium-based contrast agents that are currently pending in MDL No. 1909 or hereafter subject to transfer to MDL No. 1909.

### **III. Designation and Redaction of Confidential Information**

20. For each document produced by the Producing Party that contains or constitutes Confidential Information or Highly Confidential Information pursuant to this Protective Order, each page shall be marked “CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER”, or “HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER” or comparable notices.

21. Specific discovery responses produced by the Producing Party shall, if appropriate, be designated as Confidential Information or Highly Confidential Information by marking the pages of the document that contain such information with the notation “CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER”, or “HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER” or comparable notices.

22. Information disclosed at a deposition taken in connection with this Litigation may be designated as Confidential Information or Highly Confidential Information by designating the portions of the transcript in a letter to be served on the court reporter and opposing counsel within thirty (30) calendar days of the Producing Party’s receipt of the transcript of a deposition. The court reporter will indicate the portions designated as Confidential or Highly Confidential and segregate them as appropriate. Designations of transcripts will apply to audio, video, or other recordings of the testimony. The court reporter shall clearly mark any transcript released prior to the expiration of the 30-day period as “HIGHLY CONFIDENTIAL—SUBJECT TO FURTHER CONFIDENTIALITY REVIEW.” Such transcripts will be treated as Highly Confidential Information until the expiration of the 30-day period. If the Producing Party does not serve a designation letter within the 30-day period, then the entire transcript will be deemed not to contain Confidential Information or

Highly Confidential Information and the “HIGHLY CONFIDENTIAL—SUBJECT TO FURTHER CONFIDENTIALITY REVIEW” legend shall be removed.

23. A Party in this Litigation may designate as “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” any document or information produced by or testimony given by any other person or entity that the designating Party reasonably believes qualifies as the designating Party’s Confidential Information or Highly Confidential Information pursuant to this Protective Order. The Party claiming confidentiality shall designate the information as such within thirty (30) days of its receipt of such information. Any Party receiving information from a third party shall treat such information as Highly Confidential during this thirty (30) day period while all Parties have an opportunity to review the information and determine whether it should be designated as confidential. Any Party designating third party information as Confidential Information or Highly Confidential Information shall have the same rights as a Producing Party under this Protective Order with respect to such information.

24. This Protective Order shall not be construed to protect from production or to permit the “Confidential Information” or “Highly Confidential Information” designation of any document that (a) the party has not made reasonable efforts to keep confidential, or (b) is at the time of production or disclosure, or subsequently becomes, through no wrongful act on the part of the Receiving Party, generally available to the public through publication or otherwise.

25. In order to protect against unauthorized disclosure of Confidential Information and Highly Confidential Information, and to comply with all applicable state and federal laws and regulations, the Producing Party may redact from produced documents, materials or other things, or portions thereof, the following items, or any other item(s) agreed upon by the parties or ordered by the Court:

a. The names, street addresses (which shall not include city and state), Social Security, or tax identification numbers and other personally identifying information of employees, patients, health care providers, and individuals in clinical studies or adverse event reports. However, other general identifying information, such as patient or health care provider numbers assigned for a study, shall not be redacted unless required by state, federal or foreign law. To the extent a plaintiff's name is contained in any of these documents, a copy of the documents that have not had the plaintiff's information redacted will be produced directly to Counsel for said plaintiff;

b. Any information relating to products other than a Producing Party's Gadolinium-based contrast agent(s), except (a) that if the other product(s) is mentioned in direct comparison to the Producing Party's Gadolinium-based contrast agent in regard to matters relating to NSF/NFD, chemical structure, formulation, chelation, thermodynamic stability, or kinetic stability then the name and information about that product may not be redacted or (b) if the redaction of the name and information about the other product(s) would render the information pertaining to Producing Party's Gadolinium-based contrast agent meaningless or would remove the context of the information about Producing Party's Gadolinium-based contrast agent, the name and information about the other product may not be redacted. The Producing Party's counsel shall notify the Receiving Party's counsel in the event that documents containing comparisons not enumerated above are identified prior to redacting such information so that counsel for the parties can meet and confer concerning the producing party's ability to redact such comparisons. Nothing in this paragraph shall restrict Plaintiffs' right and ability to request information



about such other products nor restrict Defendants' right to object to or otherwise seek protection from the Court concerning any such request.

26. Pursuant to 21 C.F.R. §§ 314.430(e) & (f) and 20.63(f), the names of any person or persons reporting adverse experiences of patients and the names of any patients that are not redacted shall be treated as confidential, regardless of whether the document containing such names is designated as CONFIDENTIAL INFORMATION. No such person shall be contacted, either directly or indirectly, based on the information so disclosed without the express written permission of the Producing Party.

#### **IV. Access to Confidential and Highly Confidential Information**

27. General. A record shall be made of the names of the persons to whom disclosure of Protected Materials is made (other than to Outside Counsel). All Protected Material shall be held in the custody and control of Outside Counsel for the Receiving Party. Dissemination to the individuals set forth in Paragraphs 28 and 29 is considered to be in the custody and control of Outside Counsel.

28. In the absence of written permission from the Producing Party or an order of the Court, any Confidential Information produced in accordance with the provisions of this Protective Order shall be used solely for purposes of this Litigation (except as provided by Paragraph 28.g.) and its contents shall not be disclosed to any person other than:

- a. the Receiving Party;
- b. Outside Counsel and In-House Counsel, and the attorneys, paralegals, stenographic, and clerical staff employed by such counsel;
- c. with respect to any Confidential Information produced by any plaintiff or third party relating to plaintiff, any employee of the Receiving Party to whom it is

necessary to disclose such information for the purpose of assisting in, or consulting with respect to, the preparation of this Litigation;

d. stenographic employees and court reporters recording or transcribing testimony in this Litigation;

e. the Court, any Special Master appointed by the Court, and any members of their staffs to whom it is necessary to disclose the information;

f. formally retained independent experts and/or consultants, subject to the provisions of Paragraph 32;

g. counsel for claimants in other pending litigation alleging personal injury or economic loss arising from the alleged administration of Gadolinium-based contrast agent(s) manufactured and marketed by Defendants for use in this or such other action in which the Producing Party is a Defendant in that litigation, provided that the proposed recipient is: (i) already operating under a STIPULATED protective order(s) governing the use of confidential information that has provisions for both Confidential and Highly Confidential designations with each Defendant in This Litigation, which will be provided to Plaintiffs Liaison Counsel prior to the disclosure of Confidential Information or (ii) agrees to be bound by this Protective Order and signs a certification described in Paragraph 31;

h. any individual(s) who authored, prepared or previously received the information;

i. vendor agents retained by the parties or counsel for the parties;

j. Plaintiff's counsel of record to any Plaintiff with a case pending in MDL 1909 shall be permitted to receive the Confidential Information of any Producing Party

regardless of whether that attorney is counsel of record in any individual action against the Producing Party and there shall be no need for such counsel to execute such acknowledgement because such counsel is bound by the terms of this Protective Order; and

k. plaintiffs' treating physicians, including any personnel providing MRI and/or MRA services pursuant to the terms of this Court's Order of May 27, 2008.

29. In the absence of written permission from the Producing Party or an order of the Court, any Highly Confidential Information produced in accordance with the provisions of this Protective Order shall be used solely for purposes of this Litigation (except as provided by 29.f.) and its contents shall not be disclosed to any person other than:

a. the Receiving Party. However, if the Receiving Party is a co-Defendant or a Competitor of the Producing Party, the Receiving Party may not receive Highly Confidential Information, except as provided by Paragraph 29(b);

b. Outside Counsel, and the attorneys, paralegals, stenographic, and clerical staff employed by such counsel. The provision of Highly Confidential Data to In-House counsel will be addressed by subsequent order of the Court or agreement of the Defendants;

c. stenographic employees and court reporters recording or transcribing testimony in this Litigation;

d. the Court, any Special Master appointed by the Court, and any members of their staffs to whom it is necessary to disclose the information;

e. formally retained independent experts and/or consultants, subject to the provisions of Paragraph 32;

f. counsel for claimants in other pending litigation alleging personal injury or economic loss arising from the alleged administration of Gadolinium-based contrast agent(s) manufactured and marketed by Defendants for use in this or such other action in which the Producing Party is a Defendant in that litigation, provided that the proposed recipient is: (i) already operating under a STIPULATED protective order(s) governing the use of confidential information that has provisions for both Confidential and Highly Confidential designations with each Defendant in this Litigation, which will be provided to Plaintiffs Liaison Counsel prior to the disclosure of Confidential Information, or (ii) agrees to be bound by this Protective Order and signs a certification described in Paragraph 31;

g. any individual(s) who authored, prepared or previously received the information;

h. vendor agents retained by the parties or counsel for the parties;

i. Plaintiff's counsel of record to any Plaintiff with a case pending in MDL 1909 shall be permitted to receive the Confidential Information of any Producing Party regardless of whether that attorney is counsel of record in any individual action against the Producing Party and there shall be no need for such counsel to execute such acknowledgement because such counsel is bound by the terms of this Protective Order; and

j. plaintiffs' treating physicians, including any personnel providing MRI and/or MRA services pursuant to the terms of this Court's Order of May 27, 2008.

30. With respect to documents produced to Plaintiffs, documents designated as "HIGHLY CONFIDENTIAL" will be treated in the same manner as documents designated

“CONFIDENTIAL,” except that Plaintiffs may not disclose Highly Confidential Information to In-House Counsel, and/or current employees of any Competitor of the Producing Party. In the event that In-House Counsel, and/or current employees of any Competitor of the Producing Party is present at the deposition of an employee or former employee of the Producing Party, prior to a document Highly Confidential being used such In-House Counsel, and/or current employees of any Competitor of the Producing Party shall excuse himself or herself from the deposition room without delaying or disrupting the deposition.

**V. Confidentiality Acknowledgment**

31. Prior to the disclosure of any Confidential Information or Highly Confidential Information to any person identified above, each putative recipient of Confidential Information or Highly Confidential Information shall be provided with a copy of this Protective Order, which he or she shall read. Upon reading this Protective Order, such person shall sign an Acknowledgment, in the form annexed hereto as Exhibit A, acknowledging that he or she has read this Protective Order and shall abide by its terms. Outside Counsel to the parties in this matter, the Court, and the Court’s staff and official court reporter(s) are not required to sign an acknowledgement. These Acknowledgments are strictly confidential. Counsel for each Party shall maintain the Acknowledgments without giving copies to the other side. The parties expressly agree, and it is hereby ordered that, except in the event of a violation of this Protective Order, there will be no attempt to seek copies of the Acknowledgments or to determine the identities of persons signing them. If the Court finds that any disclosure is necessary to investigate a violation of this Protective Order, such disclosure will be pursuant to separate court order. Persons who come into contact with Confidential Information or Highly Confidential Information for clerical or administrative purposes, and who do not retain copies

or extracts thereof, are not required to execute Acknowledgements but must comply with the terms of this Protective Order.

## **VI. Litigation Experts and Consultants**

32. Formally Retained Independent Experts and Consultants. Subject to the provisions of this Protective Order, all Confidential Information or Highly Confidential Information may be disclosed to any formally retained independent expert or consultant who has agreed in writing pursuant to paragraph 31 or on the record of a deposition to be bound by this Protective Order. The party retaining an independent expert or consultant shall use diligent efforts to determine if the independent expert or consultant is currently working with or for a Competitor of a Producing Party and is currently employed or consulting in connection with Gadolinium based contrast agents. Prior to disclosing Confidential Information or Highly Confidential Information to an expert or consultant who is currently working with or for a Competitor of the Producing Party and is currently employed or consulting in connection with Gadolinium based contrast agents, the party wishing to make such a disclosure (“Notifying Party”) shall provide to counsel for the Producing Party in writing, which may include by e-mail, a statement that such disclosure will be made, identifying the subject matter category of the Discovery Material to be disclosed, providing the nature of the affiliation with the Competitor entity and name of the Competitor entity, and stating the purpose of such disclosure; the specific name of the formally retained independent expert or consultant need not be provided. The Producing Party shall have ten (10) days from its receipt of the notice to deliver to the Notifying Party its good faith written objections, which may include e-mail, to the expert or consultant, if any. Absent timely objection, the expert or consultant shall be allowed to receive Confidential and Highly Confidential Information pursuant to the terms of this

Protective Order. Upon timely objection, disclosure to the expert or consultant shall not be made. If the Notifying Party desires to challenge to the Producing Party's written objection to the expert or consultant, the Notifying Party shall so inform the Producing Party in writing, within ten (10) days of receipt of the Producing Party's written objection, of its reasons for challenging the objection. The expert or consultant shall then be allowed to receive Confidential and Highly Confidential Information pursuant to the terms of this Protective Order after ten (10) days from receipt of the Producing Party's timely challenge to the written objection to the expert or consultant, unless the Producing Party moves for relief from the Court, or the Parties stipulate to an agreement. Once a motion is filed, disclosure shall not occur until the issue is decided by the Court and, if the motion is denied, the appeal period from the Court order denying the motion has expired. In making such motion, it shall be the Producing Party's burden to demonstrate good cause for preventing such disclosure.

## **VII. Handling of Confidential and Highly Confidential Information During Sworn**

### **Testimony**

33. The handling of confidential and highly confidential information during sworn testimony shall be addressed by a separate order.

## **VIII. Filing of Confidential and Highly Confidential Information with the Court**

34. In the event that any Confidential Information or Highly Confidential Information is included with, or the contents thereof are in any way disclosed in, any pleading, motion, deposition, transcript or other paper filed with the Clerk of this Court, consistent with applicable law, the Confidential Information or Highly Confidential Information shall be filed and kept under seal by the Clerk until further order of this Court. When submitting deposition testimony pursuant to this paragraph that has been designated "CONFIDENTIAL" or

“HIGHLY CONFIDENTIAL,” the submitting Party shall submit, to the extent reasonably possible, only those pages of the deposition transcript that are cited, referred to, or relied on by the submitting Party.

**IX. Protection and Use of Confidential and Highly Confidential Information**

35. Persons receiving or having knowledge of Confidential Information or Highly Confidential Information by virtue of their participation in this proceeding, or by virtue of obtaining any documents or other Protected Material produced or disclosed pursuant to this Protective Order, shall use that Confidential Information or Highly Confidential Information only as permitted by this Protective Order. Counsel shall take reasonable steps to assure the security of any Confidential Information or Highly Confidential Information and will limit access to such material to those persons authorized by this Protective Order.

36. Nothing herein shall restrict a person qualified to receive Confidential Information and Highly Confidential Information pursuant to this Protective Order from making working copies, abstracts, digests and analyses of such information for use in connection with this Litigation and such working copies, abstracts, digests and analyses shall be deemed to have the same level of protection under the terms of this Protective Order. Further, nothing herein shall restrict a qualified recipient from converting or translating such information into machine-readable form for incorporation in a data retrieval system used in connection with this Litigation, provided that access to such information, in whatever form stored or reproduced, shall be deemed to have the same level of protection under the terms of this Protective Order.

37. All persons qualified to receive Confidential Information and Highly Confidential Information pursuant to this Protective Order shall at all times keep all notes, abstractions, or



other work product derived from or containing Confidential Information or Highly Confidential Information in a manner to protect it from disclosure not in accordance with this Protective Order, and shall be obligated to maintain the confidentiality of such work product and shall not disclose or reveal the contents of said notes, abstractions or other work product after the documents, materials, or other thing, or portions thereof (and the information contained therein) are returned and surrendered pursuant to Paragraph 43. Nothing in this Protective Order requires the Receiving Party's Counsel to disclose work product at the conclusion of the case.

38. Notwithstanding any other provisions hereof, nothing herein shall restrict any Party's Counsel from rendering advice to that Counsel's clients with respect to this proceeding or a related action in which the Receiving Party is permitted by this Protective Order to use Confidential Information or Highly Confidential Information and, in the course thereof, relying upon such information, provided that in rendering such advice, Counsel shall not disclose any other Party's Confidential Information or Highly Confidential Information other than in a manner provided for in this Protective Order.

39. Nothing contained in this Protective Order shall preclude any Party from using its own Confidential Information or Highly Confidential Information in any manner it sees fit, without prior consent of any Party or the Court.

40. . . . To the extent that a Producing Party uses or discloses to a third party its designated confidential information in a manner that causes the information to lose its confidential status, the Receiving Party is entitled to notice of the Producing Party's use of the confidential information in such a manner that the information has lost its confidentiality, and the Receiving Party may also use the information in the same manner as the Producing Party.

41. Any Party that is served with a subpoena or other notice compelling the production of Discovery Materials produced by another Party must immediately give written notice of such subpoena or other notice to the original Producing Party. Upon receiving such notice, the original Producing Party shall bear the burden of opposing, if it deems appropriate, the subpoena on grounds of confidentiality.

42. If a Receiving Party learns of any unauthorized disclosure of Confidential Information or Highly Confidential Information, it shall immediately (a) inform the Producing Party in writing of all pertinent facts relating to such disclosure; (b) make its best effort to retrieve all copies of the Confidential Information or Highly Confidential Information; (c) inform the person or persons to whom unauthorized disclosures were made of all the terms of this Protective Order; and (d) request such person or persons execute the Acknowledgment that is attached hereto as Exhibit A.

43. Within thirty (30) days of the conclusion of an attorney's last case in this Litigation (or such other case in which the Receiving Party is permitted by this Protective Order to use Confidential Information and Highly Confidential Information), including any appeals related thereto, at the written request and option of the Producing Party, such attorney and any persons to whom he or she discloses Confidential Information or Highly Confidential Information pursuant to this Protective Order shall return and surrender any such information or copies thereof to the Producing Party at the Producing Party's expense. Such persons shall return or surrender any Discovery Materials produced by the Producing Party and any and all copies (electronic or otherwise), summaries, notes, compilations, and memoranda related thereto; provided, however, that Counsel may retain their privileged communications, work product, Acknowledgments pursuant to this Protective Order, materials required to be retained

pursuant to applicable law, and all court-filed documents even though they contain Discovery Materials produced by the Producing Party, but such retained materials shall remain subject to the terms of this Protective Order. At the written request of the Producing Party, any person or entity having custody or control of recordings, notes, memoranda, summaries, or other written materials, and all copies thereof, relating to or containing Discovery Materials produced by the Producing Party shall deliver to the Producing Party an affidavit certifying that reasonable efforts have been made to assure that all such Discovery Materials produced by the Producing Party and any copies thereof, any and all records, notes, memoranda, summaries, or other written material regarding the Discovery Materials produced by the Producing Party (except for privileged communications, work product, and court-filed documents as stated above) have been delivered to the Producing Party in accordance with the terms of this Protective Order. In the alternative to returning the materials, the Producing Party may direct that the materials be destroyed in a manner that will protect the Confidential Information or Highly Confidential Information, and the returning party shall certify that it has done so.

#### **X. Changes in Designation of Information**

44. If a Party through inadvertence produces any Confidential Information or Highly Confidential Information without labeling or marking or otherwise designating it as such in accordance with the provisions of this Protective Order, the Producing Party may give written notice to the Receiving Party that the document or thing produced is deemed “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” and should be treated as such in accordance with the provisions of this Protective Order. The Receiving Party must treat such documents and things with the noticed level of protection from the date such notice is received. Disclosure, prior to the receipt of such notice of such information, to persons not authorized to

receive such information shall not be deemed a violation of this Protective Order. Any Producing Party may designate as “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” or withdraw a “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” designation from any material that it has produced consistent with this Protective Order, provided, however, that such redesignation shall be effective only as of the date of such redesignation. Such redesignation shall be accomplished by notifying Counsel for each Party in writing of such redesignation and providing replacement images bearing the appropriate description. Upon receipt of any redesignation and replacement image that designates material as “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL”, the Receiving Party shall (i) treat such material in accordance with this Protective Order; (ii) take reasonable steps to notify any persons known to have possession of any such material of such redesignation under this Protective Order; and (iii) promptly endeavor to procure all copies of such material from any persons known to have possession of such material who are not entitled to receipt under this Protective Order. It is understood that the Receiving Party’s good faith efforts to procure all copies may not result in the actual return of all copies of such materials.

45. A Receiving Party does not waive its right to challenge a confidentiality designation by electing not to mount a challenge promptly after the original designation is disclosed. A Receiving Party may challenge a Producing Party’s confidentiality designation or redesignation by notifying the Producing Party, in writing or voice-to-voice dialogue, of its good faith belief that the confidentiality designation was not proper and must give the Producing Party an opportunity to review the designated material, to reconsider the circumstances, and, if no change in designation is offered, to explain, in writing within fourteen (14) days, the basis of the chosen designation. If a Receiving Party elects to press a challenge

to a confidentiality designation after considering the justification offered by the Producing Party, the receiving party shall, in writing, notify the producing party that a resolution cannot be reached regarding the confidentiality designation of a document, then the Producing Party shall, within twenty one (21) days of receiving such notice from the Receiving Party, file and serve a motion that identifies the challenged material and sets forth in detail the basis for the “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” designation. The burden of persuasion in any such challenge proceeding shall be on the Producing Party. Until the Court rules on the challenge, all Parties shall continue to afford the material in question the level of protection to which it is entitled under the Producing Party’s designation. If after the expiration of the twenty one (21) days the Producing Party has not filed a motion with the Court, the designation of the document subject to the dispute regarding its “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL” designation will be automatically changed. If a document was originally designated as “CONFIDENTIAL,” the “CONFIDENTIAL” designation will be removed. If a document was originally designated as “HIGHLY CONFIDENTIAL,” it will be designated and treated as Confidential Information.

#### **XI. Inadvertent Production of Documents**

46. 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 a reasonable period of time from the 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 as set forth below, the Receiving Party, subject to the requirements 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 motion below. If the Receiving Party's motion is denied, the Receiving Party shall promptly comply with the immediately preceding provisions of this paragraph. No use shall be made of such Inadvertently Produced 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 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.

## **XII. Miscellaneous Provisions**

47. Nothing in this Protective Order shall abridge the right of any person to seek judicial review or to pursue other appropriate judicial action to seek a modification or amendment of this Protective Order.

48. In the event anyone shall violate or threaten to violate the terms of this Protective Order, the Producing Party may immediately apply to obtain injunctive relief against any person violating or threatening to violate any of the terms of this Protective Order, and in the event the Producing Party shall do so, the respondent person, subject to the provisions of this Protective Order, shall not employ as a defense thereto the claim that the Producing Party possesses an adequate remedy at law.

49. This Protective Order shall not be construed as waiving any right to assert a claim of privilege, relevance, or other grounds for not producing Discovery Material called for, and access to such Discovery Material shall be only as provided for by separate agreement of the Parties or by the Court.

50. It is expressly understood by and between the Parties that in producing Confidential Information or Highly Confidential Information in this Litigation, the Parties shall be relying upon the terms and conditions of this Protective Order.

51. This Protective Order may be amended without leave of the Court by agreement of Outside Counsel for the Parties in the form of a written stipulation filed with the Court. The Protective Order shall continue in force until amended or superseded by express order of the Court, and shall survive and remain in effect after the termination of this Litigation.

52. Notwithstanding any other provision in the Order, nothing in this Protective Order shall affect or modify Defendants' ability to review Plaintiffs' information and report such information to any applicable regulatory agencies.

**IT IS SO ORDERED:**

Dated: 6/4/08, 2008

/s/Dan Aaron Polster  
Honorable Dan Aaron Polster  
United States District Judge

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

IN RE: GADOLINIUM BASED  
CONTRAST AGENTS PRODUCTS  
LIABILITY LITIGATION

Case No. 1:08 GD 50000

MDL No. 1909

Honorable Dan Aaron Polster

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**EXHIBIT A TO CMO NO. 6**

**ACKNOWLEDGMENT AND AGREEMENT TO BE BOUND  
BY PROTECTIVE ORDER**

The undersigned agrees:

I declare under penalty of perjury that I have read in its entirety and understand the Protective Order (CMO No. 6) that was issued by the United States District Court for the Northern District of Ohio on \_\_\_\_\_, 2008 in In re: Gadolinium Based Contrast Agents Products Liability Litigation, Case No. 1:08 GD 50000; MDL No. 1909.

I agree to comply with and to be bound by all the terms of this Stipulated Protective Order, and I understand and acknowledge that failure to so comply could expose me to sanctions and punishment in the nature of contempt. I solemnly promise that I will not disclose in any manner any information or item that is subject to this Protective Order to any person or entity except in strict compliance with the provisions of this Protective Order.

I further agree to submit to the jurisdiction of the United States District Court for the Northern District of Ohio for the purposes of enforcing terms of this Protective Order, even if such enforcement proceedings occur after termination of these proceedings.



Date: \_\_\_\_\_

City and State where sworn and signed: \_\_\_\_\_

Printed Name: \_\_\_\_\_

Signature: \_\_\_\_\_