

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

IN RE: ZOFTRAN (ONDANSETRON)	)	
PRODUCTS LIABILITY LITIGATION,	)	
	)	
This Document Relates to :	)	
	)	
All Cases	)	MDL No. 1:15-md-2657-FDS
	)	
	)	

**CASE MANAGEMENT ORDER NO. XXX**  
(Protective Order Governing Confidential and Privileged Materials)

This is a product liability multidistrict litigation (“MDL”) involving the prescription drug Zofran®. To expedite the flow of discovery material; facilitate the prompt resolution of disputes over confidentiality; and adequately protect Confidential Information (as defined below) MDL plaintiffs and defendant GlaxoSmithKline LLC (“GSK”) have stipulated to, and the COURT HEREBY ENTERS this Protective Order governing documents, materials, or other information, including things or portions thereof (and the information contained therein), produced in discovery in this Litigation (as defined below) (“Discovery Material”).

1. **Definitions.** The following definitions shall apply to this Protective Order (hereinafter “Order”):

a) “Attorney” or “Counsel” includes all members, partners, and employees of a law firm of which the attorney or counsel is a member, partner or employee.

b) “Confidential Information” shall mean all documents, materials, or other things, or portions thereof (and the information contained therein) that are designated by any Party with the following: “CONFIDENTIAL – Subject to Protective Order USDC MA (MDL 2657).” Subject to the right of a Party to object to the designation of

information as confidential, the information that may be designated “Confidential” includes the following, provided that the designating party reasonably and in good faith believes that it is confidential information entitled to protection:

1. Patient identifying information contained in any Discovery Material, patient medical records and pharmacy records, and any such information or material protected by the Health Insurance Portability and Accountability Act (“HIPAA”) or non-U.S. data privacy laws;

2. Trade secrets that, if disclosed, would unfairly competitively disadvantage the producing Party;

3. Proprietary, non-public business information;

4. Proprietary design, development, research, and testing regarding products, whether previously or currently marketed or under development, including such documents in Investigational New Drug Application and New Drug Application (“NDA”) files and any supplemental, amended, or abbreviated NDA;

5. Non-public clinical studies and related documents to the extent not otherwise published or previously released;

6. Personnel records and information;

7. Documents and information submitted to the FDA and exempted from disclosure under exemption 4 of the Freedom of Information Act pursuant to 21 C.F.R. §§ 20.61 (trade secrets and commercial or financial information which is privileged or confidential), 20.63 (personnel, medical, and similar files, disclosure of which constitutes a clearly unwarranted invasion of personal privacy), 312.130

(investigational new drug application), and 314.430 (new drug applications and supplemental new drug applications); and

8. Copies, excerpts, or summaries of any of the information listed above.

c) “Disclose” shall mean to reveal, provide, describe, make known or allow to be made known to any person Confidential Information.

d) “Documents, materials, or other things” shall include, but not be restricted to, all documents exchanged or disclosed in discovery, such as written discovery requests, interrogatory answers, responses to requests for production or for admission(s), deposition testimony, deposition transcripts, and deposition exhibits.

e) “Litigation” means the above-captioned MDL proceeding, any actions remanded therefrom, and any appeals thereof.

f) “Party” shall mean a party to this Litigation, any officer, director, representative, or employee of such party.

g) “Person” shall mean any natural person or any business, legal, or governmental entity or association.

h) “Receiving Party” shall mean any party or any consultant or other person to whom Confidential Information is furnished.

2. **Persons Bound by this Order.** Each Receiving Party shall be subject to this Order and to the jurisdiction of this Court for appropriate proceedings in the event of any violation or alleged violation of this Order.

3. **Procedures Governing Confidentiality Designations.** The following procedures shall apply to designate Confidential Information subject to this Order:

a) **Generally**. Confidential Information produced in this Litigation shall be clearly marked with the designation: “CONFIDENTIAL – Subject To Protective Order USDC MA (MDL 2657)” (hereinafter, “Confidentiality Designation”). Any Party or non-party may place a Confidentiality Designation on any document, material, other thing, or portions thereof (and the information contained therein) that the Party or non-party produced in this Litigation if such Party or non-party reasonably believes it contains Confidential Information.

All documents produced by non-parties, even if not designated by such non-parties as Confidential Information shall be treated by the Parties to this Litigation as Confidential Information for thirty (30) days from the date of production. During that thirty (30) day period, any Party may designate such documents as Confidential Information if the Party reasonably believes it contains Confidential Information.

Any defendant who may be later added as a Party or who may produce information pursuant to discovery on jurisdictional issues may also rely and act upon this Order.

b) **Documents**. Designation of hard-copy documents as confidential shall be made by affixing to the document the following “Confidential Legend”: “CONFIDENTIAL – Subject to Protective Order USDC MA (MDL 2657).” The Confidential Legend shall be affixed to each page of material to be designated, but shall not obscure any part of the text. For documents produced in a TIFF image format, the Confidentiality Designation shall be branded on the lower left corner of the applicable image, positioned so as not to interfere with reading. To the extent applicable, no original documents may be altered with a Confidentiality Designation. Only copies of original

documents may be marked with a Confidentiality Designation. If an original document is to be produced, the producing Party must give written notice at the time of its production that the document is an original. If the producing Party asserts confidentiality over the original document, that must be done at the time of production in a written statement accompanying the document, subject to the provisions set forth in paragraph 5.

c) **ESI**. In the case of electronically stored information produced in native format, the word “Confidential” shall be included in the file or directory name, and/or the media containing the documents (e.g., CD-ROM, DVD, Hard Drive), and in the written transmittal communication. Confidentiality Designations shall be affixed in such a manner as to not obscure any written matter or interfere with the reading or validation of any electronic files.

d) **Physical Items**. To the extent that Confidential Information consists of physical items or materials other than documents or writings, said Confidential Information shall, to the fullest extent practicable, conspicuously bear the Confidentiality Designation such that said language is readily observable and linked to the item.

e) **Deposition and Pretrial Transcripts**. In the case of depositions or other pre-trial testimony, Confidentiality Designations shall be made: (i) by a statement on the record, by counsel, at the time of such disclosure or before the conclusion of the deposition or testimony; or (ii) by written notice, sent to all Parties within thirty (30) calendar days of the receipt of the final transcript of deposition or other pretrial testimony; provided that only those portions of the transcript designated as Confidential Information shall be deemed Confidential Information. During the thirty (30) day period, the final deposition testimony, transcript, and exhibits shall be treated as Confidential

Material under this Order. The Parties may modify this procedure for any particular deposition or other pre-trial testimony, through agreement on the record at such deposition or testimony, without further order of the Court. Absent agreement by the Parties, then after the expiration of the thirty (30) day period, only the specific page(s) and line number(s) and exhibits designated as being confidential, if any, shall be treated as confidential.

f) **Inspection of documents**. If a Party produces documents for inspection that include Confidential Information or original documents, the producing Party has the right to have security personnel present in the inspection room at all times during the inspecting Party's inspection of documents, materials, or other things, or portions thereof (and the information contained therein) produced pursuant hereto. The inspecting Party shall provide reasonable advance notice of the names of all individuals who will attend such inspections. The number of persons present during this process is limited to those necessary to adequately facilitate inspection and review of documents, and any such persons must comply with the terms of this Order. The original documents, materials, or other things, or portions thereof (and the information contained therein) produced under the terms of this Order shall remain in the custody and control of the producing Party at all times, but nothing in this paragraph shall preclude the Receiving Party from requesting production, within a reasonable time, of complete and accurate copies of such material, subject to any applicable orders governing discovery.

4. **Effect of Confidentiality Designation**. All produced Confidential Information, whether or not such designation is in dispute, shall retain that designation and be treated as confidential in accordance with the terms hereof unless and until (i) the producing Party agrees

in writing that the material is no longer confidential and subject to the terms of this Order; or (ii) the Court renders a decision that a particular document, material, or other thing, or portions thereof (and the information contained therein) is not subject to this Order, and any and all proceedings or interlocutory appeals challenging such decision have been concluded. If Discovery Material marked as confidential loses its confidential status, that Discovery Material shall not be treated as confidential. Upon request, the producing Party shall re-produce the Discovery Material that loses its confidential status with an identical bates number, and without a Confidentiality Designation.

5. **Inadvertent Failure to Designate.** The inadvertent failure to brand Confidential Information, or portions thereof, with the Confidential Legend shall not be deemed to waive the protected and confidential nature of the documents, materials, or other things once the producing Party designates such materials as confidential and provides notice to the Receiving Party, as provided in this paragraph. Upon receiving notice of the confidential nature of the document, the Receiving Party shall thereafter treat the document as confidential in accordance with this Order. A Party may designate as Confidential Information documents, materials, or other things that have already been produced and that the Party inadvertently failed to designate as Confidential Information, by notifying in writing the Party to whom the production has been made that the materials constitute Confidential Information and are subject to this Order. Upon receiving such notice, the Receiving Party shall make a reasonable, good-faith effort to ensure that any analyses, memoranda, notes, or other such materials generated based upon such newly designated information are promptly treated as containing Confidential Information. In addition, upon receiving such written notice, any Receiving Party who disclosed the information prior to its designation as “Confidential” shall exercise its best efforts (i) to ensure the return or destruction

of such unmarked Confidential Information, (ii) to ensure that any documents or other materials copying, excerpting or summarizing such Confidential Information are treated as if designated confidential when originally produced, (iii) to ensure such Confidential Information is not further disclosed except in accordance with the terms of the Order, and (iv) to ensure that such Confidential Information, and any information copying, excerpting or summarizing same, is used solely for the Litigation, as authorized by this Order. The producing Party shall promptly provide a replacement image with an identical Bates number for any affected page of a document bearing a Confidentiality Legend.

6. **Waiver.** A producing Party may expressly waive in writing the applicability of any provision of this Order to any information, document, material, or other thing, or portions thereof (and the information contained therein) contained in a document that Party produces. Such waiver will apply only to the information, document, material, or other thing, or portions thereof (and the information contained therein) to which the applicability of any provision of this Order is expressly waived. A partial waiver as to certain information, document, material, or other thing, or portions thereof (and the information contained therein) does not constitute a waiver as to the remainder of such information or document, material, thing, or other thing, or portions thereof (and the information contained therein).

7. **Costs.**

a) *[PLAINTIFFS' POSITION: Each Party shall bear the cost of reproducing its responsive documents for production.]*

b) *[GSK's POSITION: Nothing in this Order shall relieve the Receiving Party from its obligation to pay the reproduction costs for documents, materials, or other things produced, including documents or materials produced in electronic form. The cost will be*



based on documentation from the relevant vendor showing the actual cost. This cost is intended only as a reimbursement for reproduction. The Receiving Party's payment of this cost does not effect any transfer of ownership in the reproduced documents.]

8. **Disputes About Confidentiality Designations.** If, at any time, a Party in good faith objects to a Confidentiality Designation, such Party shall notify the designating Party of such dispute in writing, specifying the Discovery Material in dispute and the nature of the dispute. Absent good cause, no more than fifty (50) documents shall be challenged at a time, and only one challenge may be sent within a seven (7) day period. The disputing Party must give the designating Party an opportunity to review the designated material, meet and confer, and reconsider the designation. The designating Party shall within twenty one (21) days of receiving notice of the dispute either explain in writing the basis of the chosen designation or change the designation. This period and number and timing of documents challenged may be extended by agreement of the Parties. If the Parties are unable to resolve the dispute without Court intervention, the disputing Party may apply by motion to the Court for a ruling as to whether the designated Discovery Material may properly be treated as confidential. The designating Party shall have the burden of proof on such motion to establish the propriety of its Confidentiality Designation.

9. **Preservation of Confidentiality.** All outside counsel, in-house counsel, in-house paralegals and the employees and assistants of all counsel receiving discovery shall take all steps reasonably necessary to prevent the disclosure of Confidential Information other than in accordance with the terms of this Order.

10. **Permissible Disclosures of Confidential Information.** Confidential Information shall not be used or disclosed for any purpose other than for this Litigation, as authorized by this

Order. Except as otherwise provided herein, Confidential Information may be disclosed by the Receiving Party only to:

a) **Counsel**. Any counsel working in this Litigation on behalf of any Party, any counsel for another person entitled to receive Confidential Information, and any paralegals and staff employed or engaged by such counsel;

b) **Witnesses**. Any witness or potential witness for the purpose of conducting an examination of such witness during a trial or deposition or for the purpose of preparing such witness for the trial examination or deposition or interviewing such witness or potential witness, subject to the conditions set forth in paragraph 10(i) below;

c) **Court and Quasi-Judicial Personnel**. Trial and appellate courts, court personnel, jurors, mediators, special masters and alternate jurors engaged in the conduct of this Litigation;

d) **Court Reporters**. Court reporters (including persons operating video recording equipment at depositions) and persons preparing transcripts of testimony to the extent necessary to prepare such transcripts for this Litigation;

e) **Document Authors and Recipients**. As to any document, its author, its addressee, or any other person named on the face of the document or indicated on the face of the document as having received a copy, subject to the conditions set forth in paragraph 10(i) below;

f) **Experts, Advisors and Consultants**. Retained experts, advisors and consultants, including persons directly employed by such experts, advisors and consultants, subject to the conditions set forth in paragraph 10(i) below, but only to the extent necessary to perform their work in connection with this Litigation;

g) **Parties**. The Parties may view Confidential Information; and

h) **Others Directed by Court or Consented to by Producing Party**. Such other persons as the Court orders to receive access to Confidential Information.

i) **Conditions for disclosure**. Before disclosing Confidential Information, to any person who is subject to this paragraph, the Receiving Party shall ensure that the intended recipient of such disclosure has: (1) been provided a copy of this Order; and (2) executed an Acknowledgment in the form attached hereto as **Exhibit A**, or, as to any person in Sections 10(b) (witnesses) or 10(e) (document authors and recipients) above, expressly agreed on the record of a deposition or court proceeding to abide by the terms of this Order. Counsel for the Receiving Party agrees to notify the Receiving Party, other members and employees of counsel's firm receiving Confidential Information, of this Order and such persons' obligations to abide by the terms of such Order. Disclosure of Confidential Information shall not be made to any counsel (as defined in paragraph 1(a) above) who has been found by a Court to have violated the terms of a protective order in any litigation or legal proceeding. Nothing herein shall be deemed to restrict in any manner any Party's use of its own documents or materials.

11. **Use of Confidential Information in this Litigation**.

a) **At Deposition**. In the event that any question is asked at a deposition which a Party or non-party asserts calls for Confidential Information, such question may nonetheless be answered by the witness fully and completely, to the extent required by law.

b) **At Trial**. This Order does not restrict or limit the use of Confidential Information that is admissible under the Federal Rules of Evidence at any hearing or trial

in this MDL, any individual case coordinated in this MDL, or at a hearing or trial in a remanded action. Nothing in this Order, however, shall prevent any Party from seeking an appropriate protective order to govern use of such Confidential Information at evidentiary hearings or trial.

c) **Filing of Confidential Information**. Any Party reasonably and in good faith wishing to file Confidential Information (“submitting Party”) shall file a Motion to Impound such Confidential Information in accordance with Local Rule 7.2 and shall contemporaneously serve and file complete, produced versions of the confidential documents under impoundment. A submitting Party may file motions, briefs, pleadings, or deposition transcripts that contain Confidential Information in the public docket by redacting those portions that contain Confidential Information. In addition, a submitting Party may file documents that contain Confidential Information in the public docket with written agreement from the producing Party on any necessary redactions. A producing Party may file documents that it designated as Confidential Information in the public docket with redactions of those portions of the documents considered to be confidential.

A Motion to Impound shall include a request that the Court lift any impounding Order only upon further order of the Court and that the impounded Confidential Information be kept in the Clerk’s non-public information file during any post-impoundment period unless the Court vacates the impounding Order.

Upon the filing of the Motion to Impound, the submitting Party shall also file a supporting Declaration (i) identifying the submitting Party, (ii) referencing this Order, (iii) describing the general nature and purpose for submitting the paper (i.e., exhibit to

declaration in support of motion, etc.), and (iv) identifying the Party(ies) that have designated the Confidential Information (“designating Party(ies)”).

Promptly after the filing, the submitting Party shall deliver to the Court complete, produced versions or copies of such papers in a sealed envelope, addressed to chambers, and clearly marked, “FILED UNDER SEAL.” Such papers shall be accompanied by a copy of the Motion to Impound and the Declaration supporting the Motion to Impound.

Any Party shall have the opportunity to submit papers supporting or opposing the Motion to Impound. Any non-party who has produced Confidential Information that is the subject of a Motion to Impound shall have the opportunity to submit papers supporting or opposing that Motion. The papers supporting or opposing the Motion to Impound shall fully comply with applicable rules and orders and shall be served in the produced form. Nothing in this paragraph shall change the deadline for the responding Party to file any opposition or response to the underlying pleading filed with the Motion to Impound.

All papers containing a Confidential Designation submitted to the Court under seal pursuant to this Order shall be presumptively impounded and kept under seal unless and until otherwise ordered by this Court.

The decision or Order of this Court with respect to the Motion to Impound shall not affect any designation of Confidential Information or application of any other provision of this Order, unless the Court orders the Confidential Information to be un-designated as such.

If the Court orders that papers containing Confidential Information be sealed, the material shall remain under seal until further order of the Court. However, said

Confidential Information and other papers filed under seal shall be available to the Court and to all other persons entitled to receive the Confidential Information under the terms of this Order. Nothing contained herein shall prejudice the right of any Party or Non-Party from subsequently challenging the propriety of any sealing.

12. **Production of Confidential and Privileged Material.** The Parties shall comply with the Federal Rules of Civil Procedure (unless otherwise ordered by the Court) with regard to the production of privilege logs as set forth more fully below.

13. **Privilege Logs.** The Party claiming a privilege shall produce a privilege log to the Receiving Party. The privilege log shall list the privilege or privileges asserted with respect to each withheld document and describe the document with sufficient particularity to allow the Receiving Party to assess the claim of privilege but without revealing privileged information. The privilege log shall also include the date the document was prepared, the person or persons who prepared the document, and the person or persons to whom the document was addressed, directly and by carbon copy or blind copy. The Parties may seek the Court's assistance through *in camera* review in assessing claims of privilege.

a) **Materials Not Required To Be Logged.** No privilege log entries shall be required as to the following categories of materials and any applicable privilege or protection shall be preserved even if such materials are not listed on a producing Party's log:

- i. Privileged communications exclusively between a Party and its Counsel after February 16, 2015, except for communications accompanied by responsive, non-privileged attachments;
- ii. Work product created by Counsel representing any Party in this Litigation;

- iii. Internal communications within (i) a law firm, or (ii) a legal department of GSK after February 16, 2015;
- iv. Briefs, motions, legal or factual memoranda, or drafts thereof, correspondence, notes, or other similar materials created by a corporate legal department of GSK after February 16, 2015; and
- v. Privilege redactions made on the face of produced documents, provided that the unredacted portion provides information sufficient to allow the Receiving Party to assess the claim of privilege.

b) **Logging Email Threads**. For purposes of creation of a privilege log, a Party need include only one entry on the log to identify withheld privileged emails that constitute an uninterrupted dialogue between or among individuals; provided, however, that disclosure must be made that the emails are part of an uninterrupted privileged dialogue. Moreover, the beginning and ending dates and times (as noted on the emails) of the dialogue and the number of emails within the dialogue must be disclosed, in addition to other requisite privilege log disclosure referenced above, including the names of all of the recipients of the communications.

c) **Time for Serving Privilege Log**. A privilege log shall be served by any Party withholding responsive documents on the basis of privilege or work product protection on a rolling basis within sixty (60) days after the production from which it is withheld.

d) **Permissible Redactions**. In order to protect against unauthorized disclosure of Confidential Information, a defendant may redact from any Confidential Information:

- (i) names and information that would identify clinical trial subjects or patients referred to

in adverse reaction reports, product experience reports, and consumer complaints, except for patient identifiers (e.g, randomly assigned numeric or alphanumeric identifiers) that do not reveal the patient's identity, date of birth, address or other personal identifying information; (ii) home addresses of individuals; (iii) DEA numbers of medical doctors; (iv) personal medical or family information, financial account numbers, or social security numbers not the focus of the request, which is necessary to be protected to prevent undue annoyance, embarrassment, or oppression *[GSK's POSITION: ; (v) trade secrets or other highly confidential research, development, or commercial information that a defendant believes in good faith would, if disclosed, cause economic harm to the competitive position of the entity from which the information was obtained; and (vi) information about compounds and products that are not the subject of this Litigation.]* *[PLAINTIFFS' POSITION: GSK also seeks to redact the following from produced documents: trade secrets and information that GSK believes is highly confidential. Plaintiffs believe this information should be produced in unredacted form and designated as Confidential Information. Plaintiffs' Counsel are willing to stipulate to additional procedural safeguards for preserving confidentiality of such information. Information about drug compounds other than Zofran, such as Paxil, will likely be relevant and should not be redacted but may be designated as Confidential Information in accordance with this Order.]* A producing Party shall, within sixty (60) days of said production, provide a redaction log for Confidential Information that will identify, by Bates number and category, the Confidential Information that has been redacted from the identified document.



e) **Challenging Redactions and Privilege.** If the Requesting Party has a good-faith basis for challenging the redaction or privilege designation, counsel for the Parties shall initially attempt to resolve the issue through discussions. The disputing Party must give the designating Party an opportunity to review the withheld or redacted material and meet and confer. Absent good cause, no more than fifty (50) documents shall be challenged at a time, and only one challenge may be sent within a seven (7) day period. The withholding Party shall within thirty (30) days of receiving notice of the dispute either explain in writing the basis of the withholding or redaction or produce or unredact the document. This period and number and timing of documents challenged may be extended by agreement of the Parties. If these discussions prove unsuccessful, counsel may move for a ruling, which may require this Court's *in camera* inspection of a document, on the issue of whether certain information is entitled to redaction or privilege. The party asserting privilege or confidentiality shall have the burden of proof on such motion to establish the propriety of its privilege designation or redaction.

f) The fact that a Party produces a document without redactions shall not constitute an admission or concession that that all portions of the document are relevant to claims or defenses in the Litigation.

14. **Inadvertent Disclosure of Privileged Materials.**

a) Pursuant to Rule 502(d) of the Federal Rules of Evidence, if, in connection with the pending Litigation, a producing Party discloses information that the producing Party thereafter claims to be privileged or protected by the attorney-client privilege or attorney work product protection ("Disclosed Protected Information"), the disclosure of the Disclosed Protected Information shall not constitute or be deemed a waiver or

forfeiture of any claim of privilege or work product protection that the producing Party would otherwise be entitled to assert with respect to the Disclosed Protected Information and its subject matter.

b) A producing Party should promptly assert in writing attorney-client privilege or work product protection with respect to Disclosed Protected Information. The Receiving Party must—unless it contests the claim of attorney-client privilege or work product protection in accordance with paragraph (c) below—within ten (10) business days of receipt of that writing, (i) return or destroy all copies of the Disclosed Protected Information, and (ii) provide a certification of counsel that all of the Disclosed Protected Information has been returned or destroyed. Within ten (10) business days of receipt of the notification that the Disclosed Protected Information has been returned or destroyed, the producing Party must produce a privilege log with respect to the Disclosed Protected Information.

c) If the Receiving Party contests the claim of attorney-client privilege or work product protection, the Receiving Party must—within twenty-one (21) business days of receipt of the claim of disclosure—move the Court for an Order compelling disclosure of the Disclosed Protected Information (a “Disclosure Motion”). The Disclosure Motion must be filed under seal or with redactions of the disputed privileged information and any Confidential Information, as provided in this Order. The Disclosure Motion must not assert as a ground for compelling disclosure the fact of the disclosure. Pending resolution of the Disclosure Motion, the Receiving Party must not use the Disclosed Protected Information or disclose it to any person other than those required by law to be served with a copy of the sealed Disclosure Motion.

d) The Parties may stipulate to extend the time periods set forth in paragraphs (b) and (c).

e) Disclosed Protected Information that is sought to be reclaimed by the Parties to this case pursuant to this Order shall not be used as grounds by any third party to argue that any waiver of privilege or protection has occurred by virtue of any production in this case. Nothing in this Order overrides any attorney's ethical responsibilities to refrain from examining or disclosing materials that appear to be privileged and to disclose to the producing Party that such materials have been produced.

f) The producing Party retains the burden of establishing the privileged or protected nature of the Disclosed Protected Information. Nothing in this paragraph shall limit the right of any Party to petition the Court for an *in camera* review of the Disclosed Protected Information.

15. **Subpoena of Confidential Materials.** If Confidential Information in the possession of a Receiving Party is subpoenaed by any court, administrative or legislative body or authority, or any other person or organization purporting to have authority to subpoena information, other than this Court, the Party to whom the subpoena is directed shall not, to the extent permitted by applicable law, provide or otherwise disclose such documents or information without first notifying counsel for the producing Party in writing of: (1) the information and documentation sought by subpoena; (2) the date on which compliance with the subpoena is requested; (3) the location at which compliance with the subpoena is requested; (4) the identity of the party serving the subpoena; and (5) the case name, jurisdiction and index, docket, complaint, charge, civil action or other identification number or other designation identifying the litigation, administrative proceeding or other proceeding in which the subpoena has been issued.

Said notification shall be made to counsel for the producing Party or person no later than five (5) days from the date upon which the subpoenaed Party first received notice of the subpoena. No Confidential Information may be disclosed, if within seven (7) days of receipt by the producing Party or person of notice of the subpoena, such producing Party or person intervenes and objects to the disclosure.

16. **Use of Producing Party's Own Information.** Nothing herein shall (a) prevent a Party from disclosing any document, material, or other thing that a Party has produced to any other person; or (b) otherwise restrict a Party's use of such documents, materials, or other things, or portions thereafter (and the information contained therein). Except as set forth herein, such disclosure shall not be deemed to waive or otherwise modify the protections under this Order.

17. **Non-Restriction on Use of Public Information.** This Order shall not prevent persons bound hereby from making use of information or materials without the restrictions of this Order if the information or materials are already lawfully in the public domain or are otherwise lawfully available to the public.

18. **No Blanket Protection.** 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 or privileged.

19. **Survival of Order Beyond the Litigation.** The terms of this Order shall survive and remain in effect after the termination of this Litigation. The Parties shall take such measures as are necessary and appropriate to prevent the public disclosure of Confidential Information, through inadvertence or otherwise, after the conclusion of this Litigation. All Parties or persons receiving or given access to Confidential Information in accordance with the terms of this Order

consent to the continuing jurisdiction of the Court for the purposes of enforcing this Order and remedying any violations thereof. Such jurisdiction shall continue after the conclusion of the Litigation.

20. **Return or Destruction of Documents.** All Confidential Information and copies of Confidential Information, regardless of the format in which that information is produced, shall either: (1) be returned and surrendered to the producing Party or person upon the conclusion of this Litigation; or (2) be destroyed. Conclusion shall be taken and construed as the date thirty (30) days following closure of the docket in this Litigation or such other time as the Parties may agree. Upon such conclusion, counsel of record for the Receiving Party shall notify counsel for the producing Party of such return and surrender, or certify to counsel for the producing Party that such Confidential Information has been destroyed. This includes the deletion of any computer files containing Confidential Information, wherever they shall exist. Counsel for the Receiving Party shall make a reasonable effort to ensure return or destruction of Confidential Information from any Party or non-party witness to whom a copy of such information has been given and shall notify in writing counsel for the producing Party of the failure to retrieve any such information. Confidential Information that is maintained by counsel as an exhibit to a document that had been filed with the Court is not subject to this paragraph. Counsel are entitled to retain an archival copy of all pleadings, motion papers, transcripts, legal memoranda, correspondence or attorney work product, even if such materials contain Confidential Information. Any such archival copies that contain or constitute Confidential Information remain subject to this Order.

21. **Right to Seek Additional or Different Relief.** The entry of this Order shall not be interpreted as a waiver of the right to object, pursuant to the Federal Rules of Civil Procedure,

to the furnishing of information in response to discovery requests or to object to a requested inspection of documents or facilities. Neither the agreement to, or the taking of any action in accordance with the provisions of this Order, nor the failure to object thereto, shall be interpreted as a waiver of any claim or position or defense in this Litigation or any other actions. Neither this Order nor the designation of any item as Confidential Information shall be construed as an admission that such material, or any testimony concerning such material, would be admissible in evidence in this Litigation or any other proceeding. Any Party shall be allowed to apply, pursuant to Federal Rule of Civil Procedure 26(c), upon notice, for an order seeking additional safeguards with respect to the handling of discovery documents, or to modify the terms of this Order.

Dated this \_\_\_\_\_ day of \_\_\_\_\_, 2016.

---

F. Dennis Saylor, IV  
United States District Judge

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

IN RE: ZOFRAN (ONDANSETRON)	)	MDL No. 1:15-md-2657-FDS
PRODUCTS LIABILITY LITIGATION,	)	
	)	
This Document Relates to :	)	
All Cases	)	
	)	

**ACKNOWLEDGMENT OF CMO #XX REGARDING CONFIDENTIALITY**

I hereby attest to my understanding that information or documents designated confidential are provided to me subject to the Case Management Order No. XX (Protective Order Governing Confidential and Privileged Materials) dated \_\_\_\_\_, 2016, (the “Order”), in the above-captioned Litigation. I have been given a copy of and have read the Order, and I agree to be bound by its terms. I understand that my execution of this Acknowledgment is a prerequisite to my review of any Confidential Information in this Litigation.

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

I further agree that my obligation to honor the confidentiality of such Confidential Information will continue even after this Litigation concludes.

I further agree that, if I fail to abide by the terms of the Order, I may be subject to sanctions, including contempt of court, for such failure. I agree to be subject to the jurisdiction of the United States District Court, District of Massachusetts for the purposes of any proceedings relating to enforcement of the Order.

Dated: \_\_\_\_\_

Signed: \_\_\_\_\_

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

**CERTIFICATE OF SERVICE**

I, Robert K. Jenner, hereby certify that on this 7th day of March, 2016, I electronically filed the foregoing with the Court using the CM/ECF system and thereby delivered by electronic means to all registered participants as identified on the Notice of Electronic Filing:

**/s/ Robert K. Jenner**

Robert K. Jenner