UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: INVOKANA (CANAGLIFLOZIN) PRODUCTS LIABILITY LITIGATION	**3:16-md-02750-BRM-LHG**
	JUDGE BRIAN R. MARTINOTTI
	JUDGE LOIS H. GOODMAN

THIS DOCUMENT RELATES TO: ALL CASES

ADMINISTRATIVE ORDER NO. 1

In light of the tremendous efforts of the parties to achieve resolutions for the various injuries claimed in this complicated multidistrict litigation, as set forth on the record on 16 August 2018 and for good cause shown,

IT IS on this 16th day of August 2018,

ORDERED that the following groups of litigants respond and produce specified information regarding their claims as directed in this Order:

(1) plaintiffs with claims pending in MDL Docket No. 2750 ("Existing Plaintiff" or "Existing Plaintiffs") prior to August 16, 2018 who have not yet resolved their claims;

(2) plaintiffs who file new complaints ("New Plaintiff" or "New Plaintiffs") on or after August 16, 2018 alleging injury resulting from the use of Invokana, whether the case is filed directly in this Court pursuant to the Direct Filing Order ("CMO 4") or removed to or transferred to this MDL after the entry of this Order.

I. COMMENCEMENT OF NOTICE AND DISCOVERY OBLIGATIONS

All obligations of Existing Plaintiffs are stayed until October 30, 2018, absent agreement of the parties or subsequent Court Order.

As to New Plaintiffs, after the case is docketed in this Court (whether through direct filing, removal or JPML transfer), counsel for Defendants shall serve upon counsel for New Plaintiff by email (or if a New Plaintiff is proceeding *pro se*, the New Plaintiff by regular mail) a copy of this Order. All obligations of New Plaintiffs are effective immediately upon the transmittal of this Order by Defendants to counsel for New Plaintiff (or the New Plaintiff if proceeding *pro se*).

Persons who represent themselves *pro se* in this proceeding shall comply fully with all obligations required of counsel by this Order.

ALL OBLIGATIONS PURSUANT TO THIS ORDER SHALL BE THE RESPONSIBILITY OF INDIVIDUAL PLAINTIFF'S COUNSEL, OR PLAINTIFF IF SELF-REPRESENTED, AND NOT THE RESPONSIBILITY OF THE PLAINTIFFS' STEERING COMMITTEE.

II. PRESERVATION NOTICE REQUIREMENT

A. Within forty-five (45) days of the transmittal of this Order by Defendants to a New Plaintiff, or within thirty (30) days of the lifting of the stay as it applies to an Existing Plaintiff, counsel for an Existing Plaintiff or New Plaintiff shall notify the following individuals or entities, by registered mail, that they may have records relevant to the claim of the Existing Plaintiff or New Plaintiff in this MDL Proceeding ("Claim"), and that any records relating to the Existing Plaintiff or New Plaintiff must be preserved, pending collection by the Existing Plaintiff or New Plaintiff ("Notice" or "Notices"):

1. All Pharmacies that dispensed any medications to the Plaintiff for the period from January 1, 2012 to the present;

2. All Physicians, Medical Facilities, other Healthcare Providers and/or other persons ("Other Providers") who Plaintiff claims provided samples of Invokana to the Plaintiff;

3. All Physicians, Medical Facilities and/or other Healthcare Providers who prescribed Invokana for the Plaintiff; and

4. All Physicians and/or other Healthcare Providers who treated Plaintiff for the period from January 1, 2012 to the present.

B. Within fifty (50) days of the sending of this Order by Defendants to a New Plaintiff, or within thirty-five (35) days of the lifting of the stay as it applies to Existing Plaintiffs, counsel for an Existing Plaintiff or New Plaintiff shall serve a statement listing the names and addresses of all individuals or entities to which Notices were sent, along with copies of the Notices and a representation that the Notices were sent as required by this Order. Service shall be made in accordance with the service procedures set forth in Exhibit D to this Order.

C. Plaintiffs who fail to fully comply with the requirements of this Order shall be given notice by e-mail (or regular mail to only those individuals representing themselves pro se) from Defendants' Liaison Counsel or his designee, and shall be provided thirty (30) additional days from the date of notice to cure such deficiency ("Cure Period"). No other extensions will be granted, except upon application to the Court for good cause shown. If a Plaintiff fails to cure the deficiency within the Cure Period, Defendant's Liaison Counsel shall identify on the monthly case management conference agenda all Plaintiffs with deficiencies. Any Plaintiff so identified shall be required to Show Cause why the claim should not be dismissed with prejudice for failure to prosecute. The Plaintiff shall thereupon have until the next conference to cure the deficiencies or respond to the request to Show Cause. Any failure to respond within the required period of time shall lead to the dismissal for failure to prosecute of the claim with prejudice, except upon Motion and for good cause shown.

D. A Plaintiff may be prohibited from seeking to introduce into evidence at trial, or in any opposition to summary judgement or pre- or post-trial motions, any document or information asserting that Invokana was dispensed by a pharmacy or that Invokana was provided to the Plaintiff as a sample if a Notice was not sent as directed herein, subject to determination by the Court at a

later date. Similarly, a Plaintiff may be prohibited from seeking to introduce into evidence at trial, or in any opposition to summary judgement or pre- or post-trial motions, any document or information concerning a Plaintiff's treatment history, symptoms, condition, injuries or damages if a Notice was not sent as directed herein, subject to determination by the Court at a later date.

E. A Plaintiff who fails to act in good faith in complying with this Order may also be subject to other sanctions or orders deemed appropriate by this Court.

F. Defendants may elect to waive the foregoing Notice requirement for any Plaintiff who has already submitted records for Defendants' resolution consideration.

III. DISCOVERY REQUIREMENTS FOR PLAINTIFFS

A. All Plaintiffs who claim to have suffered or experienced Diabetic Ketoacidosis ("DKA"), an Acute Kidney Injury ("AKI"), a Lower Extremity Amputation ("LEA") or some other injury as a result of taking Invokana must produce all of the information described in this Section to Defendants, unless the Plaintiff has already done so, either pursuant to prior discovery obligations and/or for resolution considerations.

B. The following information must be produced to Defendants by Existing Plaintiffs and New Plaintiffs pursuant to this Section:

1. All pharmacy records regarding the dispensing of medicines to the Plaintiff or for the period from January 1, 2012 to the present. Existing Plaintiffs shall produce these records within forty-five (45) days of the lifting of the stay, as set forth in Section I, above, and New Plaintiffs shall produce these records within sixty (60) days of the transmission of this Order by Defendants.

2. If any death is claimed, a copy of the death certificate and autopsy report, if one was performed. Existing Plaintiffs shall produce any such certificate and/or report within forty-five (45) days of the lifting of the stay, as set forth in Section I, above, and New Plaintiffs shall produce any such certificate and/or report within sixty (60) days of the transmission of this Order by Defendants.

3. A completed New or Supplemental Plaintiff Fact Sheet ("PFS"), including all certifications and authorizations, in the form and manner set forth in Exhibit A to Case Management Order ("CMO") No. 18. Service of the PFS shall be made pursuant to the service protocol set forth in CMO 18.[1] Existing Plaintiffs shall produce a New or, if already produced, Supplemental PFS within forty-five (45) days of the lifting of the stay, as set forth in Section I, above. New Plaintiffs shall produce a New PFS within sixty (60) days of the transmission of this Order by Defendants.

4. All medical records relating to the Plaintiff from all healthcare providers identified in Section IV.A of Plaintiff's PFS for the period from January 1, 2012 to the present. Existing Plaintiffs shall produce these records within forty-five (45) days of the lifting of the stay, as set forth in Section I, above, and New Plaintiffs shall produce these records within sixty (60) days of the transmission of this Order by Defendants.

5. An affidavit signed by the Plaintiff (i) attesting that records have been collected from all pharmacies that dispensed drugs to, or for, the Plaintiff; (ii) attesting that all medical records described in subparagraph (1) and (4) above have been collected; and (iii) attesting that all records collected pursuant to subparagraphs (B)(1), (2) and (4) of this Section have been produced pursuant to this Order. If any of the documents described in paragraphs (B) (1), (2) and (4) of this Section do not exist, the Plaintiff shall state that fact in his or her affidavit and the reason, if known, why they do not exist and provide a "No Records Statement" from the pharmacy or healthcare provider. Existing Plaintiffs shall produce this affidavit to Defendants within forty-five (45) days of the lifting of the stay, as set forth in Section I, above, and New Plaintiffs shall produce this affidavit within sixty (60) days of the transmission of this Order by Defendants.

6. Completed, signed copies of the applicable DKA, AKI or LEA Injury Profile Form(s) attached as Exhibits A-C to this Order. To the extent a Plaintiff is claiming more than one injury, the Plaintiff shall complete each form that applies to his/her claims. To the extent Plaintiff is not claiming an injury of DKA, AKI or LEA, Plaintiff's counsel shall send a signed certification to that effect to Defendants' counsel using the service procedures set forth below. Existing Plaintiffs shall comply with this requirement within forty-five (45) days of the lifting of the stay, as set forth in Section I, above, and New Plaintiffs shall comply within sixty (60) days of the transmission of this Order by Defendants.

7. A Rule 26(a)(2) case -specific expert report from a medical expert attesting (i) to a reasonable degree of medical probability that the Plaintiff suffered an injury; and (ii) that Invokana caused the injury. The case specific expert

[1] Defendants shall have the right to serve up to fifteen (15) written interrogatories on all Plaintiffs claiming an injury of lower-extremity amputation.

report must include (i) an explanation of the basis of the attestation that Invokana caused injury to the Plaintiff, (ii) an identification of any other causes that were considered and/or excluded in formulating the opinion, (iii) a description of the specific injuries; (iv) a description of the specific medical findings that support the diagnosis of those injuries, with page references thereto; and (v) identification of all documents relied on by the expert in forming the expert's opinions. Existing Plaintiffs shall produce a copy of this case-specific expert report within seventy-five (75) days of the lifting of the stay, as set forth in Section I, above. New Plaintiffs shall produce a copy of this case-specific expert report within one hundred twenty (120) days of the transmission of this Order by Defendants.

8. For those Plaintiffs alleging an injury other than DKA, AKI or LEA, in addition to the report required by Paragraph 6, above, a case-specific Rule 26(a)(2) report from a regulatory and/or labeling expert (i) attesting that the applicable Invokana labeling in place at the time of Plaintiff or Claimant's use of Invokana was defective or deficient in some manner relating to that alleged injury; (ii) identifying the specific claimed deficiency or defect upon which Plaintiff or Claimant relies in asserting his or her claim against Defendants; (iii) identifying what specific language (i.e. warnings or indications) Plaintiff or Claimant claims should have been included in the labeling and all bases for that opinion(s); (iv) setting forth the basis for the expert's conclusion that any such change to labeling for Invokana would have altered the decision of the Plaintiff or Claimant's prescribing physician to prescribe Invokana to the Plaintiff or Claimant. The case specific labeling expert report must identify all documents relied on by the expert in forming his opinions. Existing Plaintiffs shall produce a copy of this case-specific regulatory and/or labeling expert report within seventy-five (75) days of the lifting of the stay, as set forth in Section I, above. New Plaintiffs shall produce a copy of this case specific regulatory and/or labeling expert report within one hundred twenty (120) days of the transmission of this Order by Defendants.

C. With the exception of the PFS, Plaintiffs shall serve all items set forth above in accordance with the service procedures outlined in Exhibit D to this Order.

D. For any deficiencies, the parties shall follow the Notice and Show Cause procedures set forth in Sections II.C and II.D. With respect to the PFS obligations set forth in Section III.B.3, the Notice and Show Cause procedures set forth in Sections II.C and II.D herein hereby supersede and replace the procedures for non-compliant PFS set forth in Section VI of CMO 18. Plaintiffs who fail to submit a PFS or who submit a deficient PFS and fail to cure any deficiencies identified

by Defendants within the Cure Period shall be subject to the Notice and Show Cause procedures set forth in Sections II.C and II.D.

E. Notwithstanding the foregoing deadlines, Defendants' obligation to produce Defense Fact Sheets is hereby stayed pending further order of the Court.

IV. PENALTIES FOR FRAUD AND DECEPTION

Any Plaintiff (and his or her attorneys) who submits false or intentionally misleading information, or otherwise attempts to satisfy the documentation requirements of this Order through any form of deception, dishonesty or fraud shall be subject to appropriate sanctions (including monetary sanctions and costs) and dismissal with prejudice pursuant to Fed. R. Civ. P. 37.

HON. BRIAN R. MARTINOTTI
UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: INVOKANA (CANAGLIFLOZIN) PRODUCTS LIABILITY LITIGATION	:	**MDL NO. 2750**
	:	**JUDGE BRIAN R. MARTINOTTI**
	:	**JUDGE LOIS H. GOODMAN**

Document Relates to [INSERT CASE NAME AND NUMBER]

INJURY PROFILE FORM: DIABETIC KETOACIDOSIS

Name:_____ DOB:_____

Plaintiff's Firm:_____ SSN:_____

Date of 1st Invokana[1] Use:_____ Bates/Page #[2]:_____

Date(s) of DKA event:_____ Bates/Page #:_____

Did Plaintiff's DKA event occur prior to December 4, 2015?

☐ Yes.
☐ No.

Please confirm that Plaintiff was taking Invokana as prescribed or as provided with samples at the time of his/her DKA event:

☐ Yes, Plaintiff was taking Invokana as prescribed or as provided through samples at the time of the DKA event.
☐ No.

Please identify the type of records Plaintiff has submitted contemporaneously herewith to support proof of Plaintiff's Invokana use and proof of Plaintiff's diabetic ketoacidosis event:

☐ Pharmacy | ☐ Hospital | ☐ Prescriber | ☐ Endocrinology | ☐ PCP

[Continued to Next Page]

1 "Invokana" is defined to include Invokana, Invokamet and Invokamet XR.

2 In lieu of providing a Bates reference, Plaintiff may provide either: (a) a reference to the relevant PDF and PDF page number; or (b) annotated versions of the records produced with highlighting, annotation or bookmarks calling out the relevant information.

Records Produced Supporting Invokana Use

☐ Pharmacy, insurance, prescriber records, or patient assistance program records showing patient was prescribed Invokana (Bates/Page #:_____);
☐ Pharmacy, insurance, hospital records, or patient assistance program records showing use of Invokana at to the time of the DKA event ***or*** proof that Plaintiff had and was taking Invokana samples at the time of the DKA event (Bates/Page #:_____);
Diabetes Type: ☐ Type 1 Diabetes ☐ Type 2 Diabetes (Bates/Page #:_____)
☐ Pharmacy records documenting an actual fill of an Invokana prescription in the 4-week period prior to Plaintiff's DKA event (or 12-week period, for a 90-day prescription), or proof that Plaintiff was taking Invokana samples at the time of the DKA event (Bates/Page #:_____)

Records Produced Supporting DKA Event

☐ Confirmed DKA diagnosis (Bates/Page #:_____)
☐ Identify the relevant serum pH values here:_____ (Bates/Page #:_____)
☐ Identify the relevant CO2/HCO3 values here:_____ (Bates/Page #:_____)
☐ Identify the relevant anion gap values here: _____ (Bates/Page #:_____)
☐ Identify the relevant serum ketones values (β-hydroxybutrate or acetone) here:_____ (Bates/Page #:_____)
☐ Identify the relevant urine ketones values here:_____ (Bates/Page #:_____)

Severity of Injury

Length of hospitalization: ☐ 1-2 days | ☐ 3-4 days | ☐ 5-6 days | ☐ 7+ days | ☐ 20+ days
☐ Encephalopathy (dates):_____ (Bates/Page #:_____)
☐ Respiratory failure w/ intubation (dates): _____ (Bates/Page #:_____)
☐ Dialysis (dates):_____ (Bates/Page #:_____)
☐ Acute kidney injury / renal failure (dates): _____ (Bates/Page #:_____)
☐ DKA-related death (death certificate must be produced).

Medical Condition at Time of DKA Event

☐ Underlying infection or illness:_____ (Bates/Page #:_____)
☐ Major trauma, surgery, or cardiovascular event in week prior to DKA event (type and dates): _____ (Bates/Page #:_____)
☐ Chronic alcohol abuse:_____(Bates/Page #:_____)
☐ Chronic drug abuse:_____(Bates/Page #:_____)
☐ Strenuous physical activity or exercise preceding DKA: _____ (Bates/Page #:_____)

ATTESTATION

The undersigned have reviewed and completed this Injury Profile Form in good faith.

Date: _____ _____
[INSERT PLAINTIFF NAME]

Date: _____ _____
[INSERT ATTORNEY NAME & FIRM INFORMATION]

Administrative Order No. 1
EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: INVOKANA (CANAGLIFLOZIN) PRODUCTS LIABILITY LITIGATION	:	**MDL NO. 2750**
	:	**JUDGE BRIAN R. MARTINOTTI**
	:	**JUDGE LOIS H. GOODMAN**

Document Relates to [INSERT NAME AND CASE NUMBER]

INJURY PROFILE FORM: ACUTE KIDNEY INJURY

Name:_____ DOB:_____

Plaintiff's Firm:_____ SSN:_____

Date of 1st Invokana[1] Use:_____ Bates/Page #[2]:_____

Date(s) of AKI[3] event:_____ Bates/Page #:_____

Did Plaintiff's AKI event occur prior to May 20, 2016?

☐ Yes.
☐ No.

Please confirm that Plaintiff was taking Invokana as prescribed or as provided with samples at the time of his/her AKI event:

☐ Yes, Plaintiff was taking Invokana as prescribed or as provided through samples at the time of the AKI event.
☐ No.

Please identify the type of records Plaintiff has submitted contemporaneously herewith to support proof of Plaintiff's Invokana use and proof of Plaintiff's AKI event:

☐ Pharmacy | ☐ Hospital | ☐ Prescriber | ☐ Endocrinology | ☐ Nephrology | ☐ PCP

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1 "Invokana" is defined to include Invokana, Invokamet and Invokamet XR.

2 In lieu of providing a Bates reference, Plaintiff may provide either: (a) a reference to the relevant PDF and PDF page number; or (b) annotated versions of the records produced with highlighting, annotation or bookmarks calling out the relevant information.

3 "AKI" is defined as acute kidney injury.

Records Produced Supporting Invokana Use and Injury

☐ Pharmacy insurance, prescriber records, or patient assistance program records showing patient was prescribed and/or provided with samples of Invokana(Bates/Page #:_____);
☐ Pharmacy, insurance, hospital records, or patient assistance program records show use of Invokana at the time of the AKI event ***or*** proof that Plaintiff had and was taking Invokana samples at the time the AKI event (Bates/Page #:_____);
Diabetes Type: ☐ Type 1 Diabetes ☐ Type 2 Diabetes (Bates/Page #:_____)
☐ AKI diagnosis (date) and/or laboratory results that support a diagnosis of AKI:_____ _____(Bates/Page #:_____);
☐ Pharmacy records documenting an actual fill of an Invokana prescription in the 4-week period prior to Plaintiff's AKI event (or 12-week period, for a 90-day prescription), or proof that Plaintiff was taking Invokana samples at the time of the AKI event (Bates/Page #:_____).

Medical Condition at Time of AKI Event

☐ Prior diagnosis of chronic kidney disease:_____(Bates/Page #:_____)
☐ Prior history of impaired kidney function or kidney damage: _____ (Bates/Page #:_____)

ATTESTATION

The undersigned have reviewed and completed this Injury Profile Form in good faith.

Date: _____ _____
[INSERT PLAINTIFF NAME]

Date: _____ _____
[INSERT ATTORNEY NAME & FIRM INFORMATION]

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: INVOKANA (CANAGLIFLOZIN) PRODUCTS LIABILITY LITIGATION	:	**MDL NO. 2750**
	:	**JUDGE BRIAN R. MARTINOTTI**
	:	**JUDGE LOIS H. GOODMAN**

Document Relates to [INSERT NAME AND CASE NUMBER]

INJURY PROFILE FORM: AMPUTATION

Name:_____ DOB & SSN:_____

Date of 1st Invokana[1] Use_____ Bates/Page #[2]:_____

Date(s) of Amputation(s):_____ Bates/Page #:_____

Did Plaintiff's amputation occur prior to July 25, 2017?

☐ Yes.
☐ No.

Please confirm that Plaintiff was taking Invokana as prescribed or as provided with samples at the time of his/her amputation:

☐ Yes, Plaintiff was taking Invokana as prescribed or as provided through samples at the time of his/her amputation.
☐ No.

Please identify the type of amputation:

☐ Toe(s)	☐ Entire Foot (or at ankle)
☐ Trans-metatarsal or mid-foot/partial foot	☐ Below-the-knee
	☐ Above-the-knee

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[1] "Invokana" is defined to include Invokana, Invokamet and Invokamet XR.

[2] In lieu of providing a Bates reference, Plaintiff may provide either: (a) a reference to the relevant PDF and PDF page number; or (b) annotated versions of the records produced with highlighting, annotation or bookmarks calling out the relevant information.

Please identify the type of records Plaintiff has submitted contemporaneously herewith to support proof of Plaintiff's Invokana use and proof of Plaintiff's amputation event:

☐ Pharmacy | ☐ Hospital | ☐ Prescriber
☐ Endocrinology | ☐ Podiatrist | ☐ PCP ☐ Orthopedic Surgeon

Records Produced Supporting Invokana Use and Injury

☐ Pharmacy, prescriber, insurance, or patient assistance records showing patient was prescribed Invokana and/*or* provided with samples of Invokana (Bates/Page #:_____);
☐ Pharmacy, prescriber, hospital, insurance, or patient assistance program records show use of Invokana at the time of the amputation or at the time the healthcare provider made the decision to amputate (Bates/Page #:_____);
☐ Plaintiff underwent an actual amputation procedure (Bates/Page #:_____);
Diabetes Type: ☐ Type 1 Diabetes ☐ Type 2 Diabetes
☐ Pharmacy records documenting an actual fill of an Invokana prescription in the 4-week period prior to Plaintiff's amputation (or 12-week period, for a 90-day prescription), or proof that Plaintiff was taking Invokana samples at the time of the amputation (Bates/Page #:_____).

Additional Information

Date Plaintiff was first diagnosed with diabetes: _____ (Bates/Page #:_____)

Age when Plaintiff first started taking Invokana: _____(Bates/Page #:_____)

Age when Plaintiff underwent amputation: _____(Bates/Page #:_____)

Last blood pressure reading prior to Plaintiff first taking Invokana (including date):
_____(Bates/Page #:_____)

Last blood pressure reading prior to amputation (including date):
_____(Bates/Page #:_____)

Last high-density lipoprotein (HDL) cholesterol level prior to Plaintiff first taking Invokana (including date): _____(Bates/Page #:_____)

Last high-density lipoprotein (HDL) cholesterol level prior to amputation (including date):
_____(Bates/Page #:_____)

Was Plaintiff a smoker when Plaintiff first started taking Invokana? _____(Bates/Page #:_____)

Was Plaintiff a smoker at time of amputation? _____ (Bates/Page #:_____)

Did Plaintiff suffer from microalbuminuria or macroalbuminuria prior to taking Invokana?
_____ (Bates/Page #:_____)

Did Plaintiff suffer from microalbuminuria or macroalbuminuria prior to amputation?
_____ (Bates/Page #:_____)

Records Produced Supporting Additional Information Regarding Plaintiff

☐ Patient required multiple amputations (Bates/Page #:_____)
☐ Patient required revision surgery (Bates/Page #:_____)
☐ Hx of amputations and/or foot ulcers/infections prior to Invokana use (Bates/Page #:_____)
☐ Hx of peripheral vascular or peripheral arterial disease prior to Invokana use and/or prior to amputation (Bates/Page #:_____)
☐ Hx of Charcot foot or other foot/toe deformity (i.e. hammertoe, Equinus, etc.) (Bates/Page #:_____)
☐ Hx of heart attack or stroke predating Invokana use and/or amputation (Bates/Page #:_____)
☐ Hx of coronary artery disease or coronary artery bypass grafting prior to Invokana use and/or amputation (Bates/Page #:_____)

ATTESTATION

The undersigned have reviewed and completed this Injury Profile Form in good faith.

Date: _____ _____
[INSERT PLAINTIFF NAME]

Date: _____ _____
[INSERT ATTORNEY NAME & FIRM INFORMATION]

ADMINISTRATIVE ORDER NO. 1: SERVICE & SUBMISSION INSTRUCTIONS

Note: The following submission instructions do not apply to service of new or supplemental Plaintiff Fact Sheets, as required by Section III.B.3 of this Order. As indicated in Section III.D, service of the Plaintiff Fact Sheet shall be made according to the procedures outlined in Case Management Order No. 18.

These submission instructions apply to all documents and records required to be submitted pursuant to Section III.D of Administrative Order No. 1, except the Plaintiff Fact Sheet required by Section III.B.3. Plaintiffs shall produce to Defendant any such records, documents or reports by uploading them to a secure file share site in the manner and format explained below.

I. File Share Access

Plaintiff's counsel (or Plaintiff, if proceeding *pro se*) shall send a request to Invokana@btlaw.com with the following information: The Plaintiff's name, the injury/injuries claimed by the Plaintiff, the name of Plaintiff's counsel, the names and email address of any/all team members who require access to the file transfer site. To the extent a firm represents multiple Plaintiffs subject to the Order, Plaintiffs' counsel may include the foregoing information for each Plaintiff in one email to Invokana@btlaw.com.

Following receipt of the request, counsel for Janssen will send Plaintiff's counsel an email invitation from Invokana@btlaw.com containing a link to the site and a temporary password. Once accessed, Plaintiff's counsel will see a folder with the name of his/her firm and a subfolder for Plaintiff's claimed injury type.[1] It is important that records for each Plaintiff be foldered correctly to avoid delay in review and/or unnecessary deficiency notices.

For each Plaintiff, Plaintiff's counsel shall name the top folder with the name of the claimant in the format: Last Name, First Name, Case Number (*i.e.* Doe, Jane, 16-md-2750) and shall place all records, documents and reports within that folder.

Note: In the event Plaintiff's counsel already has requested and received File Share Access from Defendants, no additional request is required.

II. Records Format

A. Pharmacy & Medical Records

All pharmacy and medical records shall be produced to Defendants as searchable PDFs with each facility or provider record produced as a separate PDF. No individual PDF produced shall exceed 100 MB (100,000 KB). In the event that PDFs larger than 100 MB are produced, Plaintiff's counsel will be advised of the issue and will be required to resubmit a new version of the file that is under 100 MB.

[1] Each firm will only have access to its own folder.

PDFs shall be named using the following format: sequential numbering, Plaintiff's Last Name, Plaintiff's First Name, and the name of the facility or provider that produced the records. For example, the second PDF produced by Plaintiff Jane Doe from Memorial Hospital shall be named "2 Doe, Jane_Memorial Hospital."

Each PDF also must be Bates-numbered in the following format: a combination of an alpha prefix containing plaintiff's initials and the initials of the facility or provider name along with a 4-digit number and be numerically sequential within a given PDF. For example, for claimant Jane Doe's records from Memorial Hospital use JD_MH_0001. Please be sure to begin Bates numbering on the first page of the PDF (even if that page is the authorization form or slip sheet).

B. Expert Reports & Affidavits

Any expert report produced to Defendants shall be named using the following format: the words "Report of" followed by the name of the expert, Plaintiff's Last Name, and Plaintiff's First Name. For example, a report from expert Frank Smith produced by Plaintiff Jane Doe should be named "Report of Frank Smith_Doe, Jane."

The affidavit required by Section III.B.5 of Administrative Order 1 shall be named "Affidavit of [Plaintiff Name]."

III. Questions & Concerns

Questions or concerns regarding these instructions and/or access to the FTP site should be directed to Invokana@btlaw.com.