

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

In re: FLUOROQUINOLONE PRODUCTS
LIABILITY LITIGATION

MDL No. 15-2642 (JRT)

This Document Relates to All Actions

PROTECTIVE ORDER

The undersigned counsel for Defendants and Plaintiffs (collectively, the “Parties” and each, a “Party”) in the above captioned action agree that the Parties and non-parties will be required to produce or disclose in this proceeding certain information and documents that are subject to confidentiality limitations on disclosure under applicable laws and regulations and applicable privacy rights. Such documents, described in more detail below, include information that is a trade secret or other confidential research, development, or commercial information or is of a private or personal nature. Disclosure of such information without reasonable restriction on the use of the information may cause harm, damage, loss, embarrassment, or disadvantage to the Producing Party or nonparty.

Accordingly, the Parties desire entry of an order, pursuant to the Federal Rules of Civil Procedure 26(c) [and applicable local procedural rule], and other applicable laws and rules, that will facilitate the prompt resolution of concerns or disputes over confidentiality, that will adequately protect material believed in good faith to be confidential and ensure that protection is afforded only to material so entitled and that will address any inadvertent production of documents or information protected from disclosure by the attorney-client privilege, work-product immunity, or other applicable privilege:

Therefore, the Parties hereby STIPULATE, subject to the Court’s approval, and the Court, for good cause shown and after having an opportunity to discuss this Protective Order with the Parties, hereby ORDERS that the following procedures shall be followed in this proceeding to facilitate the orderly and efficient discovery of relevant information while minimizing the potential for unauthorized disclosure or use of confidential or proprietary information and documents.

1. **Purpose.** The Parties recognize that preparation for any trial of this action may require the discovery of certain information that a Designating Party, as defined below, reasonably and in good faith believes should be subject to confidential treatment under a protective order. The designation of a document, material, or information (whether written, graphic or electronic) as being subject to the terms and conditions of this Protective Order, is intended solely to facilitate prompt discovery and the preparation for trial of this action.

2. **Scope**

- a. This Protective Order shall govern all hard copy and electronic materials, the information contained therein, and all other information including all copies, excerpts, summaries, or compilations thereof, whether revealed in a document, deposition, other testimony, discovery response, or otherwise, that any party to this proceeding (the “Producing Party” or “Designating Party”) produces to any other party (the “Receiving Party”) and that the Producing Party designates as confidential under this Protective Order.
- b. This Protective Order is binding upon all Parties and their counsel in this proceeding, upon all signatories to Exhibit A, and upon (as applicable) their respective attorneys, principals, experts, consultants, representatives, directors, officers, employees, and others as set forth in this Protective Order.
- c. If additional parties are added other than parents, subsidiaries or affiliates of current parties to this litigation, their ability to receive a document protected by this Protective Order will be subject to their being bound, by agreement or Court Order, to this Protective Order.
- d. Third Parties who are obligated to produce Confidential Material in this Action and who so elect may avail themselves of, and agree to be bound by, the terms and conditions of this Protective Order and thereby become a Producing Party for purposes of this Protective Order.
- e. The entry of this Protective Order does not preclude any Party from seeking further order of this Court, including modification of this order, or from objecting to discovery that the Party believes to be improper.
- f. Nothing herein shall be construed as an admission or concession by any Party that designated Confidential Material, or any Document or Information derived from Confidential Material, constitutes material, relevant, or admissible evidence in this matter.

3. **Definitions.** In this Order, the terms set forth below shall have the following meanings:

- a. “Proceeding” or “Action” means the above-entitled proceeding.
- b. “Court” means the Honorable Judge currently assigned to this proceeding or any other judge to which this proceeding may be assigned, including Court staff participating in such proceedings.
- c. “Document” or “Documents” shall have the meaning set out in Rule 34 of the Federal Rules of Civil Procedure and, for purposes of this order, shall include electronically stored information.

- d. “Testimony” means all depositions, declarations or other pre-trial testimony taken or used in this Proceeding.
- e. “Information” means the content of Documents or Testimony, as well as any matter derived therefrom or based thereon.
- f. “Confidential Material” or “Confidential Discovery Material” means any Document (electronic or hard copy), Testimony, or Information that a Designating Party reasonably and in good faith believes to be entitled to confidential treatment under applicable laws and that the Party designates as such in accordance with the provisions of this Order. “Confidential Materials” includes, but is not limited to:
 - i. A plaintiff’s personal identifying information, financial information, medical/insurance information, and, with respect to any Party, any other information believed in good faith by the Designating Party to be subject to protection from disclosure by a natural person’s right of privacy under applicable privacy laws or regulations;
 - ii. A defendant’s or non-party’s non-public information, document (electronic or hardcopy), or tangible thing, response to discovery requests, deposition testimony or transcript, and any other similar materials, or portions thereof that are properly protected under Fed. R. Civ. P. 26(c) or other applicable law, Confidential Discovery materials includes trade secrets (as defined in the Uniform Trade Secrets Act); and also includes all information which, if disclosed to a competitor, could result in business harm by revealing proprietary licensing, marketing, design, development, research, manufacturing or business strategy information regarding products or medicines related to this lawsuit; and
 - iii. All material, data, and information obtained, derived, or generated from “Confidential Material,” to the extent the same are not publicly available or otherwise subject to the exclusions herein.
- g. Any entity organized under the laws of the Federal Republic of Germany that becomes a party to this litigation may designate as “Confidential Material” those documents (including electronic or paper form) containing “personal data” within the meaning of the German Federal Data Protection Act, which is protected under German law. “Personal data” consists of any and all data that concerns an identified person or a person who is identifiable with recourse to additional information available to the data processor (*e.g.*, reference to an individual by his/her title or position with the company whose identity is specified in other available sources of information). In particular, this provision applies to the following documents:
 - i. any correspondence (electronic or paper form) that identifies or through recourse to other sources of information available to the data processor allows identification of its author(s)/sender(s) and/or its

addressees/recipients, (e.g., all email correspondence, letters and faxes, including transmission reports);

- ii. any document, such as memoranda, notes and presentations, if it identifies or allows identification of its author/sender and/or its addressee/recipient through recourse to other information available to the data processor;
 - iii. minutes of internal or external meetings as far as they include information which individual(s) did or did not attend the meeting; and
 - iv. any document containing private medical information.
- h. The phrase “Confidential Material—Defendant Restricted” refers to Confidential Material, such as protected internal financial data that is not, and would not be shared or disclosed as between the Janssen defendants and the Bayer defendants for legal and other reasons. To the extent such information is required to be produced in this matter, if a Receiving Party proposes to disclose such information to a restricted defendant, the Receiving Party and Designating Party shall meet and confer prior to any such disclosure, and the Designating Party shall have the right to seek an Order that the disclosure not be made. It is the obligation of the Designating Party to notify the Receiving Party at the time of production and identify with specificity the documents that the Designating Party contends should not be disclosed pursuant to Section 4 herein. Nothing herein shall restrict manufacturers or marketers of the same FQ product from receiving and reviewing those entities’ Defendant-Restricted documents.
- i. “Designating Party” means the Party or non-party that designates Documents, Testimony, or Information as Confidential Material.
- j. “Disclose,” “Disclosed” or “Disclosure” means to reveal, divulge, give, or make available Documents, Testimony, or any part thereof, or any Information contained therein.
- k. The Court anticipates that before designating documents as Confidential Material pursuant to this Protective Order, the Producing Party shall make a good faith analysis of its document production to determine if such documents meet confidential treatment under applicable law. This Protective Order does not confer blanket protection to all disclosures, documents 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 protections for treatment as confidential.

4. **Designations of Confidential Material.**

a. **Designation of Documents.**

- i. Documents Produced in TIFF-Image Format. With respect to any Document produced in TIFF-image format, a Designating Party may

designate the Document as Confidential Material **or Confidential Material**— Defendant Restricted by placing a stamp or marking on each page of the Document stating the following: **CONFIDENTIAL, SUBJECT TO PROTECTIVE ORDER or CONFIDENTIAL--DEFENDANT RESTRICTED, SUBJECT TO PROTECTIVE ORDER.** Such markings shall not obscure, alter, or interfere with the legibility of the original document.

1. All copies, duplicates, or extracts (hereinafter referred to collectively as “copies”) of Confidential Material produced in TIFF-image format shall be marked with the same confidential stamp or marking as contained on the original, unless the original confidential stamp or marking already appears on the copies.
- ii. Documents Produced in Native Format. With respect to any Document produced in native format (“Native-Format Document”), a Designating Party may designate the Document as Confidential Material or Confidential Material—Defendant Restricted by including in the file name of the Native-Format Document the following: **CONFIDENTIAL or CONFIDENTIAL--DEFENDANT RESTRICTED.**
 1. Native-Format Documents may have to be copied or duplicated for use in a litigation-support review application. Any such copy or duplicate shall retain the full file name as originally produced.
 2. For use outside a litigation-support review application, Receiving Parties may make native-format copies or duplicates of a Native-Format Document solely (a) for use with experts or consultants who are retained in this Action and who are Qualified Persons as defined below or (b) for use as deposition or trial exhibits. Any such copy or duplicate shall retain the full file name as originally produced.
 3. All other non-native copies or duplicates of Native-Format Documents (*e.g.*, TIFF-image, PDF, hardcopy) and all extracts of Native Format Documents shall contain a stamp or marking on each page of the Document stating the following: **CONFIDENTIAL, SUBJECT TO PROTECTIVE ORDER or CONFIDENTIAL--DEFENDANT RESTRICTED, SUBJECT TO PROTECTIVE ORDER.** Such markings shall not obscure, alter, or interfere with the legibility of the original document.

b. Designation of Deposition Transcripts.

- i. During depositions, Confidential Material may be used or marked as exhibits, but shall remain subject to this Order and may not be shown to the witness unless such witness is a Qualified Person as describe below

- ii. If deposition Testimony or exhibits contain or refer to Confidential Material, or if they contain or refer to Documents, Testimony, or Information to be designated as Confidential Material, the Designating Party, by and through counsel, shall either
 1. On the record at the deposition, designate the Testimony or exhibit(s) as Confidential Material or, as applicable, identify already-designated Confidential Material, or
 2. No later than thirty (30) days after receiving a copy of the deposition transcript, inform the deposing counsel and counsel for other Parties that the Testimony or exhibit(s) constitute Confidential Material; during the thirty-day period, the entire deposition testimony, transcript, and exhibits shall be treated as Confidential Material under this Order.
- iii. When a Party designates testimony as Confidential Material during the deposition, counsel for that Party may exclude from the deposition all persons who are not Qualified Persons under this Order.
- iv. When portions of a deposition transcript or its exhibits are designated for protection, the transcript or exhibit pages containing Confidential Material shall be separately bound by the court reporter, who must affix to the top of each page the legend **CONFIDENTIAL, SUBJECT TO PROTECTIVE ORDER or CONFIDENTIAL--DEFENDANT RESTRICTED, SUBJECT TO PROTECTIVE ORDER.**
- c. Written Pleadings, Motion Papers, and Discovery Materials. A party may designate as Confidential Material portions of interrogatories and interrogatory answers, responses to requests for admissions and the requests themselves, requests for production of documents and things and responses to such requests, pleadings, motions, affidavits, and briefs that quote, summarize, or contain Confidential Material. To the extent feasible, such Confidential Material shall be prepared in such a manner that it is bound separately from material not entitled to protection.
- d. Designation of Other Confidential Material. With respect to Confidential Material produced in some form other than as described above, including, without limitation, compact discs or DVDs or other tangible items, the Designating Party must affix in a prominent place on the exterior of the container or containers in which the Information or item is stored the legend **CONFIDENTIAL, SUBJECT TO PROTECTIVE ORDER or CONFIDENTIAL--DEFENDANT RESTRICTED, SUBJECT TO PROTECTIVE ORDER.** If only portions of the Information or item warrant protection, the Designating Party, to the extent practicable, shall identify the portions that constitute “Confidential Materials.”
- e. With respect to Documents or Information produced or disclosed by a non-party, either the non-party or a Party may designate the Documents or Information as

Confidential Material pursuant to this Order. A Party so designating material produced by a non-Party shall notify all other Parties within 30 days of receipt of such Document or Information that the same or portions thereof constitute or contain Confidential Material. Until the expiration of 30 days, such Document or Information produced or disclosed by any such non-party shall be treated as Confidential Material under this Order.

5. **Required Treatment of Confidential Material.**

- a. Except as specifically provided in this Order, counsel shall keep all Confidential Material disclosed or produced to them within their exclusive possession and control, shall take all necessary and prudent measures to maintain the confidentiality of such materials and information, and shall not permit unauthorized dissemination of such materials to anyone.
- b. Confidential Material shall not be disclosed in any way to anyone for any purpose other than as required for the preparation of trial in this action or other related actions as defined in Paragraph 11, below.
 - i. Nothing in this Order shall preclude a Party from introducing into evidence at trial or evidentiary hearing any Confidential Material that is admissible under applicable law. The Parties shall meet and confer regarding the procedures for use of Confidential Material at trial or any evidentiary hearing and shall move the Court for entry of an appropriate order. At trial or evidentiary hearings, the Court may take such other measures or enter separate orders, as the Court deems appropriate or upon request by any Party, to protect the claimed Confidential Material sought to be introduced or admitted.
- c. Access to and disclosure of Confidential Material shall be limited to those persons designated as Qualified Persons, below. Any Qualified Person who examines any Confidential Material shall not disseminate orally, or by any other means, any protected information other than as permitted by this Order.
- d. Confidential Material shall not be used for any business, competitive or other non-litigation purpose without the express written consent of counsel for the Designating Party or by order of the Court.
 - i. Nothing in this Protective Order shall limit any Designating Party's use of its own documents or shall prevent any Designating Party from disclosing its own Confidential Material to any person for any purpose.
 - ii. Nothing herein shall prevent Plaintiffs from viewing or receiving and retaining copies of their own medical records and from disclosing such medical records to, and sharing them with, their physicians.
 - iii. Nothing herein shall prevent Defendants from viewing or retaining copies of medical records of Plaintiffs that are in their possession or control or

from disclosing such records to other Qualified Persons, regardless of whether or not the documents have been designated as Confidential Material.

- iv. Disclosures described in the above sub-paragraphs shall not affect any confidential designation made pursuant to the terms of this Protective Order so long as the disclosure is made in a manner that is reasonably calculated to maintain the confidentiality of the designated Information, Testimony, and/or Document.
- e. To avoid security risks inherent in certain current technologies and to facilitate compliance with the terms of this Order, and unless otherwise ordered or agreed upon in writing by the Designating Party whose Confidential Material is at issue, all Qualified Persons with access to Confidential Material shall comply with the following:
 - i. Qualified Persons shall be prohibited from storing or transmitting any Confidential Material in or via any online or web-based storage location or service managed or maintained outside the United States. Any party using the services of a third-party service provider, shall use a reputable litigation support service provider with a secure domestic document hosting facility that uses encrypted web-enabled software that allows for the secure and protected sharing and collaboration of said Protected Material among Qualified Persons.
 - ii. Notwithstanding the foregoing provision, Qualified Persons, as defined in the following paragraph, shall not be prohibited from transmitting Confidential Material to any other Qualified Person through electronic mail, as attachments to an electronic mail in the form of separate PDF files or zip files, through tools provided by a reputable litigation support service or document management service, or via FTP file transfer, as long as the person transmitting the Protected Material takes reasonable steps to protect the confidentiality of the Confidential Material.

6. **Qualified Persons With respect to Confidential Material.** Confidential Material (as distinct from Confidential Material—Defendant Restricted, covered in Paragraph 7 below) may be disclosed only to the following persons (referred to as “Qualified Persons” throughout this Order):

- a. When produced by any defendant in the action: all other defendants, their inside and outside counsel and insurers, as applicable, the defendants’ employees (including partners, directors, and officers), and the Plaintiffs and their attorneys in the action;
- b. When produced by Plaintiffs: all defendants (including partners, directors, officers, and employees of defendants) and their inside and outside counsel and insurers;

- c. With respect to Qualified Persons encompassed by the preceding two paragraphs (a) and (b), such persons include the attorneys' employees and agents (*e.g.*, outside copy services, organizations involved in organizing, filing, coding, converting, storing, or retrieving data or designing programs for handling data connected with this action, including the performance of such duties in relation to a computerized litigation support system, and stenographers);
- d. Experts, consultants and case-specific medical professionals ("Consultants") whose assistance is necessary to assist counsel in the preparation of this Proceeding, whether or not the Consultant is designated as an expert and retained to testify, with the following qualifications:
 - i. Disclosure shall not be made to any consultant who, as described in Paragraph 9, is employed by or a consultant to a competitor of the Designating Party;
 - ii. Disclosure shall not be made to any consultant if counsel for the Party retaining that consultant has actual knowledge that the consultant has been found to have violated the terms of a protective order in any litigation or legal proceeding; and
 - iii. Any expert or medical professional to whom disclosure of Confidential Material is authorized must be informed of this Protective Order and must sign a copy of the Non-Disclosure Agreement attached hereto as Exhibit "A."
- e. A deponent or a witness at a deposition or pre-trial hearing, provided there is a reasonable basis to believe that the witness will give relevant testimony regarding the Confidential Material or that disclosure of Confidential Material is necessary to prepare the witness for the testimony.
 - i. If a Party wishes to disclose Confidential Material to such a deponent or witness¹ before or during a deposition or pre-trial hearing, the deponent or witness must be informed of this Protective Order and either sign a copy of the Non-Disclosure Agreement attached hereto as Exhibit "A," or consent under oath on the record to abide by its provisions.
 - ii. The Parties agree that this provision does not preclude the Designating Party from objecting to or moving to preclude disclosure to any deponent or

¹ The Parties expressly agree that this Protective Order is not intended to modify the regularly applicable law regarding ex parte contact with treating physicians. Accordingly, Plaintiff is not consenting for Defendants to have ex parte contact with treating physicians beyond what applicable law allows. Likewise, Defendants are not agreeing that ex parte contact or sharing of Confidential Materials with a treating physician is appropriate or permissible, and Defendants expressly reserve the right to challenge any such contact or proposed sharing of Confidential Materials with treating physicians.

witness, or to seek amendment of this provision in the future, if it believes it has a good faith basis for such objection or motion;

- f. A person identified in the Confidential Material as an author, source, addressee, or recipient of the communication, or who already has a copy of the Confidential Material;
- g. Any mediators or arbitrators selected to assist in resolution of this matter, and their personnel who are actively engaged in assisting them;
- h. The Court or any Court personnel, including any court reporters; and
- i. Any person mutually agreed upon among the Parties, provided that such person has been informed of this Protective Order and has signed a copy of the Non-Disclosure Agreement attached hereto as Exhibit "A."

7. Qualified Persons With respect to Confidential Material—Defendant Restricted.

Confidential Material—Defendant Restricted may be disclosed only to the following Qualified Persons subject to section 3h above:

- a. Attorneys of record for plaintiffs in this action or for any manufacturer or marketer of the same FQ product, and their paralegals or their other employees or agents (including litigation-support services) who require access to Confidential Material—Defendant Restricted for the purpose of litigation of this action;
- b. Plaintiffs, provided that their counsel believe in good faith that disclosure is necessary to the prosecution of the action;
- c. Consultants who are Qualified Persons described in Paragraph 6.d and its sub-paragraphs above;
- d. A deponent or witness at a deposition or pre-trial hearing described in Paragraph 6.e and its sub-paragraphs above subject to section 3h ;
- e. A person identified in the Confidential Material—Defendant Restricted as an author, source, addressee, or recipient of the communication, or who already has a copy of the Confidential Material;
- f. Any mediators or arbitrators selected to assist in resolution of this matter, and their personnel who are actively engaged in assisting them;
- g. The Court or any Court personnel, including any court reporters; and
- h. Any person mutually agreed upon among the Designating and Receiving Parties, provided that such person has been informed of this Protective

Order and has signed a copy of the Non-Disclosure Agreement attached hereto as Exhibit "A."

8. **Further Requirements With Respect to Qualified Persons.**

- a. Before being given access to any Confidential Material, each Qualified Person, other than the Court, the employees and staff of the Court, counsel of record, and the direct employees of counsel of record, and other than as set forth above with respect to those witnesses to whom Confidential Material is disclosed or shown at a deposition or pre-trial hearing as set forth in Paragraph 6(e), shall be advised of the terms of this Order, shall be given a copy of this Order, shall agree in writing to be bound by the terms of this Order by signing a copy of the Non-Disclosure Agreement attached hereto as Exhibit "A" and shall consent to the exercise of personal jurisdiction by this Court in any proceeding(s) to determine if the signatory violated this Order. The defendants' employees (including partners, directors, and officers), shall not be required to execute "Exhibit A" in order to be bound thereby.
- b. The witness who is a Qualified Person pursuant to Paragraph 6(e) but who has not signed a copy of the Non-Disclosure Agreement attached hereto as Exhibit "A" may be shown Confidential Material during his or her testimony, but shall not be given a copy of the Confidential Material to keep. Before reviewing his or her transcribed testimony containing the Confidential Material for purposes of completing the errata sheet, such witness shall sign a copy of the Non-Disclosure Agreement attached hereto as Exhibit "A" and shall consent to the exercise of personal jurisdiction by this Court in any proceeding(s) to determine if the signatory violated this Order, provided, however, that if the witness refuses to sign a copy of the Non-Disclosure Agreement attached hereto as Exhibit "A", the parties will agree that an unsigned copy of the deposition may be used at any pre-trial hearing or trial.
- c. Any Confidential Material distributed or disclosed to a Qualified Person who is a signatory of Exhibit "A" shall be returned to the Party's counsel who provided it to the Qualified Person or shall be destroyed at the completion of the Qualified Person's consultation or representation in this case. Upon the request of the Designating Party or the Court, each such Qualified Person shall execute an affidavit stating that all such Confidential Material and copies thereof have been returned or destroyed as required.
- d. The Court shall retain jurisdiction over any person or organization authorized, as set forth above, to receive Confidential Material as necessary to enforce the provisions of this Order.

9. **Non-Disclosure to Competitors.** Subject to the foregoing, without express written consent or court order, in no event shall any disclosure of a defendant's Confidential Material, or Confidential Material --Defendant Restricted, be made to any known Competitor of that defendant or to any person who, upon reasonable and good faith inquiry, could be determined to be a current

employee thereof or current paid consultant doing research under an active written agreement for a Competitor of a designating defendant irrespective of whether such consultant or person is retained as an expert in this action. A “Competitor,” in the context of this Proceeding, shall mean any manufacturer of, or manufacturer involved in the sale of, pharmaceuticals or current employee of such entity.

- a. In the case of an expert or consultant, the expert or consultant is best suited to know whether he or she is a Competitor of a defendant, or if he or she is a current employee of or consultant doing research for a Competitor of the designating defendant. Thus, Plaintiffs will be required by the Protective Order to make a full inquiry of the expert or consultant and to obtain confirmation from him or her on these topics before any information is shared with the expert or consultant. Plaintiffs shall not disclose a defendant’s Confidential Material to any expert or consultant whom Plaintiffs have not confirmed: (1) is not a competitor of a defendant; (2) is not currently employed by a Competitor; and (3) is not doing research for a Competitor pursuant to a written agreement.

10. **Challenges to Designations.**

- a. The Designating Party bears the burden of establishing confidentiality.
- b. Nothing in this Order shall constitute a waiver of any Party’s right to object to the designation or non-designation of Documents, Testimony, or Information as Confidential Material.
- c. If a Party contends that any Document, Testimony, or Information has been erroneously or improperly designated as Confidential Material, or has been improperly redacted, the material at issue shall be treated as confidential under the terms of this Order until
 - i. the Parties reach a written agreement or
 - ii. this Court issues an order determining that the material is not confidential and shall not be given confidential treatment.
- d. In the event that counsel for a Party receiving Confidential Material in discovery objects to such designation, said counsel shall advise counsel for the Designating Party, in writing, of such objections, the specific Confidential Material (identified by Bates number, if possible) to which each objection pertains, and the specific reasons and support for such objections (the “Designation Objections”).
- e. Counsel for the Designating Party shall have 30 days from receipt of the written Designation Objections to respond in writing as to whether the designations will be maintained or withdrawn, provided that no more than 50 document designations are challenged in any 30 day period.

- f. If Designating Party does not de-designate the challenged Confidential Material at issue, the parties shall meet and confer in good faith, by phone or in-person, to discuss the Designation Objections and attempt to resolve the dispute.
- g. If 14 days have passed since the Designating Party's response pursuant to paragraph 10(e) above and the meet and confer process has not resolved the dispute, the designating party may move the court for an Order maintaining the confidentiality of the challenged material.
 - i. Pending a resolution of the Designation Motion by the Court, the Designating Party is presumed to have designated the Confidential Material in good faith, and any and all existing designations challenged in such Motion shall remain in place.
 - ii. The Designating Party shall have the burden of establishing the applicability of its "confidential" designation.
 - iii. If the Designating Party does not move the court for an Order pursuant to this paragraph in the time specified, the Receiving Party shall send the Designating Party a notice that the challenged material shall be deemed non-confidential if such motion is not made within seven (7) days. Upon expiration of that seven (7) day period, the challenged material shall be deemed non-confidential.

11. **Use of Confidential Material in Court Prior to Trial.** The Parties will use the following procedure, absent further Court Order, for disclosing Confidential Material to the Court prior to trial.

- a. Confidential Material is not to be filed with the Court except when required in connection with motions or other matters pending before the Court.
- b. The Party seeking to file Confidential Material or a document reflecting or including Confidential Material in support of a motion or other proceeding pending before the Court may first notify the Designating Party of its intent and seek agreement to de-designate such material.
- c. Absent any such agreement, if Confidential Material or a document reflecting or including Confidential Material is submitted to or otherwise disclosed to the Court in connection with a motion or other proceeding pending before the Court, such Confidential Material shall be separately filed under seal with the clerk of the Court in an envelope marked: "CONFIDENTIAL – FILED UNDER SEAL PURSUANT TO PROTECTIVE ORDER AND WITHOUT ANY FURTHER SEALING ORDER REQUIRED" or "CONFIDENTIAL— DEFENDANT RESTRICTED – FILED UNDER SEAL PURSUANT TO PROTECTIVE ORDER AND WITHOUT ANY FURTHER SEALING ORDER REQUIRED." On the outside of the envelope, a copy of the caption page of the applicable pleading shall be attached. No Confidential Material, nor any part thereof, shall be included in such caption page nor otherwise be revealed on the outside of the envelope.

- i. When this litigation has concluded, the Clerk of Court may return to counsel for the Designating Party, or may destroy, any Confidential Material filed under seal pursuant to the provisions of this Order.

12. **Redaction.** The Producing Party may redact, from any hard copy document, TIFF image, metadata field, or native file, information that is protected from disclosure by applicable privilege or immunity, that is governed by the European Data Privacy Directive, German Data Privacy Law² or other applicable privacy law or regulation, or that contains non-responsive information concerning products or matters unrelated to any fluoroquinolone including:

- i. The names, street addresses, Social Security numbers, tax identification numbers, and any other personal identifying information of patients, health care providers or other voluntary reporters reporting specific adverse events, and individual patients participating in clinical studies or referenced in adverse event reports. Other general information that does not identify the person, however, such as patient or health care provider numbers, shall not be redacted unless required by state or federal law. To the extent a plaintiff's name is contained in any of these documents, a copy of the documents that have not had the plaintiff's information redacted may be produced directly to counsel for said plaintiff;
- ii. Business and proprietary information relating to products manufactured or marketed by the named Defendants other than any fluoroquinolone that does not also relate to any fluoroquinolone.
- iii. Social Security numbers, passwords, telephone conference line numbers, tax identification numbers and other private personal information of employees or other persons in any records.

To the extent that the Producing Party redacts documents or portions thereof, the redaction shall state on the face of the document a designation: "Redacted: Relevance" or "Redacted: Privilege" or a similar designation setting forth the general basis of the redaction. The Producing Party shall also provide a field in the load file that reflects whether a document has any redaction and, if so, the general type(s) of redaction on the document. Documents in families that would be entirely redacted consistent with these provisions will be replaced by a ship sheet containing a statement that the document has not been produced because it would be redacted in its entirety. To the extent practical, if information in a document is redacted because it does not relate to a

² Pursuant to Article 8 of the European Data Privacy Directive, "the processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and the processing of data concerning health or sex life" is prohibited. This is different from production of information that has "personal data", defined in these laws as any document that identifies an individual or by recourse to other information could allow identification of an individual. An example is an email of a German employee because it identifies individuals. If produced as relevant and non-privileged, the content and "personal data" (e.g., sender and recipients) would not be redacted for the reason expressed above. Rather the document would be designated Protected under this Order.

fluoroquinolone, the Producing Party will endeavor to leave in headings or similar non-substantive information concerning the redacted information to facilitate identification of the general nature of the non-relevant information.

The foregoing provisions concerning redactions are production guidelines designed to facilitate the prompt production of potentially relevant discovery material and to minimize pre-production disputes and motion practice concerning the treatment of discovery material. Nothing in the foregoing paragraph shall be construed as a waiver by the Receiving Party of any right to seek an order for good cause shown compelling production of information redacted pursuant to this Order nor restrict a Producing Party's right to object or otherwise seek protection from the Court concerning any such request. The parties shall meet and confer before engaging in any motion practice with respect to this paragraph.

Further, nothing in this paragraph precludes the Receiving Party from challenging any redaction set out above.

13. **Subpoena by Other Courts or by Agencies.**

- a. If another court or an administrative agency requests, subpoenas, or orders the disclosure of Confidential Material from a Party that has obtained such material under the terms of this Order, the Party so requested, subpoenaed, or ordered shall notify the Designating Party by electronic mail transmission, express mail, or overnight delivery to counsel of record for the Designating Party not later than ten (10) days prior to producing or disclosing any Confidential Material, and shall furnish such counsel with a copy of the requests, subpoena, or order. The recipient of the Subpoena shall not disclose any Confidential Material pursuant to the Subpoena prior to the date specified for production on the Subpoena.
- b. Upon receipt of this notice, the Designating Party may, in its sole discretion and at its own cost, move to quash or limit the request, subpoena, or order, otherwise oppose the disclosure of the Confidential Material, or seek to obtain confidential treatment of such Confidential Material, to the fullest extent available under law, by the person or entity issuing the request, subpoena, or order. The Party who received the request, subpoena, or order shall not oppose or otherwise interfere with the Designating Party's effort to quash or limit the request, subpoena, or order.

14. **Disposition of Confidential Material.**

- a. Upon the request of any Party after the final conclusion of this action (including without limitation any appeals and after the time for filing all appellate proceedings has passed), each Party so requested shall return all Confidential Material to counsel for the Party that produced it, shall destroy it, or otherwise shall comply with an applicable order of the Court, subject to the exception described herein.
- b. The return or destruction of Confidential Material under this paragraph shall include, without limitation, all copies, and duplicates thereof, including copies on any litigation-support review application, which shall not be considered work product for purposes of this paragraph.

- c. The Parties shall certify, within 60 days of receipt of a written request for certification, that all Confidential Material required to be returned or destroyed have been so returned or destroyed.
- d. As an exception to the above requirements, and unless otherwise ordered by the Court, counsel may retain: (a) copies of pleadings or other papers that have been filed with the Court and that are Confidential Material or that reflect, reference, or contain Confidential Material; (b) their work product; and (c) official transcripts and exhibits thereto. The terms and provisions of this Order shall continue to apply to any such materials retained by counsel.

15. **Order Survives Termination of Action.** After the termination of this action by entry of a final judgment or order of dismissal, the provisions of this Order shall continue to be binding. This Order is, and shall be deemed to be, an enforceable agreement between the Parties, their agents, and their attorneys. The Parties agree that the terms of this Order shall be interpreted and enforced by this Court.

16. **No Waiver of Any Privilege Upon Inadvertent Production**

- a. The Parties have agreed that, in discovery in this lawsuit, they do not intend to disclose information subject to a claim of attorney-client privilege or attorney work product protection.
 - i. This Order does not affect or constitute a waiver of any Party's right to withhold or redact information protected from disclosure by the attorney-client privilege, physician-patient privilege, work product doctrine, or any other applicable privilege, protection, law, or regulation.
 - ii. Pursuant to Federal Rule of Evidence 502(d) and Federal Rule of Civil Procedure 26(b)(5)(B), the production or disclosure of any discovery material that a Party (the "Disclosing Party") thereafter claims should not have been produced or disclosed based on privilege or work product protections ("Inadvertently Disclosed Information"), shall not constitute or be deemed a waiver or forfeiture in whole or in part—in this or any other action— of any claim of attorney-client privilege or work product immunity that the Disclosing Party would otherwise be entitled to assert with respect to the Inadvertently Disclosed Information and its subject matter regardless of the circumstances of the production or disclosure. As set forth below, such Inadvertently Disclosed material shall be returned to the Producing Party or destroyed upon request.
- b. **Attorney's Ethical Responsibilities.** Nothing in this order overrides any attorney's ethical responsibilities to refrain from examining or disclosing materials that the attorney knows or reasonably should know to be privileged and to inform the Disclosing Party that such materials have been produced. Any party receiving materials that, on their face, appear to be covered by a privilege, shall not copy, distribute, or otherwise use in any manner such materials and shall provide prompt

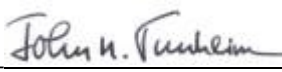
notice of the disclosure to the Producing Party to afford the Producing Party the opportunity to request return of the materials, in accordance with the terms of this paragraph.

- c. If a Disclosing Party notifies the Receiving Party of Inadvertently Disclosed Information, the Receiving Party shall, within ten (10) court days: (i) return or destroy (or in the case of electronically stored information, delete) all copies of such information (including all notes or other work product of the Receiving Party reflecting the contents of the Inadvertently Disclosed Information) within their possession, custody, or control—including all copies in the possession of experts, consultants, or others to whom the Inadvertently Disclosed Information was provided—and (ii) provide a certification of counsel that all such Inadvertently Disclosed Information has been returned or destroyed. From the moment a Disclosing Party provides notice of inadvertent production, a Receiving Party shall not copy, distribute, or otherwise use in any manner the disputed documents or information, and shall instruct all persons to whom the Receiving Party has disseminated a copy of the documents or information that the documents or information are subject to this Order and may not be copied, distributed, or otherwise used pending a motion and further notice from the Court. For purposes of this Order, Protected Information that has been stored by the Receiving Party on a source of electronically stored information that is not reasonably accessible, such as backup storage media, is sequestered. If such data is retrieved, the Receiving Party must promptly take steps to delete the restored protected information.
 - d. If the Receiving Party contests the claim of attorney-client privilege or work product protection, the Receiving Party may—within five (5) business days of receipt of the notice of disclosure—move the Court for an Order compelling production of the Inadvertently Disclosed Information (“Disclosure Motion”). Such a Disclosure Motion shall be filed or lodged conditionally under seal and shall not assert as a ground for entering such an Order the fact or circumstances of the inadvertent production. Pending resolution of the Disclosure Motion, the Receiving Party must not use the challenged information in any way or disclose it to any person other than those required by law to be served with a copy of the sealed Disclosure Motion. On any such Disclosure Motion, the Disclosing Party shall retain the burden of establishing its privilege or work product claims. Nothing in this paragraph shall limit the right of any Party to petition the Court for an *in camera* review of the Inadvertently Disclosed Information.
 - e. **Rule 502(b)**. The provisions of Federal Rule of Evidence 502(b) are inapplicable to the production of Protected Information under this Order.
17. **Inadvertent Production or Disclosure of Confidential Material.**
- a. The production or disclosure of any discovery material that a Party (the “Disclosing Party”) thereafter claims was produced or disclosed without the required confidentiality designation, of any Document, Testimony, or Information that the Disclosing Party intended to designate as Confidential Material (“inadvertent

production”) shall not be deemed a waiver in whole or in part of the producing Party’s claim of confidentiality, either as to specific documents and information disclosed or as to the same or related subject matter regardless of the circumstances of the production or disclosure.

- b. In the event that a Designating Party makes such an inadvertent production, that Party shall contact the receiving Party within 30 days of the discovery of the inadvertent production, and inform the receiving Party or Parties in writing of the inadvertent production and the specific material at issue.
 - c. Upon receipt of such notice, the receiving Party or Parties shall treat the material identified in the notice as confidential until (i) the Parties agree to non-confidential treatment of the subject material, or (ii) the Court, on motion of any Party, issues an order addressing the appropriate treatment of the subject material.
 - d. Within ten court days of receiving notice of the inadvertently disclosed Confidential Material, the receiving Party shall return or destroy all copies of such Confidential Material and provide a certification of counsel that all such Confidential Material has been returned or destroyed. Each receiving Party shall notify every person or organization that received copies of or access to the material identified in the notice that such material contains Confidential Material.
 - e. Within thirty days of providing notice of the inadvertently disclosed Confidential Material, the Disclosing Party shall re-produce the Confidential Material with the required legend.
18. **Privilege Log.**
- a. For any document or portion of any document the Producing Party designates as subject to a claim of privilege, immunity or work product protection that is responsive to a discovery request, the Producing Party shall supply a Privilege Log in the manner as set forth in attached Exhibit “B”. The Privilege Log shall be supplied within forty-five (45) days after the date upon which the documents were required to be produced or were partially produced. If documents are produced on a rolling basis, a corresponding privilege log for all redactions or withheld documents shall be produced within forty-five (45) days of the production of documents from each wave.

DATED: April 25, 2016
at Minneapolis, Minnesota.



JOHN R. TUNHEIM
Chief Judge
United States District Court

failure. I agree to be subject to the jurisdiction of the [_____], for the purposes of any proceedings relating to enforcement of the Order. I further agree to be bound by and to comply with the terms of the Order as soon as I sign this Agreement, regardless of whether the Order has been entered by the Court.

Date: _____

By: _____

EXHIBIT B

PRIVILEGE LOG

I. PRIVILEGE LOGGING PROTOCOL

A. General Principles. Privilege logs shall comply with Fed. R. Civ. P. 26(b)(5), which requires a party to:

1. Expressly identify the privilege asserted; and
2. Describe the nature of the documents, communications, or tangible things not produced or disclosed . . . in a manner that, without revealing information itself privileged or protected, will enable other parties to assess this claim. Fed. R. Civ. P. 26(b)(5).

B. Specific Principles.

1. **Asserting Privilege or Protection.** A party who withholds or redacts documents on the grounds of attorney-client privilege and/or work product protection shall provide:
 - a. a listing of such documents in electronic spreadsheet format providing the following objective metadata fields (“objective metadata” does not include substantive content from, or a subjective description of, the document being withheld or redacted):
 - i. the Bates number of the document (if redacted);
 - ii. the nature of the privilege asserted (e.g., “attorney-client privilege” or “attorney work product”);
 - iii. the name(s) of the author(s) of the document, (if known) (to the extent a document is comprised of an email chain, the name of the author on the most recent email in the chain will be identified);
 - iv. the name(s) of the recipient(s) of the document, including anyone who was sent the document as a “CC” or a “BCC,” (if known) (to the extent a document is comprised of an email chain, the name(s) of the recipient(s) on the most recent email in the chain will be identified);

- v. the custodian(s) of the document;
 - vi. the document type, including, for example, whether the document is an email, paper file, a meeting presentation, a spreadsheet, or other descriptive identifier of the document type;
 - vii. the date the document was created (if known), sent (if applicable); and last modified (if applicable).
- b. The withholding/redacting party need not provide an individualized or subjective description of the privilege or protection claimed for documents corresponding to the following categories because the parties agree that the individual review of such categories is not worth the time and/or expense necessary to do so:
- i. Communications involving outside counsel;
 - ii. Emails from an attorney and attachments;
 - iii. Emails sent to an attorney (attorney in the TO field) and attachments;
 - iv. Emails copied to an attorney (attorney in the CC field) and attachments;
 - v. Documents prepared or edited by an attorney (not attached to emails);
 - vi. Documents prepared or edited for review by an attorney (not attached to emails);
 - vii. Emails between non-lawyers conveying legal advice;
 - viii. Documents with reference to legal advice; and
 - ix. Status of legal matters, legal settlements.
- c. The withholding/redacting party shall specify the category to which a privileged or protected document corresponds.
- d. The withholding/redacting party shall provide individualized descriptions for documents that it asserts are

privileged or protected but that do not correspond to a category listed above.

2. **Documents presumptively not to be logged on Privilege Log.** The following documents presumptively need not be included on a privilege log:
 - a. Written or electronic communications regarding this action exclusively between a party and its trial counsel after commencement of this action; and
 - b. work product solely related to this action created by trial counsel after commencement of the action.
3. **Privilege Log descriptions of email threads.** A party may use electronic email threading to identify emails that are part of the same thread and need include only an entry for the most inclusive email thread on the log to identify withheld or redacted emails that constitute an email thread; provided, however, that disclosure must be made that the e-mails are part of an email thread.
4. **Privilege Log descriptions of exact duplicates.** A party need include only one entry on the log to identify withheld documents that are exact duplicates.
5. The privilege log should indicate which individuals listed on the log are attorneys.

II. PRIVILEGE LOGGING PROTOCOL

- A. **Challenging Asserted Privilege and Protection.** If a party challenges in writing an assertion of privilege or protection from discovery then the parties shall meet and confer and make a good faith effort to cooperatively classify the challenged documents into categories that are subject to common factual and legal issues in so far as practicable and shall attempt to resolve the privilege challenges. If thereafter, the parties are unable to resolve any of the privilege challenges, the parties shall jointly request a conference with the Court to devise a plan for resolving the challenges, which normally will include:
 1. a schedule for briefing the legal issues relevant to each category;
 2. a ruling date for issues that can be resolved on the briefs alone; and

3. a schedule for providing representative samples for the Court's review in camera with respect to any categories that cannot be resolved on the briefs; and
4. a schedule for the parties to meet and confer to attempt in good faith to apply the Court's rulings on the samples to whole categories or within categories insofar as possible; and
5. a schedule for repeating this process as needed.