UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
----------x
In re:

AREDIA and ZOMETA	**No. 3:06-MD-1760**
PRODUCTS LIABILITY LITIGATION	**JUDGE CAMPBELL**
(MDL No. 1760)	**MAGISTRATE JUDGE BROWN**

This Documents Relates to: **All Cases**
----------x

CASE MANAGEMENT ORDER

This Case Management Order is hereby entered in all actions in *In re: Aredia® and Zometa® Products Liability Litigation*, No. 3:06-MD-1760 (M.D. Tenn.) ("MDL 1760").

In view of the length of this Order, the following index to general topics is provided:

This Order shall apply to all cases currently a part of MDL 1760, as well as all cases subsequently filed in, removed to, or transferred to this Court as part of MDL 1760. In cases subsequently filed in this district, the Clerk shall provide a copy of the Order to each Plaintiff at the time of filing of the complaint. In cases subsequently removed or transferred to this Court, the Clerk shall provide a copy of this Order to each new party upon removal or transfer. This Order vacates any prior case management or scheduling order issued by a federal court prior to the transfer of a case to MDL 1760, including the case management orders entered in matters pending before this Court prior to entry of the Order of the Judicial Panel on Multidistrict Litigation ("JPML") creating this MDL. The local rules of a federal transferor court will not be binding on the parties once a case has been transferred to this MDL so long as the case remains before this transferee court. As it relates to any event or filing in MDL 1760, the term "party" means Plaintiffs collectively and Novartis Pharmaceuticals Corporation individually. This Order shall be binding on all parties with cases docketed in MDL 1760.

The actions described in paragraph 1 of this order are coordinated for pre-trial purposes, and discovery obtained herein may be used by all parties in all cases.

I. Jurisdiction and Venue.

A. The Plaintiffs contend that jurisdiction exists under 28 USC § 1332 because there is diversity of citizenship and the amount in controversy exceeds $75,000 exclusive of interests and costs. Plaintiffs contend that venue is proper pursuant to 28 USC §1391(a)(1) because the Defendant is subject to personal jurisdiction here and is therefore deemed to reside in this district for venue purposes pursuant to 28 USC §1391(c).

B. For the purposes of pre-trial proceedings, Defendant has not challenged the existence of diversity jurisdiction but reserves the right to challenge venue as appropriate under 28 U.S.C. § 1404 or other applicable statutes.

II. Status of Service and Responsive Pleadings.

A. Plaintiffs have effectuated service on the single defendant of the cases currently in MDL 1760 as of the date of this Order. There is no dispute regarding service in those cases. However, Defendant is not precluded from challenging the sufficiency of service in any case not currently part of MDL 1760.

B. All proceedings in any case transferred to MDL 1760, now or in the future, are stayed except (i) specific proceedings outlined in this Order or any subsequent order of the Court, or (ii) any pending motions to remand presently before this Court. All prior written discovery requests to which responses have not yet been served are deemed withdrawn and the party upon whom the written discovery was served is not required to respond absent further order of the Court. All deadlines for filing an answer or pre-answer motion are hereby stayed until forty (40) days after the Clerk of this Court establishes a specific case number for the case in the United States District Court for the Middle District of Tennessee or the original complaint is served, whichever is later.

III. Parties' Theories of the Case

A. **Plaintiffs' Theory of the Case:** Since 1991, 1.9 million people have been treated with Aredia. Since 2001, one million people have been treated with Zometa. According to Novartis, Zometa is today the most widely used bisphosphonate in oncology. The Plaintiffs seek compensatory damages and punitive damages for personal injuries. The theories of liability are strict liability and negligence. In addition, the Plaintiffs seek certification of a class action for the creation of a dental monitoring program for persons exposed to the drugs who do not yet have osteonecrosis of the jaw. The large number of persons treated with Aredia and Zometa establish that, when certified, the class will be made up of thousands of people who have taken both drugs.

Novartis filed a New Drug Application (NDA) for Aredia on December 20, 1989. The NDA was approved by the Food and Drug Administration (FDA) on October 31, 1991. At that time, the approved use was for the treatment of hypercalcemia of malignancy (HCM). Subsequently, Aredia was approved for the treatment of Paget's disease, osteolytic bone metastases of breast cancer and osteolytic lesions of multiple myeloma.

On December 21, 1999, Novartis filed a NDA for Zometa. The NDA was approved by the FDA on August 20, 2001. As of that date, the approved use was for HCM. Subsequently, Zometa was approved for the treatment of multiple myeloma and documented bone metastases from solid tumors.

Both Aredia and Zometa are bisphosphonates. Bisphosphonates contain phosphorus. In 2001, the FDA began receiving reports of osteonecrosis of the jaw (ONJ) associated with bisphosphonate therapy. This should have come as no surprise to Novartis. "Phossy jaw" first

appeared in a case series reported in Vienna in 1845. The condition was caused by exposure to white phosphorous during the manufacture of matches. The average time from first exposure to diagnosis was five years. Occasionally, the period was as short as a few months. Also, it has been reported that once taken, bisphosphonates remain in the body for more than twelve (12) years.

Novartis admits receiving reports of ONJ in cancer patients treated with bisphosphonates as early as December, 2002. As of that date, the labeling for Aredia and Zometa contained no warnings or other information about ONJ. This is so even though the clinical trials for both Aredia and Zometa contained patients with findings consistent with ONJ.

Novartis finally took some action in September, 2003, when the package insert for Zometa was revised to contain the following language under post-marketing experiences in the adverse events section:

> Cases of osteonecrosis (primarily of the jaws) have been reported since market introduction. Osteonecrosis of the jaws has other well documented multiple risk factors. It is not possible to determine if these events are related to Zometa or other bisphosphonates, to concomitant drugs or other therapies (e.g., chemotherapy, radiotherapy. corticosteroid), to patient's underlying disease, or to other comorbid risk factors (e.g., anemia, infection, preexisting oral disease).

There were no changes made at that time to the package insert for Aredia.

In October, 2003, Novartis finally took some action with regard to Aredia when the following paragraph was added to the package insert under post-marketing experiences in the adverse events section:

> Cases of osteonecrosis (primarily of the jaws) have been reported since market introduction. Osteonecrosis of the jaws has other well documented multiple risk factors. It is not possible to determine if these events are related to Aredia or other bisphosphonates, to concomitant drugs or other therapies (e.g., chemotherapy, radiotherapy, corticosteroid), to patients's underlying disease, or to other comorbid risk factors (e.g. anemia, infection, preexisting oral disease).

In 2003, Robert E. Marx, DDS, Chairman of Oral and Maxillofacial Surgery at the University of Miami School of Medicine, published a letter to the editor of the *Journal of Oral and Maxillofacial Surgery* wherein he described 36 cases of painful bone exposure in the mandible, maxilla or both, that were unresponsive to surgical or medical treatment. These patients had received either Aredia, Zometa, or both.

In November, 2003, the FDA Office of Drug Safety (ODS) began a search of the FDA's Adverse Event Reporting System for reports of cases of osteonecrosis or osteomyelitis associated with the use of Aredia, Zometa, Fosamax, or Actenol. In a memorandum dated August 25, 2004, the ODS identified 139 cases of which 47 had taken Aredia only, 33 had taken Zometa only, and 59 had taken both Aredia and Zometa. The review concluded that the language in both the Aredia and Zometa package inserts needed to be changed to highlight this adverse event as being associated with the therapeutic class of bisphosphonates. In addition, the review concluded that the labeling should be changed to reflect that the condition could be osetonecrosis, osteomyelitis or a combination of the two.

In 2004, Salvatore L. Ruggiero, DMD, MD, Chief of Oral and Maxillofacial Surgery at the Long Island Jewish Medical Center, in collaboration with others, published an article in the *Journal of Oral and Maxillofacial Surgery* in which he described 63 cases of necrotic lesions in the jaw. All 63 had one thing in common: they had all received chronic bisphosphonate therapy. Of the 63 patients, 57 had taken either Aredia or Zometa, or both.

On March 4, 2005, the Oncologic Drugs Advisory Committee of the FDA conducted a public hearing during which testimony was presented relating to the connection between bisphosphonate therapy and osteonecrosis of the jaw. Part of the testimony included an analysis

of the mean time from exposure to the appearance of suspicious findings. For Aredia, the mean time was just under six years; for Zometa, 18 months. The need for monitoring was acknowledged by Novartis and it submitted to the Committee a list of recommendations for the prevention, diagnosis and treatment of osteonecrosis of the jaw. These recommendations are a starting point for the creation of the dental monitoring program sought by Plaintiffs in their complaint and request for class certification. Novartis's recommendations include: education of patients regarding the importance of good dental hygiene and symptom reporting; physical and dental evaluation; and imaging with panoramic radiographs. Novartis further recommended that these evaluations occur at a minimum of every six months.

The facts clearly establish that Novartis knew or should have known of the risk of osteonecrosis and/or osteomyelitis of the jaw at the time it first sold Aredia in 1991 and Zometa in 2001. That knowledge only increased with time, yet Novartis did nothing to warn prescribers or users of Aredia until October, 2003 and of Zometa until September, 2003. Even then, the warnings provided were inadequate and were not made available to dentists or oral surgeons. This inexcusable failure to warn supports Plaintiffs' claim for punitive damages and the necessity for a dental monitoring program. The facts establish the existence of a readily definable class of thousands of persons who took both Aredia and Zometa and which have already developed, or are at significant risk of developing, osteonecrosis and/or osteomyelitis of the jaw. The funding by Novartis of a dental monitoring program similar to, but more complete than the one recommended to the FDA earlier this year, will serve to reduce the risk of developing these conditions. It will also lead to a more timely diagnosis and treatment of the conditions should they develop.

B. **Defendant's Theory of the Case:** Plaintiffs allegedly either have osteonecrosis of the jaw ("ONJ") or are at an increased risk of developing it as a result of their use of Aredia® and/or Zometa®, both of which are distributed by Novartis Pharmaceuticals Corporation.[1] Aredia® and Zometa® are used by cancer patients with multiple myeloma, metastases to the bone in certain types of cancers, or hypercalcemia of malignancy. Patients with multiple myeloma or bone metastases from solid cancerous tumors lose bone density as a result of the increased resorption of bone tissue associated with the cancer and are therefore more susceptible to debilitating bone fractures, spinal compression, and other skeletal related events ("SREs"). Hypercalcemia is increased calcium in the blood resulting from the over resorption of the bone. It can result in the excessive distribution of calcium to organs and other locations in the body, resulting in impairment of various systems, coma, and death. Aredia® and Zometa® reduce the number, and delay the time to first onset, of SREs suffered by these patients and reduce the effects of hypercalcemia of malignancy. As a result, these drugs provide significant, scientifically documented benefits to their users by enabling them to enjoy a better quality of life. ONJ is a rare, ill defined, and poorly understood disease with an unknown etiology. There are multiple risk factors for developing ONJ, including but not limited to trauma to the jaw, dental surgery, cancer itself (particularly multiple myeloma), treatment with corticosteroids, hormone therapy, and poor dental hygiene. Further, there are several other disorders that present with symptoms similar to ONJ, but are in fact distinct disease entities.

[1] Aredia® is the trade name under which Novartis distributes the drug pamidronate disodium for intravenous infusion. The Food and Drug Administration ("FDA") first approved it for use in 1991, and Aredia® is indicated for the treatment of hypercalcemia associated with malignancy; Paget's disease of bone; osteolytic bone metastases of breast cancer; and osteolytic lesions of multiple myeloma. Zometa® is the trade name under which Novartis distributes the drug zoledronic acid for intravenous infusion. The FDA first approved Zometa® for use in 2001. Zometa® is indicated for the treatment of hypercalcemia of malignancy; multiple myeloma; and bone metastases from solid tumors (including prostate and other cancers).

Plaintiffs' claims fail for several reasons. First, the claims are preempted. At all times, Novartis, in consultation with and with the approval and oversight of the FDA, has provided full and adequate information to physicians prescribing Aredia® and Zometa® regarding the known and/or knowable potential risks associated with the drugs. Novartis has provided the medical community with ample, timely and adequate information concerning ONJ as it has become available through FDA-approved changes to its product labeling and by other means. Plaintiffs' state law tort claims alleging that Novartis's warnings were deficient conflict with the FDA's regulatory system – the same system that has continuously approved the labeling and marketing for Aredia® and Zometa® – and therefore must be dismissed.

Second, no scientifically reliable evidence establishes a causal relationship between treatment with Aredia® or Zometa® and ONJ. Plaintiffs only refer to unreliable case reports or retrospective chart reviews – none of which are a suitable basis for a causation determination under applicable law. Additionally, no dependable science establishes a mechanism of action regarding how either product allegedly causes ONJ.

Third, under any applicable legal standard, including but not limited to a risk/benefit analysis; the Restatement (Second) of Torts § 402A, Comment K; or Restatement (Third) of Torts Product Liability §§ 4, 6, any alleged undisclosed risk posed by treatment with either or both drugs is outweighed by the benefits provided by them, thereby defeating Plaintiffs' claims. Aredia® and Zometa® allow terminal cancer patients to engage in more of their normal activities for an expanded period of time because of the reduction in risk of SREs. Even if reliable science were to establish that ONJ is a possible side effect of using either product (which it currently does not), expert and other testimony will demonstrate that doctors prescribed and will continue to prescribe Aredia® and Zometa® because their benefits clearly outweigh any of the low risks for

side effects and would likely do so regardless of what language is or was in place in the labeling.

Fourth, Plaintiffs have identified no safer alternative design and have provided no evidence that the state of the art, assumption of risk, the learned intermediary doctrine, or other similar defenses are inapplicable. As discussed above, the labeling has always contained various warnings approved by the FDA as appropriate at the given time.

In addition to the above substantive deficiencies, Plaintiffs' request for a dental monitoring class fails to satisfy Federal Rule of Civil Procedure 23's certification requirements. In this MDL, the "general causation" inquiry will focus in part on whether either Aredia® or Zometa® can be isolated as the cause of ONJ in cancer patients receiving chemotherapy, radiation treatments, or other treatments or conditions that are independent risk factors for ONJ. Similarly, the specific causation analysis is inherently individual – it will require an examination of, among other things, each individual's medical history, whether a given individual has ONJ or a "look alike" disease, and what other risk factors for ONJ are present in that plaintiff. Further, Plaintiffs suffer from several different cancers and were prescribed the drug(s) by different doctors at different times, thereby potentially receiving different information regarding the risk associated with therapy with Aredia® or Zometa®. In addition to sharing no meaningful common factual issues, Plaintiffs seek a nationwide medical monitoring class even though no uniformity exists among various states' laws on either the availability of medical monitoring as an independent cause of action or a remedy, or on the elements of the underlying medical monitoring cause of action. Class certification is inappropriate in such circumstances.[2]

---

[2] For many of the same reasons, the individual Plaintiffs' claims are not properly joined in one action, even under the permissive standards of Federal Rule of Civil Procedure 20(a). *See Thorn, et al. v. Novartis Pharm. Corp.*, No.

Medical monitoring is not an appropriate remedy in these cases because Plaintiffs cannot meet any potentially applicable state law burden for such relief, including for example showing that a substantially increased risk exists, that uniformly useful diagnostic testing is available to allow "early detection", or that uniform preventative measures apply.

IV. Motion Practice; Service of Documents Not Filed

A. Motions. Motion practice shall be governed by applicable Federal and Local Rules except as otherwise provided herein or in any subsequent case management order. Absent an Order of the Court, briefs in response to all motions shall be filed no later than twenty-one (21) days after the date of service. Replies, limited to five (5) pages, may be filed without leave of Court, and shall be filed within fourteen (14) days after service of the response. In calculating the time periods set forth in this Order, the provisions of Fed. R. Civ. P. 5 and 6 apply. No additional memorandum of law shall be permitted without leave of court.

B. Service of Documents Not Filed With the Court. A party serving a document not filed with the Court that applies to all cases in the MDL shall provide one (1) copy to Plaintiffs' Liaison Counsel and one (1) copy to Defendant's Lead Counsel. Plaintiff's Liaison Counsel will be responsible for providing copies of the document to all other Plaintiffs' counsel. A party serving a document not filed with the Court that applies only to a specific action or actions shall provide one (1) copy to Designated Counsel as described below in the specific action or actions, one (1) copy to Defendant's Lead Counsel, and one (1) copy to liaison counsel.

3:04-CV-586 (E.D. Tenn., August 30, 2005) (Docket #s 73, 74) (Jordan, S.J.) (denying joinder in part because proposed Plaintiffs' claims did not arise out of the same transaction or occurrence as pending claims.). The personal injury claims are also ill suited for certification under Rule 23.

V. Substitution of Plaintiffs.

In the event that a Plaintiff dies before his or her individual action is remanded, the following procedures shall govern the substitution of an individual as plaintiff in place of the deceased plaintiff:

A. Suggestion of Death. Within thirty (30) days of entry of this Order or the death of a plaintiff, whichever is later, plaintiff's counsel shall file a "Suggestion of Death" that identifies the plaintiff and describes the time, date, and circumstances of the plaintiff's death.

B. Timing of Motion for Substitution. The ninety (90) day time period for filing a Motion for Substitution, as required by Fed. R. Civ. P. 25(a), will commence upon the filing of a Suggestion of Death or upon the passage of 30 days from the entry of this Order, whichever is later.

C. Contents of Motion for Substitution.

1. The Motion for Substitution shall identify the proposed substitute plaintiff by name and shall describe why the proposed substitute plaintiff is a "proper" party and why the claim has not been extinguished under the applicable state survivorship statute or applicable state common law.

2. In the event that applicable state law requires the opening of an estate and the appointment of a personal representative to pursue the claims of a deceased plaintiff, plaintiff's counsel shall initiate or cause to be initiated proceedings to open an estate and/or obtain the appointment of a personal representative for plaintiff within thirty (30) days of the

plaintiff's death or thirty (30) days from entry of this Order, whichever is later.

a. If available at the time of filing, plaintiff's counsel shall attach as an exhibit to the Motion to Substitute a copy of any Order appointing the person sought to be substituted as the personal representative of the deceased plaintiff.

b. In the event that no personal representative has been appointed by the deadline for filing a Motion for Substitution, plaintiff's counsel shall describe in the Motion to Substitute the steps taken to obtain the appointment of a personal representative and state whether there are any competing applications. If the Court determines that the person sought to be substituted would be a proper party if appointed a personal representative of the deceased plaintiff and that the provisions of this Section of the Order and Fed. R. Civ. P. 25(a) have otherwise been complied with, the Court will provisionally grant the Motion for Substitution on the condition that the substituted plaintiff submit to the Court prior to remand of the plaintiff's claims a copy of the Order appointing him or her as the deceased plaintiff's personal representative.

3. Plaintiff's failure to comply with the provisions of this Section, including the requirement that an Order appointing the substitute plaintiff as the decedent's personal representative be filed prior to remand where the Court grants a provisional substitution, will entitle Defendant to request a dismissal of plaintiff's action with prejudice in accord with Fed. R. Civ. P. 25(a).

D. Opposition to Substitution. Nothing in this section shall preclude Defendant from challenging the authority or capacity of the proposed substitute plaintiff.

VI. Pre-Trial Proceedings.

A. Stay of Discovery. There shall be no stay of discovery with respect to class certification, Defendant's liability, causation, and facts pertaining to and damages claimed by Plaintiffs named in the original three cases, 3:05-cv-0716, 3:05-cv-0718, and 3:05-cv-0719. In addition, the Defendant may select up to five (5) additional cases in which they wish to begin discovery. Plaintiffs may select two (2) such additional cases. Except for the limited discovery authorized Defendant in subsections (E)-(G) of Section X of this Order and required of Defendant in Section IX of this Order, all discovery in cases outside of the original three and additional seven test cases is **STAYED** until **July 2, 2007**, whereupon full fact discovery in all MDL cases will begin, in the absence of a further order of the Court or an agreement by the parties to commence discovery earlier.

Defendant's counsel shall furnish Plaintiffs' counsel with a proposed Plaintiffs' Fact Sheet (PFS) to be completed by all Plaintiffs. If Plaintiffs have any objections to the proposed questionnaire, they shall conduct a telephone conference with the Magistrate Judge about the matter.

The parties to the original three cases shall commence discovery as described in Section XV of this Order. The parties to the seven additional test cases may commence full fact discovery immediately upon service by all plaintiffs in the individual case of a PFS completed in all material respects (as described in Section X of this Order), to the extent that those cases do not involve a class certification issue (see Section XV of this Order). The framework of deadlines established in Section XV.B. of this Order shall apply to these additional test cases.

B. Rule 26(a)(1) Disclosures. Defendant's Fed. R. Civ. P. 26(a)(1) disclosures made in *Anderson, et al. v. Novartis Pharmaceuticals Corp.*, No. 3:05-CV-0718 (M.D. Tenn.), *Becker, et al. v. Novartis Pharmaceuticals Corp.*, No. 3:05-CV-0719 (M.D. Tenn.), and *Wood, et al. v. Novartis Pharmaceuticals Corp.*, No. 3:05-CV-0716 (M.D. Tenn.), shall constitute Defendant's initial disclosures in all cases transferred into MDL 1760. Defendant shall supplement these disclosures as appropriate. Submission of a PFS that is complete in all respects shall satisfy that Plaintiffs' initial disclosure obligations under Fed. R. Civ. P. 26(a)(1).

C. Meeting of Counsel and Parties to Discuss Settlement Prospects. At this stage of the proceedings, the parties are in agreement that settlement is unlikely and also believe that ADR would not be productive.

D. Status of the Issues Presented. The issues and facts in this case are in dispute at this time.

E. Other Claims. At this time the parties are not aware of the need for any counterclaims, cross-claims, third-party claims, joinder of the other parties or claims. Should the parties become aware of the need for such pleadings, they will inform the other.

F. Admission of Fact and Stipulations to Authenticity. It is hereby ordered that copies of all documents maintained in "hard" form produced by Defendant are deemed to be a true and accurate copy of documents in the possession and control of that Defendant, unless otherwise indicated on the face of the copy produced or otherwise disclaimed. It is further ordered that the "hard" copies of all documents maintained in electronic form produced by Defendant are deemed to be true and accurate representations of the data or other information

maintained in electronic format by that Defendant, unless otherwise indicated on the face of the "hard" copy produced or otherwise disclaimed. It is further ordered that all documents produced by Plaintiffs, any physician, psychiatrist, hospital, clinic, or any other health care provider that treated any plaintiff, and any documents obtained from insurance companies, employers, or state or federal governments are deemed true and accurate copies of hard copy documents, including x-rays or films, if any, and "hard" copy documents or electronic documents produced by such persons or entities are deemed a true and accurate representation of the data or other information maintained in electronic format, unless otherwise indicated or disclaimed. The parties may request admissions of fact or stipulations regarding the authenticity of documents pursuant to Fed. R. Civ. P. 36.

G. Appearance of Counsel.

1. Liaison Counsel/Committee Structure. By separate order (Docket Entry No. 87) **,** the Magistrate Judge has designated Charles Patrick Flynn to serve as Plaintiffs' Liaison Counsel and has appointed a Plaintiffs' Steering Committee and Executive Committee.

2. Defendant's Lead Counsel in MDL 1760. Joe Hollingsworth and Katharine Latimer, of the law firm of Spriggs & Hollingsworth, 1350 I Street, N.W., Washington, D.C., 20005, are hereby designated Lead Counsel for Defendant.

3. Designated Counsel. In each specific action, Plaintiffs will each designate one attorney to act as Designated Counsel for purposes of receiving service. Each plaintiff will file a Notice of Designation in each specific action naming their

Designated Counsel within fifteen (15) days of the entry of this Order, unless they have previously done so, or within fifteen (15) days of docketing of their action in MDL 1760, whichever is later.

H. Document Production Protocol. The Defendant will furnish to Plaintiffs on or before August 3, 2006, Defendant's proposed document production protocol which will include electronic word searchable document production.

I. Counsel Communications. In addition to the local rule requirement of counsel communication before submission of discovery disputes to the Court, counsel shall attempt to confer in good faith to resolve all issues before submission of any matter to the Court. No discovery dispute motion shall be filed until the parties concerned have conducted a telephone conference with the Magistrate Judge about the matter.

VII. Written Discovery - Generally.

A. Compliance with Rules. Except as expressly set forth herein, and absent an agreement of the parties under Fed. R. Civ. P. 29 or an order of the Court to the contrary, all discovery shall be conducted with and comply with the provisions of the Federal Rules of Civil Procedure and the Local Rules of the United States District Court for the Middle District of Tennessee.

B. Confidentiality of Produced Materials or Deposition Testimony. On or before August 3, 2006, Defendant will furnish Plaintiffs a proposed confidentiality agreement which will permit Plaintiffs' counsel, Plaintiffs' experts, and the respective necessary staff for counsel

and experts to execute the confidentiality agreement and then have access to the documents and confidential materials produced in this case. This confidentiality agreement will be submitted to the Court for approval in the form of a jointly-agreed upon Protective Order that will govern all actions and counsel involved in this MDL.

Any inadvertent or unintentional production of any confidential or proprietary material will not be construed as a waiver, in whole or in part, of (a) the producing party's claims of confidentiality either as to the specific information inadvertently or unintentionally disclosed or more generally as to the subject matter of the information disclosed, or (b) the party's right to designate the material as confidential pursuant to the Protective Order. In the event that a party inadvertently or unintentionally produces any confidential material without attaching one of the legends described in the Protective Order, the party may subsequently designate the material as Confidential at any time by forwarding to the opposing party copies of the material bearing one of the legends required by the Protective Order and requesting that the opposing party destroy all prior copies of the Confidential Material. Upon receipt of such a request, the opposing party shall destroy all copies of the Confidential Material produced inadvertently and replace them with copies bearing the appropriate confidentiality legend.

C. Assertion of Privilege in Response to Production Requests. Any party that withholds the production of requested documents or materials, regardless of the manner in which they are kept or maintained, on the ground of any privilege or application of the work-product doctrine must specify in writing, as to each document or thing not produced, the specific privilege(s) or doctrine(s) it is relying upon to withhold each document ("Privilege Log"). Each

Privilege Log shall describe each document or thing to which a privilege or work product doctrine is asserted in sufficient detail to reasonably permit the party seeking discovery to assess whether or not to dispute any such assertion of privilege or application of the work product doctrine, unless such detail would destroy the privilege. A Privilege Log need not be produced contemporaneously with the documents, but may be produced at reasonable rolling intervals subsequent to production.

The inadvertent production by any party in the course of discovery in these proceedings of a document subject to a claim of privilege, work product, or other statutory or court-ordered confidentiality, will not result in a waiver of any of the foregoing protections, whether in these or any other proceedings, for the produced document or any other withheld document covering the same or similar subject matter. If any party should inadvertently produce a document, upon notice of such disclosure, all originals and copies thereof, as well as all notes or other work product reflecting the contents of such materials, shall be immediately returned to the producing party, and such returned material shall be deleted from any litigation-support or other database.

D. Preservation of Documents.

1. While this Order remains in effect, each of the parties herein who receive actual notice of this order by personal service or otherwise, are restrained and enjoined from altering, destroying, permitting the destruction of, or in any other fashion changing any document or tangible item in the actual or constructive care, custody, or control of such person that is reasonably within the scope of discovery in this case, wherever such document or tangible item is physically located. Except as otherwise provided below, this Order imposes no duty on

any party to notify third parties regarding this Order and parties have no responsibility for actions taken by third parties unless taken at the direction of a party.

2. Given the multitude of documents involved in this case, the Magistrate Judge will not attempt at this point in the litigation to further specify the retention policies to be employed. If either side believes that additional procedures not covered in this Order are needed, they shall confer and, if they are unable to agree, conduct a telephone conference with the Magistrate Judge to discuss their competing requests.

3. Each plaintiff must forward a copy of the letter attached to this Order as Exhibit A to each of his or her treating physicians and any hospital or clinic that treated plaintiff, thereby notifying those persons of the terms of this Order.

4. The duty to preserve newly created documents shall not extend to (a) documents that have been determined to be protected by the attorney client privilege or work product doctrine, or (b) multiple identical copies of documents so long as the original document, or identical copy thereof, remains in the possession, custody or control of a party. The retention of full back-up of any server or other computer on a monthly basis shall relieve the party of any obligation to maintain any incremental or interim back-ups of such server or other computer. Nothing in this Order shall require any party to implement any procedure relating to the backing-up of electronic data that such party does not already have in place, absent further Court order.

5. The preservation obligations of this Order are not intended to displace, lessen, or heighten any parties' preservation obligations pursuant to law.

VIII. Fact Depositions - Generally.

A. Deposition Procedure. Unless otherwise agreed by all parties, depositions will proceed according to the Federal Rules of Civil Procedure and Local Rules, except as specified below. Any agreement to deviate from the Federal Rules of Civil Procedure, the Local Rules of this Court, or this Order must be recorded on the transcript at the time the deposition commences.

B. Scheduling.

1. The Magistrate Judge will not set specific deadlines for beginning depositions or the amount of notice that will be given. The Magistrate Judge expects the parties to use good judgment in scheduling depositions and in noticing depositions. Individuals to be deposed should be given a reasonable amount of advance notice. All notices propounded pursuant to Fed. R. Civ. P. 30(b)(6), must give the witness to be deposed adequate time to prepare himself or herself on the subject matter of the deposition.

2. If there is a material risk that any plaintiff may become incapacitated – that is, become physically or mentally incapable of providing complete and accurate testimony – plaintiff's counsel may take a preservation deposition of the plaintiff. Prior to taking such a preservation deposition, the plaintiff must have filed a PFS that is complete in all material respects, then the Defendant shall be allowed to submit and receive answers to interrogatories from that Plaintiff. If counsel are unable to agree on the taking of a preservation deposition they shall contact the Magistrate Judge for further guidance about the matter.

3. Counsel shall attempt in good faith to cooperate in the scheduling of

depositions permitted in this section considering the demands on the time and schedules of both the parties and their respective counsel. Counsel shall meet and confer as soon as practicable to resolve any scheduling dispute(s).

C. Length of Direct Examination in Fact Depositions. Except as otherwise stated in this paragraph, the examination by the party noticing the deposition shall be no more than seven (7) hours of actual examination time absent agreement or further order of this Court upon a showing of good cause. The Court expects that if a deposition requires additional time, the parties will make a good faith effort to agree on an extension before coming to the Court for resolution. A deposition of a treating physician may be taken more than once if that physician has treated more than one plaintiff. In taking successive depositions of such physicians, the party taking the deposition should not replow ground already covered. Thus, repetitive questions concerning qualification should not be asked. The successive depositions should be related to new facts concerning the additional Plaintiff treated.

D. Production of Documents by Deposition Witnesses. Depending upon the quantity of documents to be produced by the deponent, some time may be needed for inspection of the documents before the interrogation commences. Time spent examining documents produced by the deponent at a deposition is not considered examination time. However, the parties should take care that this time does not become excessive and prevent the taking of the deposition on the day scheduled. Responsive documents that are identical to those already produced in discovery to the Plaintiffs or to the Defendant do not have to be produced by the deponent a second time, provided the deponent clearly identifies when and where the documents

have previously been produced.

E. Location of Depositions. Unless otherwise agreed by the parties, depositions shall be taken in the federal district where the deponent resides or maintains his or her place of business.

F. Conduct of Depositions.

1. Cooperation. Counsel are expected to cooperate with, and be courteous to, each other and deponents during the course of any deposition. Counsel shall recess from time to time during the deposition for meals and to permit periods of rest or refreshment reasonably required by the deponent, stenographer(s) and/or counsel conducting or defending the deposition.

2. Deposition Day. Absent agreement of the parties to the deposition, a deposition day shall be no longer than seven (7) hours of actual examination time.

3. Continuance of Deposition. Depositions will not be noticed from day to day, but will be noticed for a single, specific day. Should a deposition not be completed on the scheduled day, the deposition will continue on a date agreed upon by the parties. If there is no agreement on when the deposition will be continued, the parties shall consult with the Magistrate Judge about a new date.

4. Examination. The party noticing a fact deposition shall designate one attorney to conduct the examination of the deponent.

5. Disputes During Depositions. Disputes between the parties arising during a deposition should be addressed to this Court rather than to the court in the district in

which the deposition is being conducted.

6. Copies of Exhibits. A copy of any document about which examining counsel expects to question the deponent should ordinarily be provided to primary counsel for the parties and for the deponent at the time presented to the deponent.

G. Stenographic Recording. Absent agreement by the parties, a certified court reporter shall stenographically record all deposition proceedings and testimony.

H. Videotaped Depositions. Any deposition may be videotaped at the request of any party, provided that the deposition notice or subpoena contains or is accompanied by a notice that the deposition will be videotaped.

1. The party requesting videotaping of the deposition shall bear the expense of both the videotaping and the stenographic recording. Requests for the taxation of these costs and expenses may be made at the conclusion of the litigation in accordance with applicable law.

2. The Magistrate Judge expects that the video recording to be done in a professional manner but will not specify the exact method of conducting the video recording. If a dispute about the video recording occurs during the course of the deposition, the parties shall contact the Magistrate Judge about the matter.

I. Copies of Transcripts and Videotapes. Subject to any restrictions contained within the protective order entered in this litigation, any party may at its own expense obtain a copy of the videotape and the stenographic transcript by contacting counsel that noticed the deposition or the court reporter.

IX. Discovery From Defendant.

A. Production of Documents.

1. Prior Production and Responses to Requests to Produce. Requests for production have been propounded on and answered by Defendant in several cases. Within fifteen (15) days of the entry of this Order, Defendant will supplement its prior answers to requests for production in *Anderson, et al. v. Novartis Pharmaceuticals Corp.*, No. 3:05-CV-0718 (M.D. Tenn.), *Becker, et al. v. Novartis Pharmaceuticals Corp.*, No. 3:05-CV-0719 (M.D. Tenn.), and *Wood, et al. v. Novartis Pharmaceuticals Corp.,* No. 3:05-CV-0716 (M.D. Tenn.), and provide the same to any plaintiff who requests copies. Defendant's answers to requests for production in these referenced cases shall be applicable to any case docketed in this MDL. All objections raised previously by Defendant in response to requests for production are preserved, and all rights held by plaintiff(s) to contest any objections made are similarly preserved. In addition, Defendant may assert additional objections, if any, in response to the previously served requests for production within fifteen (15) days of the entry of this Order.

2. Protocol of Document Production.[3] The following protocol shall apply to the Defendant's production of documents existing in hard-copy form and, as limited below, documents existing in native electronic form:

a. General. Except as limited below, all documents that originally existed in either hard-copy or native electronic form that are not privileged or otherwise

[3]The Defendant has advised in their proposed case management order (Docket Entry No. 85) that this protocol has been generally agreed to by Plaintiffs' counsel, with the exception of defining of a technical term. The Magistrate Judge therefore will incorporate the protocol from Docket Entry No. 85, subject to objection by the Plaintiffs on or before August 14, 2006.

protected from production and are responsive to discovery requests or Court order (or are otherwise produced in these proceedings) shall be produced in electronic image form in the manner provided herein. Each document's electronic image shall convey the same information and image as the original document. Documents that present imaging or formatting problems shall be promptly identified; the parties shall meet and confer to attempt to resolve the problems.

b. Document Image Format. All hard-copy documents shall be scanned as black and white images at 300 d.p.i. resolution and shall be saved and produced in a Group 4 compression single-page "TIFF" format. All native electronic documents shall be saved electronically (or "printed") in a Group 4 compression single-page "TIFF" image that reflects how the source document would have appeared if printed out to a printer attached to a computer viewing the file. Defendant shall produce a "load file" to accompany the images, which load file shall facilitate the use of the produced images by a document management or litigation support system. The parties shall meet and confer to the extent reasonably necessary to facilitate the import and use of the produced materials with commercially available document management or litigation support software.

c. Document Unitization. Each page of a document shall be scanned into an image and if a document is more than one page, the unitization of the document shall be maintained.

d. "Bates Numbering." Each page of a produced document shall have a legible, unique page identifier ("Bates Number") electronically "burned" onto the image at a location that does not obliterate, conceal, or interfere with any information from the source

document except where such information has been redacted in accordance with applicable law or a Court order. Each document shall also have a "confidential" legend electronically "burned" onto the image at the bottom of each page in such a way so as not to obliterate, conceal or interfere with any information from the source document. In addition, each page shall bear a "MDL" watermark across the face of the document in a way so as not to obliterate, conceal, or interfere with any information from the source document. At the time of trial, Defendant will provide "clean" copies of all documents that Plaintiffs intend to use at trial as indicated by the exhibit list the parties shall exchange pursuant to the final pre-trial order or other Court order.

e. File Naming Conventions. Each document image file shall be named with the unique Bates Number of the page of the document in the case of single-page TIFFs, followed by the extension ".TIF".

f. Production Media. Defendant shall produce documents on CD-ROM, DVD, external hard drive (with standard PC compatible interface), or such other readily accessible computer or electronic media as the parties may hereafter agree upon (the "Production Media"). Each piece of Production Media shall identify its general contents, *e.g.*, "Zometa® New Drug Application," "Aredia® New Drug Application," "John F. Smith's Documents," etc., as well as the volume of the material in that production.

g. Production of Hard-Copy Documents from Defendant's Employees and Archive Documents. Hard-copy documents located by Defendant during review of Defendant's archives and business premises will be produced in the manner described in paragraph 2, above, for hard-copy documents. Defendant has elected to have these documents

objectively coded. Accordingly, upon the production of documents within this category (or upon creation of the objective coding), Defendant will produce an ASCII text file, appropriately delimited, setting forth the objective coding for each document (the "Objective Coding"). The Objective Coding shall contain the following information: Author, Recipient, Date, Subject Line/Title (if applicable), Document Type, and Copyees. If Plaintiffs have problems importing and using the Objective Coding for document management, Plaintiffs and Defendant shall meet and confer to attempt to resolve the problems. Defendant's production of Objective Coding shall not constitute any certification as to the reliability, accuracy or completeness of the coding, and shall not constitute any waiver of work product protection or the attorney-client privilege with respect to that coding.

h. Production of New Drug Application Files. Documents encompassed within the New Drug Application ("NDA") files for Aredia® and Zometa® will be produced in the manner described above for hard-copy documents, because that is the manner in which they are primarily maintained by Defendant. The NDA documents have not been objectively coded. The NDAs contain a number of indices of particular sections. Defendant will produce the NDAs in the same order they were presented to the FDA, with all of the indices contained therein intact. Without waiving any work-product protection, Defendant will provide a list of the Bates Number ranges that contain the volume indices it has located within the NDA files. Without waiving any work-product protection, Defendant will also provide Plaintiffs with a separate list that indicates the Bates Number range for and identifies the text appearing on the cover of each volume of the NDAs.

i. Electronic Source Documents: Electronic Text Files. Electronic documents maintained on network home directories and electronic mail, which exist natively in electronic format, will be produced in the manner described in paragraph 2, above, for native electronic documents. Defendant will also produce text files reflecting the full text that has been electronically extracted from the original, native electronic files ("Extracted Text"). The Extracted Text shall be provided in ASCII text format and shall be labeled and produced on Production Media. The text data will be provided in delimited ASCII format with the production Bates Number information. Defendant shall not be obligated to produce Extracted Text for documents that have been redacted in accordance with applicable law or Court order. For those documents, Defendant will produce an ASCII file containing text obtained through the use of commercially-available optical character recognition ("OCR") software after redactions have been made. Should extracted text from an electronic source document contain privileged or otherwise protected information, such production shall not be deemed a waiver of any privilege that might attach to the extracted text or the related document.

j. Original Documents. Defendant shall retain the original hard copy and native electronic source documents for all documents produced in this MDL proceeding. Subject to preservation of appropriate privileges and other protections of Defendant's information from production in accordance with applicable law, Defendant shall, upon reasonable request, make originals of any produced document available for inspection by the requesting party in the form in which such documents are kept in the ordinary course of business.

k. Production of Other Electronic Documents. This Protocol shall not apply to native electronic files (1) where access to the native electronic file or data contained within such file is material to the analysis, use, or understanding of the information or data within such file, or (2) that otherwise present imaging or pagination problems, including statistical analysis files and database files (such as mainframe-, DB2-, Access-, or Oracle-based files). Plaintiffs and Defendant shall meet and confer to agree on the form for the production of these other electronic materials.

l. Discovery and Admissibility. Nothing in this Protocol shall be construed to affect the discoverability or admissibility of any document or data. All objections to the discoverability or admissibility of any document or data are preserved and may be asserted at any time.

B. Interrogatories to Defendant.

1. Prior Answers to Interrogatories. Interrogatories have been propounded to and answered by Defendant in several cases. Within fifteen (15) days of the entry of this Order, Defendant will provide answers to interrogatories in *Anderson, et al. v. Novartis Pharmaceuticals Corp.*, No. 3:05-CV-0718 (M.D. Tenn.), *Becker, et al. v. Novartis Pharmaceuticals Corp.*, No. 3:05-CV-0719 (M.D. Tenn.), and *Wood, et al. v. Novartis Pharmaceuticals Corp.*, No. 3:05-CV-0716 (M.D. Tenn.), to any plaintiff who requests copies. Defendant's answers to interrogatories in these referenced cases shall be applicable to any case docketed in this MDL. All objections raised previously by Defendant in response to interrogatories are preserved, and all rights held by plaintiff(s) to contest any objections made

are similarly preserved. In addition, Defendant may assert additional objections, if any, in response to the previously served interrogatories within fifteen (15) days of the entry of this Order.

2. Additional Interrogatories. In the absence of an agreement of the parties, no further interrogatories may be propounded to Defendant without leave of Court.

C. Depositions of Defendant.

1. Current Employees. Plaintiffs shall in good faith take only those depositions of Defendant and its current employees deemed reasonably necessary under the circumstances of this case. Defendant shall make available, without requiring a subpoena, all current employees requested by Plaintiffs for deposition, subject to the limits set on the number of depositions set forth within this Order and to Defendant's right to object to the taking of any particular employee's deposition for good cause shown.

2. Former Employees. Defendant shall take reasonable steps to make available requested former employees, to the extent possible. If Defendant is unable, despite its best good faith efforts, to produce former employees, then Defendant shall provide upon request the former employee's last known address and shall cooperate in any effort to obtain this Court's, or another court's, assistance to compel the former employee's attendance at the deposition. Plaintiffs shall not contact former employees of Defendant, absent notice to the Defendant, and if the Defendant objects, permission of the Court.

3. Number of Depositions. Plaintiffs collectively shall be limited to fifty (50) depositions of Defendant's current employees and former employees, including depositions

noticed pursuant to Fed. R. Civ. P. 30(b)(6). Absent agreement by the Defendant, Plaintiffs may apply to the Court to conduct further depositions or a subsequent deposition of an individual previously deposed only upon a showing of good cause and the specific identification of the individual(s) sought to be deposed.

X. Discovery From Plaintiffs.

A. Plaintiff's Fact Sheet. Each plaintiff in each case filed in or transferred to this Court shall complete a separate PFS. Plaintiffs in all cases currently docketed in this Court as of the date of entry of this Order shall complete a PFS in all material respects and serve the same upon Defendant's Lead Counsel in the applicable case as specified elsewhere in this Order. Plaintiffs in all cases in which this Court subsequently receives the case file, or in cases filed in this Court but made part of MDL 1760 after the date of entry of this Order, shall be served with a copy of the PFS by Plaintiffs' Liaison Counsel as described below and shall complete a PFS in all material respects and serve the same upon Defendant's Lead Counsel and counsel of record in the applicable case.

B. Plaintiffs to Complete PFS in All Respects. Plaintiff(s) in each case filed in or transferred to the Court shall complete a PFS in all material respects, including providing Defendant with all applicable accompanying authorizations, within forty-five (45) days of service of the PFS. To "complete a PFS in all material respects" means to answer every question on the PFS and leave no blanks, even if a plaintiff can only answer the question in good faith by indicating "not applicable" or "I don't know." This definition of "complete in all material respects" shall be applicable throughout this Order.

C. Plaintiff's Failure to Serve PFS. Should any plaintiff fail to serve a PFS within the time allotted, Defendant's Lead Counsel shall send a warning letter to that plaintiff's Designated Counsel in the specific case involved, with a copy to the Plaintiffs' Liaison Counsel. Plaintiff shall then have an additional fifteen (15) days to serve a PFS completed in all material respects. The letter shall include a warning that the case is subject to dismissal under this Order if a PFS completed in all material respects is not received within fifteen (15) days of the service of the warning. Should a plaintiff fail to provide a PFS completed in all material respects (including signatures on all applicable authorizations) within fifteen (15) days of service of the warning letter, Defendant is entitled to seek an Order to Show Cause why the case should not be dismissed. Any such filing shall be served on Plaintiff's Designated Counsel and Plaintiffs' Liaison Counsel, with any response to such filing to be submitted within fourteen (14) days following the date of service.

D. Plaintiff's Failure to Complete PFS in All Material Respects. If Defendant receives a PFS in the allotted time, but the PFS is not completed in all material respects, Defendant's Lead Counsel shall send a deficiency letter to that Plaintiff's Designated Counsel allowing plaintiff an additional fifteen (15) days to serve a PFS that is complete in all material respects. The deficiency letter shall include a warning that the case is subject to dismissal under this Order if a PFS complete in all material respects is not received within fifteen (15) days of service of the warning. Should a plaintiff fail to cure the deficiencies identified and fail to provide responses that are complete in all material respects (including signatures on all applicable authorizations) within fifteen (15) days of service of the deficiency letter, Defendant

is entitled to seek an Order to Show Cause why the case should not be dismissed. Any such filing shall be served on Plaintiff's Designated Counsel and Plaintiffs' Liaison Counsel, with any response to such filing to be submitted within fourteen (14) days following the date of service.

E. Requests for Production to Plaintiffs. At any time after a plaintiff serves a PFS on Defendant's Lead Counsel, Defendant may propound and serve on that plaintiff five (5) Requests for Production in accord with Fed. R. Civ. P. 34. Plaintiff will respond in accord with Fed. R. Civ. P. 34.

F. Interrogatories to Plaintiffs. At any time after a plaintiff serves a PFS on Defendant's Lead Counsel, Defendant may propound and serve on that plaintiff five (5) Interrogatories in accord with Fed. R. Civ. P. 33. Plaintiff will respond in accord with Fed. R. Civ. P. 33.

G. Physical and Mental Examinations of Plaintiffs. Defendant shall be entitled to conduct physical and/or mental examinations of Plaintiffs, in accord with Fed. R. Civ. P. 35, any time after the plaintiff serves on Defendant a PFS. All examinations must be completed at a point sufficiently in advance of the close of expert discovery to allow plaintiff to conduct the discovery described in Fed. R. Civ. P. 35(b)(1) prior to the close of any period established for expert discovery.

H. Depositions of Plaintiff. The Defendant shall be entitled to take the deposition of the Plaintiffs in the cases not stayed.

XI. Discovery From Third Parties.

A. Document Subpoenas to Non-Parties. Upon entry of this Order, any party may

serve subpoenas on non-parties for the production of documents without testimony pursuant to Fed. R. Civ. P. 45.

B. Depositions of Non-Parties. Defendant shall be entitled to conduct a total of fifteen (15) depositions of non-parties per plaintiff, and each plaintiff shall be entitled to conduct a total of fifteen (15) depositions of non-parties as part of case-specific fact discovery in each case transferred to this Court or otherwise made a part of MDL 1760. For purposes of this Order, treating physicians are considered "fact" witnesses. Absent agreement by the opposing party, the party seeking to notice additional depositions may apply to the Court to conduct further depositions only upon a showing of good cause and the specific identification of the individuals(s) sought to be deposed.

C. *Ex Parte* Communications. Ex parte communications with Plaintiffs' treating physicians may expedite the discovery process and reduce expenses in this litigation. However, before initiating such communications, unless the parties are agreeable thereto, the Defendant shall file a specific request to do so subject to objection by the Plaintiffs and the Magistrate Judge will rule on the matter at that time.

XII. Timing of Fact Discovery.

Except as agreed to by the parties or where the Court has entered an order providing otherwise, case-specific fact discovery shall commence no later than July 2, 2007 in all MDL cases. Fact discovery shall conclude no later than March 14, 2008 in all MDL cases. Absent mutual consent of the parties thereto or further order of the Court, no case shall be subject to

remand to its transferor court prior to the deadline for the completion of fact discovery applicable in that case.

XIII. Expert Discovery.

Experts will be disclosed and expert discovery will be conducted on class certification issues pursuant to a Court ordered discovery and briefing schedule. Whether there will be a need for any additional expert opinion and discovery on general issues in this MDL will be determined after the class certification question is resolved. Expert depositions taken shall be limited to seven (7) hours of deposition testimony absent agreement of the parties, or permission of the Court upon a showing of need.

XIV. Remand.

Remand procedures appear to be premature at this stage. The parties are free to suggest specific remand procedures at a later date.

XV. Schedule of Pre-Trial Proceedings.

Unfortunately, the parties' submission of pretrial proceeding dates are not in agreement and leave the Magistrate Judge somewhat adrift. Accordingly, the following will be adopted, subject to further modification as needed. In proposing any modification, the parties shall confer and schedule a telephone conference with the Magistrate Judge about the matter.

Discovery in the three (3) putative class actions originally filed in the Middle District of Tennessee, cases 3:05-cv-0716, 3:05-cv-0718, and 3:05-cv-0719, and in any of the other seven test cases where a class action is proposed, shall be conducted in two (2) phases. The first phase will address class certification. The second phase will address the merits of the action. The

deadlines established in the merits phase section below will also apply to those test cases which do not purport to be class actions.

A. Class Certification Phase.

1. In the initial phase, discovery shall be addressed to matters bearing on class certification. The parties are directed to work together in a good faith effort to resolve any disputes that may arise between them on the issue of whether discovery is class or merits related before seeking Court intervention.

2. For good cause shown, the sixty (60) day requirement of Local Rule 23.01(b) is waived. Plaintiffs shall file their Motion for and Memorandum in Support of Class Certification in accordance with the schedule set forth below.

3. Discovery shall commence with the transmission by Plaintiffs' Liaison Counsel or his designee on or before August 14, 2006 of a blank PFS to each plaintiff whose claims were originally included in the three actions filed in this District (Case Nos. 3:05-cv-0716; 3:05-cv-0718; and 3:05-cv-0719), and to each plaintiff in any of the other seven test cases which purport to be class actions. Plaintiffs' Liaison Counsel shall certify transmission of the PFS to each plaintiff to Defendant's Lead Counsel. These Plaintiffs shall constitute "Wave One Plaintiffs" for purposes of discovery of Plaintiffs.

4. On or before September 15, 2006, each plaintiff in these putative class actions shall serve a PFS, complete in all respects (as defined elsewhere in this Order), upon Defendant's Lead Counsel.

5. On September 18, 2006, Defendant may commence depositions of the

Wave One Plaintiffs, including but not limited to depositions of Plaintiffs, treating and consulting physicians, and family and friends of Plaintiffs.

6. On or before February 2, 2007, Plaintiffs shall give notice in writing of their desire to be granted class certification, including a definition of the purported class.

7. On or before February 2, 2007, Plaintiffs shall serve Defendant with all affidavits (by lay or expert witnesses) and expert reports upon which Plaintiffs are relying with respect to class certification (including without limitation an expert report or expert affidavit by each person Plaintiffs may call to testify as an expert witness at any hearing on class certification).

8. All fact discovery related to class certification shall be completed by January 16, 2007.

9. On or before March 9, 2007, Defendant shall serve Plaintiffs with all affidavits (by lay or expert witnesses) and expert reports upon which Defendant is relying with respect to class certification (including without limitation an expert report or expert affidavit by each person Defendant may call to testify as an expert witness at any hearing on class certification).

10. All discovery motions regarding class certification fact discovery shall be filed by January 16, 2007.

11. All expert discovery related to class certification shall be completed no later than May 4, 2007.

12. On or before June 1, 2007, Plaintiffs shall file their motion for and

memorandum in support of class certification.

13. On or before June 22, 2007, Defendant shall file its memorandum in opposition to Plaintiffs' motion for class certification.

14. If the District Judge believes that a hearing is necessary on the class certification motions, such a hearing will be set by separate order of the District Judge.

B. Merits Phase (Case Nos. 3:05-cv-0716, 3:05-cv-0718, 3:05-cv-0719, and other designated test cases). Merits-based fact discovery in these cases may begin as previously stated in this Order, on July 2, 2007, or earlier pursuant to the agreement of the parties. The following deadlines shall apply:

1. On or before January 4, 2008 the parties shall file motions to name additional parties or otherwise amend their pleadings. The Court may sever any joint actions into single Plaintiff actions, except that loss of consortium claims will remain in the same action as the related injury claims.

2. On or before January 7, 2008, the parties shall brief the appropriate venue of the severed actions for trial.

3. Should any individual action(s) be tried in this Court, the individual action(s) shall proceed on separate tracks so as to stagger trial and other key dates. Separate scheduling orders will be entered in each case after consideration of this Court's docket. Parties can expect the first case to proceed on the following schedule, with deadlines in the remaining cases to be staggered.

4. On or before February 8, 2008, Plaintiff shall provide Defendant with

Plaintiff's Fed. R. Civ. P. 26(a)(2) disclosures and serve Defendant with reports or affidavits of testifying experts.

5. On or before March 7, 2008, Defendant shall provide Plaintiff with its Fed. R. Civ. P. 26(a)(2) disclosures and serve Plaintiff with reports or affidavits of its testifying experts.

6. On or before March 14, 2008, all fact discovery shall be completed.

7. On or before March 24, 2008, Plaintiff may supplement Plaintiff's expert reports or expert affidavits. No further supplementation shall be permitted. The opportunity for supplementation, as it relates to expert reports or affidavits, is not intended to excuse Plaintiff from fully complying with initial expert disclosure obligations, but instead is intended to provide for disclosure of expert work that is truly in the nature of rebuttal to Defendant's expert(s).

8. All discovery motions regarding merits discovery shall be filed by April 4, 2008.

9. On or before April 11, 2008, Defendant may supplement its expert reports or expert affidavits. No further supplementation shall be permitted. The opportunity for supplementation, as it relates to expert reports or affidavits, is not intended to excuse Defendant from fully complying with its initial expert disclosure obligations, but instead is intended to provide for disclosure of expert work that is truly in the nature of sur-rebuttal to Plaintiff's expert(s).

10. On or by April 25, 2008, all expert discovery shall be completed.

11. On or before May 16, 2008, the parties shall file all motions for summary

judgment, other potentially dispositive motions (including Fed. R. Civ. P. 12 motions), motions related to the admissibility of expert testimony, and motions for a *Daubert* hearing.

XVI. Recommended Trial Date.

In accordance with this schedule, the Magistrate Judge believes that the cases that can be tried in the Middle District of Tennessee should be ready for trial on or after September 16, 2008. The District Judge will set trial dates by separate order and his order will include his requirements for the trial and the final pretrial conference. The parties estimate that the trial of an individual case will take approximately three (3) weeks.

XVII. Scheduling Order for the Remaining MDL Cases.

The Magistrate Judge believes that, outside of establishing the dates which bound the fact discovery period, the scheduling of specific dates for the remaining cases at this time is not necessary or practical given the difference between the parties' competing plans. Accordingly, dates for the remaining cases will not be set at this time but will be taken up in a subsequent case management conference in Court on **Thursday, October 12, 2006, at 10:00 a.m.,** in Courtroom 774,[4] U. S. Courthouse, 801 Broadway, Nashville, TN. The Magistrate Judge believes by that time the number of cases to be transferred to this District for MDL proceedings will be fairly complete and the parties will have undertaken sufficient discovery to be in a realistic position to set deadlines for the remaining cases and to discuss the potential for entering a remand schedule and making additional adjustments in the case management order.

The parties are advised that cases without proper venue in the Middle District of

[4]The Courtroom is subject to being changed at a later date. The parties will be notified of any change.

Tennessee should not be filed in this District but should be filed in the appropriate district, then identified as potential tagalong cases to be transferred to this District under the MDL procedures.

It is so **ORDERED**.

/s/ Joe B. Brown
JOE B. BROWN
United States Magistrate Judge