

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE: INVOKANA (CANAGLIFLOZIN)	:	MDL NO. 2750
PRODUCTS LIABILITY LITIGATION	:	3:16-md-2750 (BRM)(LHG)
	:	
	:	JUDGE BRIAN R. MARTINOTTI
	:	
	:	JUDGE LOIS H. GOODMAN

**CASE MANAGEMENT ORDER NO. 17
(PROTECTIVE ORDER)**

The undersigned counsel for Defendants and Plaintiffs (collectively, the “Parties” and each, a “Party”) in the above captioned multi-district litigation (“MDL”) 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), Local Civil Rule 5.3, 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 corporate parents, subsidiaries, and affiliates, including their successors, and 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.
- g. This Protective Order shall not be construed to protect from production or to permit the designation of any documents or information as “Confidential” that: (a) the party has failed to make reasonable efforts to keep confidential other than by inadvertent production or disclosure of confidential material, (b) has lawfully obtained by or from another source on a non-confidential basis, without breach of law, regulation, court order, or privilege, or (c) is at the time of production or disclosure, or subsequently become, through no wrongful or negligent act of the Receiving Party, readily accessible to others on a non-confidential basis. In the

event the Receiving Party identifies any document that it reasonably believes falls under this paragraph, it shall continue to treat the document as “Confidential” and follow the procedure set forth in Paragraph 10 of this Order.

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 Federal Rule of Civil Procedure 34(a) 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 Federal Rule of Civil Procedure 26 and/or other applicable laws and that the Party designates as such in accordance with the provisions of this Order. “Confidential Material” 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 trade secrets (as defined in the Uniform Trade Secrets Act) and other proprietary or confidential business information of commercial value and believed in good faith to be subject to protection from disclosure under Federal Rule of Civil Procedure 26 and/or applicable statutes, laws, or regulations.
 - 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.
 - iv. Specifically excluded from the definition of “Confidential Material” are:

1. Any Documents, Testimony, or Information that have been, or in the future will be, designated as “not confidential” by order of any court;
 2. Any Documents, Testimony, or Information obtained, in the past or in the future, by any person or entity through procedures established under the Freedom of Information Act or other public records request. In the event of a dispute as to whether a Document, Testimony, or Information is available through the Freedom of Information Act or other public records request, the issue will be resolved by Plaintiffs’ counsel making an appropriate request for the release of such material from the appropriate governmental agency and the granting of such request by the agency or a court;
 3. Documents or articles published in trade magazines or other general circulation publications; or
 4. Documents previously provided to any individual or entity, or readily accessible to third-parties, on a non-confidential basis and without limitation on scope of use.
- g. The phrase “Confidential Material—Attorney Eyes Only” refers to Confidential Material that the Designating Party believes in good faith to contain highly confidential information the disclosure of which to the Party’s competitors would cause the Designating Party serious competitive and commercial harm. As used in this Order, and unless otherwise specified, “Confidential Material” shall encompass “Confidential Material-Attorney Eyes Only.”
- h. “Designating Party” means the Party or non-party that designates Documents, Testimony, or Information as Confidential Material.
- i. “Disclose,” “Disclosed” or “Disclosure” means to reveal, divulge, give, or make available Documents, Testimony, or any part thereof, or any Information contained therein.

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—Attorney Eyes Only by placing a stamp or marking on each page of the Document stating the following: **CONFIDENTIAL, SUBJECT TO PROTECTIVE ORDER, PRODUCED BY [PARTY NAME] IN [NAME OF LITIGATION] or CONFIDENTIAL-ATTORNEY EYES ONLY, SUBJECT TO PROTECTIVE ORDER**

PRODUCED BY [PARTY NAME] IN [NAME OF LITIGATION]. Such markings shall not obscure, alter, or interfere with the legibility of the original document.

1. All copies, duplicates, extracts, summaries, or descriptions (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—Attorney Eyes Only by renaming the Document to include, at the end of the file name and prior to the file extension, the following language: **CONFIDENTIAL, SUBJECT TO PROTECTIVE ORDER, PRODUCED BY [PARTY NAME] IN [NAME OF LITIGATION] or CONFIDENTIAL—ATTORNEY EYES ONLY, SUBJECT TO PROTECTIVE ORDER, PRODUCED BY [PARTY NAME] IN [NAME OF LITIGATION].**
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.
2. All other copies or duplicates of Native-Format Documents (*e.g.*, TIFF-image, PDF, hardcopy) and all extracts, summaries, or descriptions of Native-Format Documents shall contain a stamp or marking on each page of the Document stating the following: **CONFIDENTIAL, SUBJECT TO PROTECTIVE ORDER, PRODUCED BY [PARTY NAME] IN [NAME OF LITIGATION] or CONFIDENTIAL—ATTORNEY EYES ONLY, SUBJECT TO PROTECTIVE ORDER, PRODUCED BY [PARTY NAME] IN [NAME OF LITIGATION].** 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 described 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
 - 3. 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 IN [NAME OF LITIGATION]**” or **CONFIDENTIAL—ATTORNEY EYES ONLY, SUBJECT TO PROTECTIVE ORDER IN [NAME OF LITIGATION]**.
- 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, PRODUCED BY [PARTY NAME]**”

IN [NAME OF LITIGATION]” or CONFIDENTIAL—ATTORNEY EYES ONLY, PRODUCED BY [PARTY NAME] IN [NAME OF LITIGATION]. 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 10, 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. They shall use secure means to store and transmit Confidential Material whether stored or transmitted physically or electronically.
 - ii. 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.
 - iii. 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 as described herein, 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—Attorney Eyes Only, 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 and consultants (“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 consultant 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 witness during a deposition or pre-trial hearing, the deponent or witness must be informed of this Protective Order and the fact that the material is confidential. No Confidential Material may be left with such a deponent

or witness unless he or she has signed a copy of the Non-Disclosure Agreement attached hereto as Exhibit A.

- ii. If a Party wishes to disclose Confidential Material to a treating physician deponent before a deposition¹, the treating physician must be informed of this Protective Order and the fact that the material is confidential. No Confidential Material may be left with the physician deponent unless he or she has signed a copy of the Non-Disclosure Agreement attached hereto as Exhibit A. The Parties expressly agree that all documents shown to any treating physician witness by any party (other than the provider's own treatment records relating to the patient) and all documents provided to any treating physician witness by any party shall be disclosed to the other parties. The disclosure should include the documents, cover letters, letters about scheduling and letters about compensation to the treating physician. If the copies shown to or provided to the treating physician have markings, highlighting or tabs affixed to them, these should be disclosed. The disclosure shall be within seven days after the document has been shown to or provided to the treating physician, or at least 48 hours before any deposition of the healthcare provider, whichever comes first.
- iii. The Parties agree that this provision does not preclude the Designating Party from objecting to or moving to preclude disclosure to any deponent or 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."

¹ The Parties expressly agree that this Protective Order is not intended to modify the regularly applicable law regarding ex parte contact with any such treating physician. 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 pursuant to this paragraph on all bases other than the existence of this Protective Order.

7. **Qualified Persons With Respect to Confidential Material—Attorney Eyes Only.** Confidential Material—Attorney Eyes Only may be disclosed only to the following Qualified Persons:

- a. Attorneys of record in this action, and their paralegals or their other employees or agents (including litigation-support services) who require access to Confidential Material—Attorney Eyes Only 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 subparagraphs above;
- d. A person identified in the Confidential Material—Attorney Eyes Only as an author, source, addressee, or recipient of the communication, or who already has a copy of the Confidential Material;
- e. Any mediators or arbitrators selected to assist in resolution of this matter, and their personnel who are actively engaged in assisting them;
- f. The Court or any Court personnel, including any court reporters; and
- g. 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.”

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. Counsel for each Party shall maintain a list of all Qualified Persons to whom they or their client(s) have provided any Confidential Material, which list shall be available for inspection by the Court.
- 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.

- 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.** Notwithstanding the foregoing, without express written consent or court order, in no event shall any disclosure of a defendant's Confidential Material or Confidential Material-Attorney Eyes Only 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 (whose job responsibilities include work on medical treatments for diabetes mellitus) or consultant doing research for a competitor of a designating defendant (whose research relates to diabetes mellitus) 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, medications or other medical treatments for diabetes mellitus or any 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 a declaration from him or her on these topics before any information is shared with the expert or consultant.
- b. To this end, the expert or consultant shall provide written certification whether he or she is a Competitor of a defendant, whether he or she is currently employed by a Competitor, and whether he or she is contracted with a Competitor and doing research for such Competitor.
- c. Plaintiffs shall not disclose a defendant's Confidential Material to any expert or consultant who certifies that he or she is a Competitor of a defendant, is currently employed by a Competitor, or is contracted with a Competitor and doing research for such Competitor.
- d. Plaintiffs shall maintain each respective expert's or consultant's certification under this paragraph for the duration of the litigation so they may be submitted to the Court for *in camera* review in the event of a dispute between the parties.

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"). There shall be no time limit for which Party is to make such objections.
- e. Counsel for the Designating Party shall have 7 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 100 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, after meeting and conferring in good faith, the Parties are unable to resolve the dispute regarding the Designation Objections or after 14 days have passed since service of the Designation Objections, whichever comes first, the Party challenging the designations may file a motion with the Court seeking an order to de-designate (*i.e.*, to rule to be not confidential) the Confidential Material subject to the Designation Objections (the "Designation Motion").
 - 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 there is no ruling on the Designation Motion within thirty (30) days, the parties shall jointly move before the Court for a ruling.

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 or otherwise consent to its filing.
- 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 filed in accordance with Local Civil Rule 5.3(c).
- d. Once filed under seal, the Designating Party will comply with the Court's rules regarding sealing.
- e. 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. **Redactions**

- a. To protect against unauthorized disclosure of Confidential Discovery Material, and to comply with all applicable state and federal laws and regulations, the Producing Party may redact from produced documents, materials and other things, the following items, or any other item(s) protected from disclosure by statute or decisional authority or agreed upon by the parties or ordered by the Court:
 - i. The names, street addresses, Social Security numbers, tax identification numbers, and other personal identifying information of patients, health care providers, and individuals in clinical studies or adverse event reports. Other general identifying information, however, such as patient or health provider numbers, shall not be redacted unless required by state or federal law.
 - ii. The Social Security numbers, tax identification numbers and other personal identifying information of employees in any records.

- b. Defendants reserve the right to redact information that is nonresponsive (including but not limited to proprietary financial material and products unrelated to this litigation). Such responsiveness redactions may only be applied to materials not discoverable pursuant to Federal Rule of Civil Procedure 26(b)(1).
- c. Pursuant to 21 C.F.R. §§ 314.430(e) & (f) and 20.63(f), the names of any person or persons reporting adverse experiences of patients and the names of any patients that are not redacted shall be treated as Confidential, regardless of whether the document containing such names is designated as Confidential Material.
- d. Notwithstanding any of the foregoing provisions, nothing contained herein shall be construed as a waiver of a party's ability to challenge such redactions pursuant to the procedures set forth in Section 11 herein. The burden as to the propriety of any redaction remains on the Designating Party at all times.

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 Producing Party shall—within thirty (30) business days of receipt of the notice of disclosure—move the Court for a Protective Order requiring return of the production of the Inadvertently Disclosed Information (“Motion”). The Receiving Party shall not assert as a ground for opposing such an Order the fact or circumstances of the inadvertent production. Pending resolution of the 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 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. Inadvertent or unintentional disclosure, 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.

- 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, or as promptly as reasonably possible thereafter, 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. As promptly as reasonably possible thereafter, the Disclosing Party shall re-produce the Confidential Material with the required legend.

DATED: October 31, 2016

DRINKER BIDDLE & REATH LLP

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Attorneys for Defendants Johnson & Johnson and
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DATED: October 31, 2016

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Email: cseeger@seegerweiss.com
Plaintiffs' Co-Lead Counsel

IT IS SO ORDERED

DATED: _____



HON. LOIS H. GOODMAN

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE: INVOKANA (CANAGLIFLOZIN)	:	MDL NO. 2750
PRODUCTS LIABILITY LITIGATION	:	3:16-md-2750 (BRM)(LHG)
	:	
	:	JUDGE BRIAN R. MARTINOTTI
	:	JUDGE LOIS H. GOODMAN
	:	

EXHIBIT A

ENDORSEMENT OF PROTECTIVE ORDER

I hereby attest to my understanding that information or documents designated as Confidential Discovery Material are provided to me subject to the Protective Order dated _____, 2017 (the “Order”), in the above-captioned litigation (“Litigation”); that I have been given a copy of and have read the Order; and, that I agree to be bound by its terms. I also understand that my execution of this Endorsement of Protective Order, indicating my agreement to be bound by the Order, is a prerequisite to my review of any information or documents designated as Confidential Discovery Material pursuant to the Order.

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

I further agree to return all copies of any Confidential Discovery Material or any document or thing containing Confidential Discovery Material I have received to counsel who provided them to me, or to destroy such materials, upon completion of the purpose for which they were provided and no later than the conclusion of this Litigation.

I further agree and attest to my understanding that my obligation to honor the confidentiality of such Confidential Discovery Material will continue even after this Litigation concludes.

I further agree and attest to my understanding that, if I fail to abide by the terms of the Order, I may be subject to sanctions, including contempt of court, for such failure. I agree to be subject to the jurisdiction of the District of New Jersey, 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: _____