

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

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

CASE MANAGEMENT ORDER NO. 18
(Plaintiff Fact Sheets and Defense Fact Sheets)

I. SCOPE OF ORDER

This Order shall apply to all product liability cases currently pending in MDL 2750 and to all related actions that have been or will in the future be originally filed in, transferred to, or removed to this Court and assigned thereto (“Member Actions”). This Order is binding on all parties and their counsel in all such Member Actions.

II. PLAINTIFF FACT SHEET

A. The form of Plaintiff Fact Sheet (“PFS”) that shall be used in MDL 2750 for all Member Actions is attached as **Exhibit A**. In accordance with the schedule set forth in Section III below, every Plaintiff in each Member Action shall:

1. Complete and execute a PFS;
2. Produce to Defendants all documents requested in the PFS that are in the Plaintiff’s possession and the required declaration demonstrating proof of use and proof of injury as set forth in Section V below;
3. Provide executed release authorizations included with the PFS;
4. Serve the completed and executed PFS, documents, and authorizations upon counsel for Defendants and serve a courtesy copy thereof upon

Plaintiffs' Executive Committee in the manner described in Section IV below.

B. Plaintiffs' responses to the PFS shall be treated as answers to interrogatories under Fed. R. Civ. P. 33 and responses to requests for production of documents under Fed. R. Civ. P. 34 and shall be supplemented in accordance with Fed. R. Civ. P. 26.

III. DEADLINE FOR SERVICE OF PFS

A. Current Cases. For all cases assigned to MDL 2750 as of May 3, 2017, Plaintiff shall complete and serve a PFS not later than July 7, 2017.

B. Future Cases. For all cases assigned to MDL 2750 after May 3, 2017, Plaintiff shall complete and serve a PFS no later than forty-five (45) days after Defendants file a Notice of Answer and Affirmative Defenses pursuant to Case Management Order No. 14 (Doc. 166).

IV. SERVICE OF PFS

Plaintiffs shall serve upon Defendants the completed and executed PFS and authorizations and produce documents uploading them to the secure file drop site, <https://cle-files.tuckerellis.com/filedrop/InvokanaPFS>, in a zip file as follows or in a similar fashion:

Top folder named for plaintiff in the format: Last Name_First Name;

PFS contained within the top level folder named: Last Name_First Name_PFS.pdf;

Subfolder named "Authorizations" with executed authorizations;

Subfolder named "Medical Records" with medical records;

Subfolder named "Pharmacy Records" with pharmacy records;

Subfolder named "Other Records" with other records.

If supplementation is needed, Plaintiffs are strongly encouraged to append text to each relevant file and folder name showing that it is a supplement and the supplement number—i.e. Last Name_First Name_PFS_Supplemental_1.pdf, Other Records_Supplemental_3.

Pursuant to Section VII below and Document Demands in Section XI of the PFS, medical and pharmacy records shall be produced as searchable PDFs with each facility or provider record contained in a separate PDF.¹ Upload to the secure file drop site in the aforementioned manner shall constitute effective service of the PFS upon Defendants. All other documents, if any, shall be produced in the format set forth in the Order Regarding Electronically Stored Information (Dkt. 6).

The production of a PFS and/or records in hard copy is strongly discouraged but may be permitted for *pro se* plaintiffs or upon a showing of good cause. If hard copy documents are provided, they should be provided to the following address: Attn: Joshua Wes; Tucker Ellis LLP, 515 South Flower Street, Suite 4200, Los Angeles, CA 90071

Concurrent with service to Defendants, Plaintiffs shall serve the completed PFS, documents, and authorizations upon the Plaintiffs' Executive Committee by sending an email to InvokanaPFS@weitzlux.com with the following information for each case you are sending: (law firm name, lawyer name, E-mail of individuals from law firm uploading the PFS and records, and Case Name and Docket number of case to be uploaded. Upon emailing this information the individual on the designated email will receive a secure email with a reusable upload link specific to that individual case. If the law firm has more than one case, they must send the email to get the link for each separate case or a list of the separate cases requiring a link.

The Plaintiffs' Executive Committee as well as any duly authorized agents or designees of the Plaintiffs' Executive Committee shall be permitted to review any and all PFSs and accompanying medical and other records.

¹ Endorsement of such records with Bates-numbers is strongly encouraged, in the following format: a combination of an alpha prefix containing plaintiff's initials and the facility or provider name along with an 8-digit number and be numerically sequential within a given PDF. (e.g. JD_Memoral_Hospital_00000001).

V. PROOF OF INGESTION AND INJURY

In connection with the obligations of providing a completed PFS, Plaintiff shall also produce a declaration that confirms ingestion of Invokana and/or Invokamet at the time of alleged injuries and specifies the injuries alleged. The form Declaration is attached to the PFS.

VI. PROCEDURES FOR NON-COMPLIANT PFS

This Section sets forth the procedures to be followed for Plaintiffs who fail to provide substantially complete PFS responses or fail to timely produce a PFS.

A. Failure to Provide Substantially Complete PFS Responses.

If any Plaintiff fails to produce a substantially completed and verified PFS providing, to the best of Plaintiff's ability, substantially complete responses to the requested information and attaching all of the responsive documents and things requested in the PFS including but not limited to all required records and duly executed authorizations, counsel for Defendants shall notify said Plaintiff's counsel in writing of the specific deficiencies. If Plaintiff's counsel fails within forty-five (45) days of this written notice to produce the required information and/or authorizations or provide an objection to doing so, Defendants' counsel shall notify Plaintiff's counsel in writing that Defendants intend to move to compel. The parties will then have fourteen (14) days to meet and confer to resolve the alleged failure to produce the required information and/or authorizations. If after expiration of the fourteen (14) day meet-and-confer period Plaintiff has not produced the required information and/or authorizations, or has not provided a reasonable justification for failure to do so, Defendants may then submit to the Court a motion to compel. Plaintiff will have twenty-one (21) days to file a response to the motion and the Defendants will have seven (7) days from the date of Plaintiff's response to file a reply. Either party may request oral argument on the motion, or the Court may direct it. In the absence of

such request or direction, the Court will rule on the basis of the submitted papers. If either party fails to timely file a response or a reply, the Court may consider the motion fully briefed.

B. Dismissal After Expiration of PFS Production Deadline.

If any Plaintiff wholly fails to produce a PFS by the deadline set forth in Section III, counsel for Defendants shall notify said Plaintiff's counsel in writing of the failure to produce the PFS within the deadline ("notice of overdue fact sheet letter" or "notice letter"). The notice letter will state that the failure to produce a PFS within forty-five (45) days of the date of the letter will result in Defendants seeking immediate dismissal. If within forty-five (45) days of the date of the notice letter, a Plaintiff fails to produce a PFS, counsel for Defendants may file with the Court a motion to dismiss without prejudice for failure to comply with this Order with a proposed order of dismissal. Defendants and/or the Court should consider any and all good cause excuses in granting extensions or non-dismissals. The proposed order of dismissal will initially be without prejudice, but will contain language converting it automatically after the expiration of sixty (60) days to a dismissal with prejudice. Plaintiffs shall have twenty-one (21) days from the date of filing of the motion to file a response. Defendants shall have seven (7) days from the date of the response to file a reply in support of the motion to dismiss. Either party may request oral argument on the motion, or the Court may direct it. In the absence of any such request of direction, the Court will rule on the basis of the submitted papers.

VII. MEDICAL RECORDS

A. Production of Records Obtained by Authorizations. Absent claim of privilege or relevance, Defendants' counsel (or MCS Group) shall make available medical records received pursuant to the authorizations provided in accordance with this Order to Plaintiffs' counsel at Plaintiffs' counsel's request. Absent claims of privilege or relevance, Plaintiffs'

counsel (or its designated vendor) shall make available records received pursuant to authorizations (or through other means) to Defendants' counsel at Defendants' counsel's request.

B. Documents Obtained Designated As Confidential. Any records obtained pursuant to an authorization provided by any Plaintiff pursuant to this Order shall be deemed confidential under the terms of the Stipulated Protective Order (Doc. 5) entered in this MDL.

VIII. DEFENDANT FACT SHEET

A. The form of Defendants' Fact Sheet ("DFS") that shall be used in MDL 2750 for all Member Actions is attached as **Exhibit B**. In accordance with the schedule set forth in Section IX below, Defendants in each Member Action shall:

1. Complete and execute a DFS;
2. Produce to Plaintiffs all records required under the DFS;
3. Serve the completed and executed DFS and documents upon counsel for Plaintiff(s) and serve a courtesy copy thereof upon Plaintiffs' Executive Committee in the manner described in Section X below.

B. Defendants' responses to the DFS shall be treated as answers to interrogatories under Fed. R. Civ. P. 33 and responses to requests for production of documents under Fed. R. Civ. P. 34 and shall be supplemented in accordance with Fed. R. Civ. P. 26.

IX. DEADLINE FOR SERVICE OF DFS

A. For all cases assigned to MDL 2750 as of May 3, 2017, Defendants shall complete and serve a DFS not later than ninety (90) days after receiving service of its corresponding PFS.

B. For all cases assigned to MDL 2750 after May 3, 2017, Defendants shall complete and serve a DFS not later than sixty (60) days after receiving service of its corresponding PFS.

X. SERVICE OF DFS

A. Defendants shall serve the completed and executed DFS and related documents upon Plaintiff(s) by emailing them to counsel of Plaintiff(s). Service by email shall constitute effective service of the DFS upon Plaintiffs. Concurrent with service to Plaintiff(s)' counsel, Defendants shall serve the completed DFS and documents upon the Plaintiffs' Executive Committee by emailing them to InvokanaDFS@weitzlux.com.

B. Failure to Provide Full and Complete DFS Responses.

If any Defendants fail to produce a fully completed and verified DFS providing, to the best of Defendant's ability, full and complete responses to all of the requested information and attaching all of the documents requested in the DFS, counsel for Plaintiffs shall notify said Defendants' counsel in writing of the specific deficiencies. If Defendants' counsel fails within forty-five (45) days of this written notice to produce the required information and/or documents, Plaintiff's counsel shall notify Defendants' counsel in writing that Plaintiff intends to move to compel. The parties will then have fourteen (14) days to meet and confer to resolve the alleged failure to produce the required information. If after expiration of the fourteen (14) day meet-and-confer period Defendants have not produced the required information and/or documents, or have not provided a reasonable justification for failure to do so, Plaintiff may then submit to the Court a motion to compel. Defendants will have twenty-one (21) days to file a response to the motion and Plaintiff will have seven (7) days from the date of Defendants' response to file a reply. Either party may request oral argument on the motion, or the Court may direct it. In the absence of such request or direction, the Court will rule on the basis of the submitted papers. If either party fails to timely file a response or a reply, the Court may consider the motion fully briefed.

So Ordered this 16TH day
of JUNE, 2017



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
:

PLAINTIFF FACT SHEET

Each plaintiff who alleges personal injury as a result of taking Invokana and/or Invokamet must complete a Plaintiff Fact Sheet (“PFS”).

If you are completing this PFS in a representative capacity on behalf of someone who has died or who otherwise cannot complete the PFS, please answer as completely as you can for that person. Those questions using the term “You” refer to the person whose treatment involved the use of Invokana and/or Invokamet. If the individual is deceased, please respond as of the time immediately before his or her death unless a different time period is specified.

In completing this PFS, please use the following definitions: (1) “you” refers to the person who used Invokana and/or Invokamet, unless otherwise specified; (2) “healthcare provider” means any hospital, clinic, medical center, physician’s office, urgent care center, infirmary, laboratory, or other facility that provides medical care or advice, and any pharmacy, physical therapist, rehabilitation specialist, physician, osteopath, homeopath, chiropractor, , or any other persons or entities involved in the, care and/or treatment of you; (3) “prescribing healthcare provider” means healthcare provider(s) from whom plaintiff received a prescription and/or sample for the relevant drug(s) before the alleged injury; (4) “treating healthcare provider” means healthcare provider(s) treating plaintiff’s alleged injury; and (5) “document” means any writing or record of any type in your possession or the possession of your attorney, including, but not limited to, written documents, electronic documents, e-mails, cassettes, videotapes, DVDs, photographs, medical records, charts, computer discs, tapes, or CDs, x-rays, drawings, graphs, non-identical copies, and other data from which information can be obtained and translated, if necessary, through electronic devices into a reasonably usable form. **You may attach as many sheets of paper as necessary to fully answer these questions.**

If you have any documents (as defined above), including, but not limited to, packaging, labeling, or instructions for Invokana and/or Invokamet, materials or items that you are requested to produce as part of answering this PFS or that relate to Invokana and/or Invokamet, or that relate to the injuries, claims, and/or damages that are the subject of your complaint, you must NOT dispose of, alter, or modify these documents or materials in any way. You are required to give all of these documents and materials to your attorney as soon as possible. If you are unclear about these obligations, please contact your attorney.

If you are aware that any document that was, or is likely to have been, responsive to this PFS was lost or destroyed, you must notify your attorney who must then notify Defendants' counsel of the nature of the information and the circumstances of the loss or destruction.

In completing the PFS, you are under oath and must provide information that is true and correct to the best of your knowledge. If you cannot recall all of the details requested, please provide as much information as you can. You must supplement your responses if you learn that they are incomplete or incorrect.

Information provided will only be used for purposes related to this litigation and may be disclosed only as permitted by the Protective Order in this litigation. This Fact Sheet is completed pursuant to the Federal Rules of Civil Procedure governing discovery

I. Case Information

Caption:	
Court and Docket No.	
Plaintiff's Attorney:	
Firm Name	
Address	
Telephone Number	
E-Mail Address	

B. If you are completing this PFS in a representative capacity (on behalf of the estate of a deceased person or a minor), please complete the following:

Your Name:	
Your Address:	
The individual/estate you are representing:	
Capacity in which you are representing the individual/estate:	
If you were appointed as a representative by a court, state the State, Court and Case Number:	
Relationship to the Individual/Estate:	
State the date and place of death of the decedent (if applicable):	

THE REMAINDER OF THIS PFS REQUESTS INFORMATION ABOUT THE PERSON WHO USED INVOKANA AND/OR INVOKAMET. IF YOU ARE COMPLETING THIS PFS FOR SOMEONE ELSE, PLEASE ASSUME THAT "YOU" MEANS THE INVOKANA AND/OR INVOKAMET USER.

II. Personal Information for the Invokana and/or Invokamet User

A. Name: _____

B. Have you ever used any other names and, if so, when? _____

C. Address: _____

D. Previous addresses in the past five (5) years, if any:

Street Address	City, State, Zip	Date Resided (approx.)	
		From	To

E. Social Security Number: _____

F. Date and place of birth: _____

G. Gender: Male: Female:

H. Marital Status: _____

I. Spouse's name and date of marriage (if applicable): _____

If applicable, has your spouse filed a loss of consortium or other claim in connection with this lawsuit? Yes: No: N/A:

J. Children (if applicable):

Name	Age	Current Address

K. Have you ever served in any branch of the military? Yes: No:

1. If Yes, branch and dates of service: _____

2. Were you ever rejected or discharged from military service for any reason related to your medical, physical, psychiatric or emotional condition?
Yes: No:

3. If Yes, state the reason and date of the occurrence: _____

L. Education:

Provide the following information regarding your education, beginning with high school and continuing through your highest level of education:

Name of School	City/State	Degree awarded and/or area of study/major	Dates of Attendance (approx.)

M. Are you currently employed? Yes: No:

If Yes, please provide the following information regarding your current employer:

Name: _____

Address: _____

Your occupation: _____

If No, did you leave your last job for a medical reason? Yes: No:

If Yes, describe why you left: _____

Are you making a claim for lost wages or lost earning capacity? Yes: No:

If Yes, please complete the following information regarding any employers (other than your current employer) that you have had in the last ten (10) years:

Name of Employer	Address	Job Title/Duties	Dates Employed

** Please attach additional pages as needed.*

N. During the previous ten (10) years, have you been out of work for more than

thirty (30) days during any calendar year for reasons related to your health (medical, physical, or psychiatric)? Yes: No:

If Yes, please state the dates, employer, and health condition: _____

- O. Identify each insurance carrier with whom you have had health insurance coverage at any time during the past ten (10) years:

Insurance Company	Policy Number	Policy Holder	Approximate Dates of Coverage

- P. Within the past ten (10) years, have you ever received Medicare, Medicaid, DOD Tricare, State Children's Health Insurance Program (SCHIP), Veterans Health Administration (VHA), or Indian Healthcare Services (HIS)? Yes: No:

If Yes, please identify the benefits received: _____

If Yes, are you receiving those benefits now? Yes: No:

- Q. Have you applied for workers' compensation, social security, and/or state or federal disability benefits within the past ten (10) years? Yes: No:

If Yes, then as to each application, separately state:

1. Date (or year) of application: _____
2. Nature of the claimed injury/disability: _____
3. The agencies to which you submitted your application: _____

- R. During the previous ten (10) years, have you ever been convicted of, or pled guilty to, a felony? Yes: No:

If Yes, please describe each charge to which you pled guilty or were convicted of,

the court, and the outcome: _____

S. In the last five (5) years, have you ever filed for bankruptcy? Yes: No:

If Yes, please identify the Court in which the bankruptcy proceeding was filed, the case number, and the disposition: _____

T. In the last ten (10) years, have you filed a lawsuit or made a claim, other than in the present suit, relating to any bodily injury? Yes: No:

If Yes, please state the following for each such lawsuit or claim:

1. Party you sued or made a claim against: _____

2. Court in which suit was filed: _____

3. Attorney who represented you: _____

4. Nature of injury/claim: _____

III. Use of Invokana and/or Invokamet

Date(s) of Use	Medication Prescribed	Dose (e.g. 100mg)	Full Name of Prescribing Healthcare Provider(s)	Address of Prescribing Healthcare Provider(s)	Name & Address of Dispensing Pharmac(ies) (if applicable)

** Please attach additional pages as needed.*

A. Do you currently use Invokana and/or Invokamet? Yes: No:

If No, state when you stopped: _____

Has any healthcare provider recommended that you discontinue your use of Invokana and/or Invokamet?

Yes: No: Do Not Recall:

If Yes, provide the following information for the healthcare provider who made the recommendation:

Name: _____

Address: _____

Date Recommendation Made: _____

** If any such advice or recommendation was given in writing, please attach a copy.*

B. Did you ever receive any samples of Invokana and/or Invokamet?

Yes: No:

If Yes, please state the following:

1. Name of prescribing healthcare provider from whom you received any samples: _____

2. When samples were provided: _____

3. Did you initiate the conversation with your healthcare provider about prescribing Invokana and/or Invokamet to you?

Yes: No: Do Not Recall:

If Yes, state the full name of the healthcare provider(s):

C. Have you had any direct communication, written or oral, with Janssen Pharmaceuticals, Inc., Janssen Ortho, LLC, Janssen Research & Development, LLC, or Johnson & Johnson or any of their representatives? Yes: No:

If Yes, please describe the communication and the approximate date(s) on which it occurred: _____

D. Did you ever receive any written information or instructions about Invokana and/or Invokamet, including any package inserts, literature, medication guides, or dosing instructions,? Yes: No:

If Yes, please describe the documents if you no longer have them. If you have the documents, please produce them: _____

- E. Did you ever receive any oral instructions about Invokana and/or Invokamet?
 Yes: No: Do Not Recall:

If Yes, please identify each Healthcare Provider who provided the oral instructions: _____

- F. From 2013 to the present, have you ever visited a website, chatroom, message board, or other electronic forum containing information or discussion about Invokana and/or Invokamet?
 Yes: No: Do Not Recall:

If Yes, please provide the name/address of the website(s): _____

If Yes, please identify the approximate date(s) on which you visited the website(s): _____

- G. Have you ever seen any advertisements (e.g., in magazines or television commercials) for Invokana and/or Invokamet? Yes No Do Not Recall

If Yes, identify the advertisement or commercial, and approximately when you saw the advertisement or commercial: _____

IV. Healthcare Providers and Pharmacies

- A. Identify the following for each healthcare provider with whom you have consulted during the ten (10) years before your first ingestion of Invokana and/or Invokamet up to the present,

Name & Specialty	Address	Approximate Dates of Treatment	Reason for Treatment, if known or recalled

** Please attach additional pages if necessary.*

- B. Identify each hospital, clinic, surgery center, physical therapy or rehabilitation center, or other healthcare facility where you have received inpatient or outpatient treatment (including emergency room treatment) in the ten (10) years before your first ingestion of Invokana and/or Invokamet up to the present:

Name & Specialty	Address	Approximate Dates of Treatment	Reason for Treatment, if known or recalled

** Please attach additional pages if necessary.*

- C. Identify the following for each pharmacy, drug store and/or other supplier (including mail order and internet pharmacies) where you have filled prescriptions during the ten (10) years before your first ingestion of Invokana and/or Invokamet up to the present:

Name of Pharmacy	Address of Pharmacy	Approximate Dates

** Please attach additional pages if necessary.*

V. Injuries and Damages Alleged in this Lawsuit

- A. Are you claiming any one of the following injuries related to your use of Invokana/Invokamet?

DKA	
Kidney	
Heart Attack	
Stroke	
Death	
Other*	

*If you checked "Other", identify all injuries that you allege to have suffered as a result of taking Invokana and/or Invokamet that are not listed in the above chart.

If you checked any of the boxes above, describe in detail the injuries, illnesses or disabilities you claim are related to your treatment with Invokana/Invokamet:

Please identify all healthcare provider(s) who treated each alleged injury, including their name and address and the approximate date(s) of treatment:

Name & Specialty	Address	Approximate Dates of Treatment	Reason for Treatment

B. Has any healthcare provider told you that any of your alleged injuries are the result of your use of Invokana and/or Invokamet?

Yes: No: Do Not Recall

If Yes, provide the healthcare provider's name and address and the approximate date of this conversation: _____

C. Did you ever experience the type of injury(ies) you allege were caused by Invokana and/or Invokamet **before** the date(s) set forth above?

Yes: No:

If Yes, please identify which injury(ies), when you experienced them, and the healthcare provider(s) who treated you for that injury: _____

D. Do you claim that your use of Invokana and/or Invokamet caused or aggravated any psychiatric and/or psychological condition(s) (other than pain and suffering or emotional distress) for which treatment was sought and for which damages are being sought in this lawsuit? Yes: No:

If Yes, please describe: _____

If Yes, please identify any healthcare provider(s) with whom you have treated for this condition, including their name and address and the approximate date(s) of treatment: _____

VI. Medical Background of the Invokana and/or Invokamet User

A. Current Height: _____ Current Weight: _____

B. Smoking History: For the ten (10) year period before your use of Invokana and/or Invokamet up to the present, check the answer and fill in the blanks applicable to

your history of smoking.

I have never used tobacco

I used tobacco in the ten-year period before my use of Invokana and/or Invokamet

I currently use tobacco: Yes No

Types of Tobacco Used: Cigarettes Cigars Pipes

Approximate Amount Used: On average _____ per day for _____ years

C. Alcohol History:

1. Do you currently drink alcohol (beer, wine, liquor, etc.)? Yes: No:

If Yes, approximately how many drinks per week/month/year? _____

2. During the previous ten (10) years, have you consumed alcohol?

Yes: No:

If Yes, during what period of time did you consume alcohol? _____

If Yes, approximately how many drinks per week/month/year? _____

D. Use of Illicit Drugs:

1. During the previous ten (10) years, have you used any illicit drugs (such as cocaine, heroin, or LSD)?

Yes: No: Do Not Recall:

If Yes, which drug(s)? _____

If Yes, approximately dates of use? _____

E. Medical History: Have you ever been diagnosed with any of the following conditions?

Condition	Yes	No	Do Not Recall	If Yes, Approximate Date of Diagnosis
Type 2 diabetes				
Type 1 diabetes				
Latent autoimmune diabetes in adults (LADA or Type 1.5 diabetes)				

Condition	Yes	No	Do Not Recall	If Yes, Approximate Date of Diagnosis
Gestational diabetes				
Diabetic coma				
Diabetic ketoacidosis (DKA)				
High cholesterol				
High blood pressure/hypertension				
Low blood pressure/hypotension				
Bladder infection				
Urinary tract infection or blockage				
Gall stones				
Kidney injury/failure/disease				
Kidney stones				
Myocardial infarction/heart attack				
Coronary artery disease				
Cerebrovascular disease, including stroke				
Atrial fibrillation				
Pancreatitis				
Congestive heart failure				
Urosepsis				
Pyelonephritis				
Bone fracture/loss of bone density				
Diabetic neuropathy				
Sepsis				

VII. List the Medications You Currently Use

Medication	Reason for Taking	Dose (if known) and Approximate Date You Started Use

If you have ever taken insulin, please identify the type(s) of insulin used, dose and time period of use: _____

Identify whether you have used any of the following:

Medication	Yes	No	Do Not Recall	If Yes, Dose and Approximate Dates of Use
Metformin (Glucophage, Glumetza, Riomet or Fortamet)				
Byetta (exenatide)				
Victoza (liraglutide)				
Tanzeum (albiglutide)				
Trulicity (dulaglutide)				
Farxiga/Xigduo (dapagliflozin)				
Jardiance/Glyxambi/Synjardy (empagliflozin)				
Januvia (sitagliptin)				
Onglyza (saxagliptin)				
Tradjenta (linagliptin)				
Nesina/Oseni (alogliptin)				
Actos (pioglitazone)				
Avandia (rosiglitazone)				
Rezulin (troglitazone)				
Glyset (miglitol)				
Precose (acarbose)				
DiaBeta (glyburide)				
Glucotrol (glipizide)				
Amaryl (glimepiride)				
Other medications used to treat diabetes (specify _____)				

VIII. Family Medical History

To the best of your knowledge, please indicate whether your *parents, siblings, children or grandparents* have ever suffered from or been treated for any of the following:

Condition	Yes	No	Unknown	If Yes, Identify the Family Relationship(s)
Type 2 diabetes				
Type 1 diabetes				
Kidney injury/failure/disease				
Cerebrovascular disease, including stroke				
Myocardial infarction/heart attack				

IX. Fact Witnesses

Other than your healthcare providers, please identify all persons whom you believe possess information concerning your alleged injury and/or other facts related to your claims.

Name	Address	Relationship to You

X. **Declaration**

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that all of the information provided in this PFS is true and correct to the best of my knowledge, information and belief formed after due diligence and reasonable inquiry.

Date: _____ Signature: _____

XI. Documents: These Document Demands Are Made Pursuant to FED. R. CIV. P. 34

- A. Please sign and attach to this PFS authorizations allowing for release of all relevant records. (Please be sure that either you or your attorney complete the top portion of each authorization form for each provider for whom an authorization is being provided. For medical, health insurance, Medicare, and Social Security Administration record authorizations, be sure that either you or your attorney also insert the date that is ten (10) years before your first ingestion of Invokana and/or Invokamet.)
- B. If completing this PFS on behalf of a deceased person, please attach the legal documentation establishing that you are the legal representative of the estate and the Decedent's death certificate and autopsy report (if applicable).
- C. Please indicate whether you have any of the following materials in your possession by placing a checkmark next to the word "yes" or "no." **If Yes, produce a copy of all the documents in the manner set forth in Section IV of the Implementing Order on Plaintiff and Defendant Fact Sheets.**
1. Medical records from any physician, hospital or healthcare provider from ten (10) years before your first ingestion of Invokana and/or Invokamet up to the present that are currently in your possession. Yes: No:
 2. Pharmacy records from ten (10) years before your first ingestion of Invokana and/or Invokamet up to the present, including receipts, prescriptions or records of purchase that are currently in your possession. Yes: No:
 3. Advertisements for Invokana and/or Invokamet or articles discussing Invokana and/or Invokamet which you reviewed before and/or during the time you took Invokana and/or Invokamet. Yes: No:
 4. The packaging, including the box and label, for Invokana and/or Invokamet and any remaining medication (plaintiffs or their counsel must retain the originals of the items requested). Yes: No:
 5. A copy of all product use instructions, product warnings, package inserts, pharmacy handouts or other materials distributed with or provided to you in connection with your use of Invokana and/or Invokamet. Yes: No:
 6. A copy of all other documents or materials that mention Invokana, or any alleged health risks or hazards related to Invokana and/or Invokamet in your possession at or before the time of the injury alleged in your complaint, other than legal documents, documents provided by your attorney, or documents obtained or created for the purpose of seeking legal advice or assistance. Yes: No:

7. Statements obtained from or given by any person, other than your attorney(s) or retained expert(s), having knowledge of facts relevant to the subject of this litigation. Yes: No:
8. Other than pleadings filed in connection with this litigation, documents constituting any communications or correspondence between you and any of the defendants or representative of the defendants. Yes: No:
9. If you claim you have suffered a loss of earnings or earnings capacity, your W-2s and all tax records reflecting your income for the last five (5) years preceding the injury you allege to be caused by Invokana and/or Invokamet, and every year thereafter. Yes: No:
10. If you claim you have suffered a loss of earnings or earnings capacity, all employment records in your possession, including employment applications, performance evaluations, paychecks and pay stubs for the five (5) years before the injury that you associate with Invokana and/or Invokamet to the present. Yes: No:
11. If you claim any loss due to medical expenses, copies of all bills from any physician, hospital, pharmacy or other healthcare provider documenting those medical expenses. Yes: No:
12. If you have been the claimant or subject of any worker's compensation, Social Security or other disability proceeding within the last ten (10) years, all documents relating to such proceeding that are in your possession. Yes: No:
13. Journals, diaries, notes, letters, e-mails, tweets, Facebook posts, internet postings, and all other documents written or received by you from 2013 to the present which refer to your general health, including any injuries or illness, or which refer to Invokana and/or Invokamet. Yes: No:
14. Print-outs of all websites or blogs maintained or created by you from 2013 to the present which refer to your general health, including any injuries or illness, or which refer to Invokana and/or Invokamet. Yes: No:

Declarations re Proof of Use/Injury

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

IN RE: INVOKANA (CANAGLIFLOZIN)
PRODUCTS LIABILITY LITIGATION

:
:
: MDL NO. 2750
: Master Docket No. 3:16-md-2750
:
:
: JUDGE BRIAN R. MARTINOTTI
: JUDGE LOIS H. GOODMAN
:
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:
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:

PLAINTIFF FACT SHEET – USE/INJURY DECLARATION (Product User)

1. I am over the age of 18.
2. I, _____, am a plaintiff who has brought a claim alleging injury as a result of the use of the drug Invokana and/or Invokamet.
3. I used the drug Invokana and/or Invokamet at or about the time of the alleged injury(ies) set forth below.
4. I believe I suffered the following injury(ies) while using Invokana and/or Invokamet:
_____.
5. Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the information above is true and correct to the best of my knowledge, information and belief.

Date: _____ Signature: _____

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

IN RE: INVOKANA (CANAGLIFLOZIN)
PRODUCTS LIABILITY LITIGATION

:
:
: MDL NO. 2750
: Master Docket No. 3:16-md-2750
:
:
: JUDGE BRIAN R. MARTINOTTI
: JUDGE LOIS H. GOODMAN
:
:
:
:
:

PLAINTIFF FACT SHEET – USE/INJURY DECLARATION (Representative)

1. I, _____, am a representative who has brought a claim alleging that _____ was injured as a result of the use of the drug Invokana and/or Invokamet.
2. _____, used the drug Invokana and/or Invokamet at or about the time of the alleged injury(ies) set forth below.
3. I believe _____ suffered the following injury(ies) while using Invokana and/or Invokamet: _____.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the information above is true and correct to the best of my knowledge, information and belief.

Date: _____ Signature: _____

AUTHORIZATIONS

LIMITED AUTHORIZATION TO DISCLOSE HEALTH INFORMATION
Pursuant to the Health Insurance Portability and Accountability Act "HIPAA" of 4/14/03 (Excluding Psychiatric, Psychological, and Mental Health Treatment Notes/Records)

To: _____
Name

Address

City, State and Zip Code

Re: _____
Name of Patient Date of Birth Social Security Number

This will authorize you to furnish copies of the following records and/or information **from the time period of ten (10) years before Patient's first ingestion of Invokana and/or Invokamet to the present, which is from _____ to the present:**

- * All medical records, including inpatient, outpatient, and emergency room treatment, all clinical charts, reports, documents, correspondence, test results, statements, questionnaires/histories, office and doctor's handwritten notes, and records received by other physicians. Said medical records shall include all information regarding AIDS and HIV status.
- * All autopsy, laboratory, histology, cytology, pathology, radiology, CT Scan, MRI, echocardiogram and catheterization reports.
- * All radiology films, mammograms, myelograms, CT scans, photographs, bone scans, pathology/cytology/histology/autopsy/immunohistochemistry specimens, cardiac catheterization videos/CDs/films/reels, and echocardiogram videos.
- * All pharmacy/prescription records including NDC numbers and drug information handouts/monographs.
- * All billing records including all statements, itemized bills, and insurance records.
- * To include all archived records, records in storage, and all items as may be stored in a computer database or in electronic form.
- **Notwithstanding the broad scope of the above disclosure requests, the undersigned does not authorize the disclosure of notes or records pertaining to psychiatric, psychological, or mental health treatment or diagnosis as such terms are defined by HIPAA, 45 CFR §164.501.**

1. To my medical provider: **This authorization is being forwarded by, or on behalf of, attorneys for the defendants for the purpose of litigation. You are not authorized to discuss any aspect of the above-named person's medical history, care, treatment, diagnosis, prognosis, information revealed by or in the medical records, or any other matter bearing on his or her medical or physical condition. Subject to all applicable legal objections, this restriction does not apply to discussing these matters at a deposition or trial.**
2. I understand that the information in my health record may include information relating to sexually transmitted disease, acquired immunodeficiency syndrome (AIDS), or human immunodeficiency virus (HIV).
3. I understand that I have the right to revoke this authorization at any time. I understand that if I revoke this authorization I must do so in writing and present my written revocation to the health information management department. I understand the revocation will not apply to information that has already been released in response to this authorization. I understand the revocation will not apply to my insurance company when the law provides my insurer with the right to contest a claim under my policy. Unless otherwise revoked, this authorization will expire in one year.
4. I understand that authorizing the disclosure of this health information is voluntary. I can refuse to sign this authorization. I need not sign this form in order to assure treatment. I understand I may inspect or copy the information to be used or disclosed as provided in CFR §164.524. I understand that any disclosure of information carries with it the potential for an unauthorized re-disclosure and the information may not be protected by federal confidentiality rules. If I have questions about disclosure of my health information, I can contact the releaser indicated above.
5. A notarized signature is not required. A copy of this authorization may be used in place of an original.
6. This authorization shall be considered as continuing in nature and is to be given full force and effect to release information of any of the foregoing learned or determined after the date hereof.

You are authorized to release the above records to the following representatives of defendants, who have agreed to pay reasonable charges made by you to supply copies of such records: **The MCS Group, Inc., 1601 Market Street, Suite 800, Philadelphia, PA 19103; c/o Tucker Ellis LLP, 515 South Flower Street, Forty-Second Floor, Los Angeles, California 90071 and 950 Main Avenue, Suite 1100, Cleveland, Ohio 44113.**

Date: _____

Patient/Representative Signature *[Print name if not Patient]*

Date: _____

Witness Signature

**LIMITED AUTHORIZATION TO DISCLOSE PSYCHIATRIC,
PSYCHOLOGICAL AND/OR MENTAL HEALTH TREATMENT NOTES/RECORDS**
(Pursuant to the Health Insurance Portability and Accountability Act "HIPAA" of 4/14/03)

To:

Name

Address

City, State and Zip Code

Re:

Name of Patient

Date of Birth

Social Security Number

This will authorize you to furnish copies of the following records and/or information **from the time period of ten (10) years before Patient's first ingestion of Invokana and/or Invokamet to the present, which is from _____ to the present:**

- All "psychotherapy notes", as such term is defined by the Health Insurance Portability and Accountability Act, 45 CFR §164.501. Under HIPAA, the term "psychotherapy notes" means notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversations during a private counseling session or a group, joint or family counseling session and that are separated from the rest of the individual's record. This authorization does not authorize ex parte communication concerning same. To include all archived records, records in storage, and all items as may be stored in a computer database or in electronic form.
- 1. To my medical provider: **This authorization is being forwarded by, or on behalf of, attorneys for the defendants for the purpose of litigation. You are not authorized to discuss any aspect of the above-named person's medical history, care, treatment, diagnosis, prognosis, information revealed by or in the medical records, or any other matter bearing on his or her medical or physical condition. Subject to all applicable legal objections, this restriction does not apply to discussing these matters at a deposition or trial.**
- 2. I understand that the information in my health record may include information relating to sexually transmitted disease, acquired immunodeficiency syndrome (AIDS), or human immunodeficiency virus (HIV).
- 3. I understand that I have the right to revoke this authorization at any time. I understand that if I revoke this authorization I must do so in writing and present my written revocation to the health information management department. I understand the revocation will not apply to information that has already been released in response to this authorization. I understand the revocation will not apply to my insurance company when the law provides my insurer with the right to contest a claim under my policy. Unless otherwise revoked, this authorization will expire in one year.
- 4. I understand that authorizing the disclosure of this health information is voluntary. I can refuse to sign this authorization. I need not sign this form in order to assure treatment. I understand I may inspect or copy the information to be used or disclosed as provided in CFR §164.524. I understand that any disclosure of information carries with it the potential for an unauthorized re-disclosure and the information may not be protected by federal confidentiality rules. If I have questions about disclosure of my health information, I can contact the releaser indicated above.
- 5. A notarized signature is not required. A copy of this authorization may be used in place of an original.
- 6. This authorization shall be considered as continuing in nature and is to be given full force and effect to release information of any of the foregoing learned or determined after the date hereof.

You are authorized to release the above records to the following representatives of defendants, who have agreed to pay reasonable charges made by you to supply copies of such records: **The MCS Group, Inc., 1601 Market Street, Suite 800, Philadelphia, PA 19103; c/o Tucker Ellis LLP, 515 South Flower Street, Forty-Second Floor, Los Angeles, California 90071 and 950 Main Avenue, Suite 1100, Cleveland, Ohio 44113.**

Date: _____

Patient/Representative Signature *[Print name if not Patient]*

Date: _____

Witness Signature

**LIMITED AUTHORIZATION TO DISCLOSE EMPLOYMENT RECORDS
AND INFORMATION (HIPAA COMPLIANT AUTHORIZATION FORM
PURSUANT TO 45 CFR 164.508)**

To:

Name of Employer

Address

City, State and Zip Code

I authorize the limited disclosure of my employment records for the purpose of review and evaluation in connection with a legal claim, including medical information protected by HIPAA, 45 CFR §164.508; copies of all applications for employment; resumes; records of all positions held; job descriptions of positions held; wage and income statements and/or compensation records; wage increases and decreases; evaluations, reviews and job performance summaries; records of disciplinary actions; W-2s; time sheets and records of time off the job and reasons therefor including sick leave and vacation; employee health files, and correspondence and memoranda regarding the undersigned. To include all archived records, records in storage, and all items as may be stored in a computer database or in electronic form. **This authorization only authorizes release of employment records and/or information from the time period of ten (10) years before the date on which this authorization is signed.**

Name of Employee

Date of Birth

Social Security Number

You are authorized to release the above records to the following representatives of defendants, who have agreed to pay reasonable charges made by you to supply copies of such records. **The MCS Group, Inc., 1601 Market Street, Suite 800, Philadelphia, PA 19103; c/o Tucker Ellis LLP, 515 South Flower Street, Forty-Second Floor, Los Angeles, California 90071 and 950 Main Avenue, Suite 1100, Cleveland, Ohio 44113.**

This authorization does not authorize you to disclose anything other than documents and records to anyone. This authorization shall be considered as continuing in nature and is to be given full force and effect to release information of any of the foregoing learned or determined after the date hereof. It is expressly understood by the undersigned and you are authorized to accept a copy or photocopy of this authorization with the same validity as through the original had been presented to you.

I acknowledge the right to revoke this authorization by writing to you at the above referenced address. However, I understand that any actions already taken in reliance on this authorization cannot be reversed, and my revocation will not affect those actions. Any facsimile, copy or photocopy of the authorization shall authorize you to release the records herein.

Date: _____

Employee/Guardian/Personal Representative
Signature *[Print name if not Employee]*

Date: _____

Witness Signature

LARGER FONT VERSIONS OF THIS AUTHORIZATION AVAILABLE ON REQUEST

LIMITED AUTHORIZATION FOR RELEASE OF HEALTH INSURANCE RECORDS

To:

Name

Address

City, State and Zip Code

This will authorize you to furnish copies of any and all insurance claims applications and benefits, and all medical, health, hospital, physicians, nursing or allied health professional reports, records or notes, invoices and bills, in your possession that pertain to the named insured identified below. To include all archived records, records in storage, and all items as may be stored in a computer database or in electronic form.

This authorization only authorizes release of Health Insurance records and/or information from the time period of ten (10) years before Patient's first ingestion of Invokana and/or Invokamet to the present, which is from _____ to the present.

Name of Insured

Date of Birth

Social Security Number

You are authorized to release the above records to the following representatives of defendants, who have agreed to pay reasonable charges made by you to supply copies of such records. **The MCS Group, Inc., 1601 Market Street, Suite 800, Philadelphia, PA 19103; c/o Tucker Ellis LLP, 515 South Flower Street, Forty-Second Floor, Los Angeles, California 90071 and 950 Main Avenue, Suite 1100, Cleveland, Ohio 44113.**

This authorization only authorizes release of documents and records from the period of fifteen (15) years prior to the date on which this authorization is signed. This authorization does not authorize you to disclose anything other than documents and records to anyone.

This authorization shall be considered as continuing in nature and is to be given full force and effect to release information of any of the foregoing learned or determined after the date hereof. It is expressly understood by the undersigned and you are authorized to accept a copy or photocopy of this authorization with the same validity as through the original had been presented to you.

Date: _____

Insured/Guardian/Personal Representative
Signature *[Print name if not Insured]*

Date: _____

Witness Signature

LARGER FONT VERSIONS OF THIS AUTHORIZATION AVAILABLE ON REQUEST



Authorization to Use and Disclose Health Information

PLEASE PRINT CLEARLY
Patient's Name: _____ ID Number _____
Address: _____ SSN: _____
Street _____
City, State, Zip _____ Date of Birth: ____/____/____
MM DD YYYY
Plan Sponsor/Employer (if available) _____
[] Check here if Plan Sponsor is Department of Defense

I authorize Express Scripts, Inc. or one of its subsidiaries or affiliates to use or disclose my health information as described below. I understand that the information I authorize a person or entity to disclose may be shared with other people or entities and no longer protected by federal privacy regulations.

- 1. The following health information may be used or disclosed:
[] Prescription Claims Information/ Prescription History (PBM records)
[] Check here if only mail order records are requested
2. The health information identified above may be used or disclosed for the following purpose(s):

LITIGATION

- 3. The health information identified above may only be disclosed to the following individual(s) or organization(s):

Name: MCS Group, Inc. c/o Tucker Ellis LLP
Address: 1601 Market Street, Suite 800
Philadelphia, PA 19103 (215) 405-8213 or (215) 531-5756

- 4. I understand that the health information that I authorized to be used or disclosed may include information relating to sexually transmitted disease, acquired immunodeficiency syndrome (AIDS), human immunodeficiency virus (HIV), mental health or substance abuse.
5. I understand that this authorization is voluntary and that I may refuse to sign this authorization. I understand that my refusal to sign this authorization does not affect payment for services, my ability to obtain treatment, or my eligibility for benefits or enrollment.

This document includes information confidential and proprietary to Express Scripts, Inc., and should not be released, disclosed or otherwise distributed to anyone (including clients) outside of the company. It is for internal use only. Improper use may result in disciplinary action including termination. Questions concerning this policy should be directed to a supervisor or the legal department



MCS#

6. I understand that if this authorization is for the disclosure of health information for a research study, I may refuse to sign this authorization. I understand that if I refuse to sign this authorization, I may not receive the treatment related to the research study.
7. I understand that I may revoke this authorization at any time provided that the information has not already been disclosed. Information that has already been disclosed may not be further disclosed by Express Scripts, Inc. once the authorization has been revoked. I understand that if I choose to revoke this authorization, I must do so in writing to the following address:

Express Scripts, Inc.
Claims Dept – Records/B402-01
8931 Springdale Avenue
St. Louis, MO 63134
FAX: 866-254-2313

8. I understand that I have a right to request and receive a copy of Express Scripts' Notice of Privacy Practices at www.express-scripts.com.
9. A photocopy of this authorization is as valid as the original.
10. I understand that this authorization will expire ten (10) years from the date signed below.

SIGNATURE	
_____	_____
Signature of patient or patient's personal representative	Date

Printed name of patient or patient's personal representative	
If signed by patient's personal representative, please complete the following and attach supporting documentation:	
Relationship to patient: _____	
Authority to act for the patient: _____	

Prescription Claims Information is readily available from 2006 to present. Patients wanting prescription claim information sent to the address on file should call the number on the back of the prescription identification card.

Please return completed form along with a check or money order for the non-refundable processing fee of \$75.00 to:

Express Scripts, Inc.
Claims Dept – Records/B402-01
8931 Springdale Avenue
St. Louis MO 63134
Fax 866-254-2313

Please allow 6-8 weeks for the request to be processed.
For questions or concerns, please call toll-free 800-332-5455, ext 326584.

This document includes information confidential and proprietary to Express Scripts, Inc., and should not be released, disclosed or otherwise distributed to anyone (including clients) outside of the company. It is for internal use only. Improper use may result in disciplinary action including termination. Questions concerning this policy should be directed to a supervisor or the legal department



**Express Scripts
PUBLIC**

201087.1

1-800-MEDICARE Authorization to Disclose Personal Health Information

Use this form if you want 1-800-MEDICARE to give your personal health information to someone other than you.

1. **Print Name** **Medicare Number** **Date of Birth**
(First and last name of the person with Medicare) (Exactly as shown on the Medicare Card) (mm/dd/yyyy)

2. Medicare will only disclose the personal health information you want disclosed.

2A: Check only one box below to tell Medicare the specific personal health information you want disclosed:

- Limited Information (go to question 2b)
 Any Information (go to question 3)

2B: Complete only if you selected “limited information”. Check all that apply:

- Information about your Medicare eligibility
 Information about your Medicare claims
 Information about plan enrollment (e.g. drug or MA Plan)
 Information about premium payments
 Other Specific Information (please write below; for example, payment information)
- _____

3. **Check only one box below indicating how long Medicare can use this authorization to disclose your personal health information** (subject to applicable law—for example, your State may limit how long Medicare may give out your personal health information):

- Disclose my personal health information indefinitely
 Disclose my personal health information for a specified period only
beginning: (mm/dd/yyyy) _____ and ending: (mm/dd/yyyy) present
- _____

4. Fill in the name and address of the person(s) or organization(s) to whom you want Medicare to disclose your personal health information. Please provide the specific name of the person(s) for any organization you list below:

1. Name: Tucker Ellis LLP
Address: 515 South Flower Street, Forty-Second Floor
Los Angeles, CA 90071

2. Name: Tucker Ellis LLP
Address: 950 Main Avenue, Suite 1100
Cleveland, Ohio 44113

3. Name: The MCS Group, Inc.
Address: 1601 Market Street, Suite 800
Philadelphia, PA 19103

5. I authorize 1-800-MEDICARE to disclose my personal health information listed above to the person(s) or organization(s) I have named on this form. I understand that my personal health information may be re-disclosed by the person(s) or organization(s) and may no longer be protected by law.

Signature Telephone Number Date (mm/dd/yyyy)

Print the address of the person with Medicare (Street Address, City, State, and ZIP)

Check here if you are signing as a personal representative and complete below.
Please attach the appropriate documentation (for example, Power of Attorney).
This only applies if someone other than the person with Medicare signed above.

Print the Personal Representative's Address (Street Address, City, State, and ZIP)

Telephone Number of Personal Representative: _____

Personal Representative's Relationship to the Beneficiary: _____

6. Send the completed, signed authorization to:

Medicare BCC, Written Authorization Dept.
PO Box 1270
Lawrence, KS 66044

7. Note:

You have the right to take back (“revoke”) your authorization at any time, in writing, except to the extent that Medicare has already acted based on your permission. If you would like to revoke your authorization, send a written request to the address shown above.

Your authorization or refusal to authorize disclosure of your personal health information will have no effect on your enrollment, eligibility for benefits, or the amount Medicare pays for the health services you receive.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is **0938-0930**. The time required to complete this information collection is estimated to average **15 minutes** per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

Consent for Release of Information

You must complete all required fields. We will not honor your request unless all required fields are completed. (*Signifies a required field. **Please complete these fields in case we need to contact you about the consent form).

TO: Social Security Administration

***My Full Name**

***My Date of Birth
(MM/DD/YYYY)**

***My Social Security Number**

I authorize the Social Security Administration to release information or records about me to:

***NAME OF PERSON OR ORGANIZATION:**

***ADDRESS OF PERSON OR ORGANIZATION:**

The MCS Group, Inc. c/o Tucker Ellis LLP

1601 Market Street, Suite 800

Philadelphia, PA 19103

***I want this information released because:** Litigation

We may charge a fee to release information for non-program purposes.

***Please release the following information selected from the list below:**

Check at least one box. We will not disclose records unless you include date ranges where applicable.

- 1. Verification of Social Security Number
- 2. Current monthly Social Security benefit amount
- 3. Current monthly Supplemental Security Income payment amount
- 4. My benefit or payment amounts from date _____ to date present
- 5. My Medicare entitlement from date _____ to date present
- 6. Medical records from my claims folder(s) from date _____ to date present

If you want us to release a minor child's medical records, do not use this form. Instead, contact your local Social Security office.

- 7. Complete medical records from my claims folder(s)
- 8. Other record(s) from my file (We will not honor a request for "any and all records" or "the entire file." You must specify other records; e.g., consultative exams, award/denial notices, benefit applications, appeals, questionnaires, doctor reports, determinations.)

The entire claims file of _____, including but not limited to claim information, medical records, medical insurance coverage paid and any and all disability records.

I am the individual, to whom the requested information or record applies, or the parent or legal guardian of a minor, or the legal guardian of a legally incompetent adult. I declare under penalty of perjury (28 CFR § 16.41(d)(2004) that I have examined all the information on this form and it is true and correct to the best of my knowledge. I understand that anyone who knowingly or willfully seeking or obtaining access to records about another person under false pretenses is punishable by a fine of up to \$5,000. I also understand that I must pay all applicable fees for requesting information for a non-program-related purpose.

***Signature:** _____ ***Date:** _____

****Address:** _____ ****Daytime Phone:** _____

Relationship (if not the subject of the record): _____ ****Daytime Phone:** _____

Witnesses must sign this form ONLY if the above signature is by mark (X). If signed by mark (X), two witnesses to the signing who know the signee must sign below and provide their full addresses. Please print the signee's name next to the mark (X) on the signature line above.

1. Signature of witness	2. Signature of witness
Address(Number and street, City, State, and Zip Code)	Address(Number and street, City, State, and Zip Code)

Request for Copy of Tax Return

OMB No. 1545-0429

- ▶ **Do not sign this form unless all applicable lines have been completed.**
- ▶ **Request may be rejected if the form is incomplete or illegible.**
- ▶ **For more information about Form 4506, visit www.irs.gov/form4506.**

Tip. You may be able to get your tax return or return information from other sources. If you had your tax return completed by a paid preparer, they should be able to provide you a copy of the return. The IRS can provide a **Tax Return Transcript** for many returns free of charge. The transcript provides most of the line entries from the original tax return and usually contains the information that a third party (such as a mortgage company) requires. See **Form 4506-T, Request for Transcript of Tax Return**, or you can quickly request transcripts by using our automated self-help service tools. Please visit us at IRS.gov and click on "Get a Tax Transcript..." or call 1-800-908-9946.

1a Name shown on tax return. If a joint return, enter the name shown first.	1b First social security number on tax return, individual taxpayer identification number, or employer identification number (see instructions)
2a If a joint return, enter spouse's name shown on tax return.	2b Second social security number or individual taxpayer identification number if joint tax return

3 Current name, address (including apt., room, or suite no.), city, state, and ZIP code (see instructions)

4 Previous address shown on the last return filed if different from line 3 (see instructions)

5 If the tax return is to be mailed to a third party (such as a mortgage company), enter the third party's name, address, and telephone number.
The MCS Group, Inc., 1601 Market Street, Suite 800, Philadelphia, PA 19103; c/o Tucker Ellis LLP, 515 South Flower Street, Forty-Second Floor, Los Angeles, California, 90071 and 950 Main Avenue, Suite 1100, Cleveland, Ohio 44113

Caution: If the tax return is being mailed to a third party, ensure that you have filled in lines 6 and 7 before signing. Sign and date the form once you have filled in these lines. Completing these steps helps to protect your privacy. Once the IRS discloses your tax return to the third party listed on line 5, the IRS has no control over what the third party does with the information. If you would like to limit the third party's authority to disclose your return information, you can specify this limitation in your written agreement with the third party.

6 **Tax return requested.** Form 1040, 1120, 941, etc. and all attachments as originally submitted to the IRS, including Form(s) W-2, schedules, or amended returns. Copies of Forms 1040, 1040A, and 1040EZ are generally available for 7 years from filing before they are destroyed by law. Other returns may be available for a longer period of time. Enter only one return number. If you need more than one type of return, you must complete another Form 4506. ▶ _____

Note: If the copies must be certified for court or administrative proceedings, check here

7 **Year or period requested.** Enter the ending date of the year or period, using the mm/dd/yyyy format. If you are requesting more than eight years or periods, you must attach another Form 4506.

<u>12/31/2016</u>	<u>12/31/2015</u>	<u>12/31/2014</u>	<u>12/31/2013</u>
<u>12/31/2012</u>	<u>12/31/2011</u>	<u>12/31/2010</u>	<u>12/31/2009</u>

8 **Fee.** There is a \$50 fee for each return requested. Full payment must be included with your request or it will be rejected. Make your check or money order payable to "United States Treasury." Enter your SSN, ITIN, or EIN and "Form 4506 request" on your check or money order.

a Cost for each return	\$ 50.00
b Number of returns requested on line 7	
c Total cost. Multiply line 8a by line 8b	\$

9 If we cannot find the tax return, we will refund the fee. If the refund should go to the third party listed on line 5, check here

Caution: Do not sign this form unless all applicable lines have been completed.
Signature of taxpayer(s). I declare that I am either the taxpayer whose name is shown on line 1a or 2a, or a person authorized to obtain the tax return requested. If the request applies to a joint return, at least one spouse must sign. If signed by a corporate officer, 1 percent or more shareholder, partner, managing member, guardian, tax matters partner, executor, receiver, administrator, trustee, or party other than the taxpayer, I certify that I have the authority to execute Form 4506 on behalf of the taxpayer. **Note:** For tax returns being sent to a third party, this form must be received within 120 days of the signature date.

Signatory attests that he/she has read the attestation clause and upon so reading declares that he/she has the authority to sign the Form 4506. See instructions.

Phone number of taxpayer on line 1a or 2a

Sign Here

Signature (see instructions)	Date
Title (if line 1a above is a corporation, partnership, estate, or trust)	
Spouse's signature	Date

**LIMITED AUTHORIZATION FOR RELEASE
OF WORKERS' COMPENSATION RECORDS**

To:

Name

Address

City, State and Zip Code

This will authorize you to furnish copies of any and all workers' compensation records of any sort **for any workers' compensation claims filed within the last ten (10) years**, including, but not limited to, statements, applications, disclosures, correspondence, notes, settlements, agreements, contracts or other documents, concerning:

Name of Claimant

Date of Birth

Social Security Number

To include all archived records, records in storage, and all items as may be stored in a computer database or in electronic form.

You are authorized to release the above records to the following representatives of defendants, who have agreed to pay reasonable charges made by you to supply copies of such records. **The MCS Group, Inc., 1601 Market Street, Suite 800, Philadelphia, PA 19103; c/o Tucker Ellis LLP, 515 South Flower Street, Forty-Second Floor, Los Angeles, California 90071 and 950 Main Avenue, Suite 1100, Cleveland, Ohio 44113.**

This authorization only authorizes release of documents and records from the period of ten (10) years prior to the date on which this authorization is signed. This authorization does not authorize you to disclose anything other than documents and records to anyone.

This authorization shall be considered as continuing in nature and is to be given full force and effect to release information of any of the foregoing learned or determined after the date hereof. It is expressly understood by the undersigned and you are authorized to accept a copy or photocopy of this authorization with the same validity as through the original had been presented to you.

Date: _____

Claimant/Guardian/Personal Representative
Signature *[Print name if not Claimant]*

Date: _____

Witness Signature

LARGER FONT VERSIONS OF THIS AUTHORIZATION AVAILABLE ON REQUEST

**LIMITED AUTHORIZATION FOR RELEASE OF
DISABILITY CLAIMS RECORDS**

To:

Name

Address

City, State and Zip Code

This will authorize you to furnish copies of any and all records of disability claims of any sort **for any disability claim(s) filed within the last ten (10) years**, including, but not limited to, statements, applications, disclosures, correspondence, notes, settlements, agreements, contracts or other documents, concerning:

Name of Claimant

Date of Birth

Social Security Number

To include all archived records, records in storage, and all items as may be stored in a computer database or in electronic form.

You are authorized to release the above records to the following representatives of defendants, who have agreed to pay reasonable charges made by you to supply copies of such records. **The MCS Group, Inc., 1601 Market Street, Suite 800, Philadelphia, PA 19103; c/o Tucker Ellis LLP, 515 South Flower Street, Forty-Second Floor, Los Angeles, California 90071 and 950 Main Avenue, Suite 1100, Cleveland, Ohio 44113.**

This authorization only authorizes release of documents and records from the period of ten (10) years prior to the date on which this authorization is signed. This authorization does not authorize you to disclose anything other than documents and records to anyone.

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Date: _____

Claimant/Guardian/Personal Representative
Signature *[Print name if not Claimant]*

Date: _____

Witness Signature

LARGER FONT VERSIONS OF THIS AUTHORIZATION AVAILABLE ON REQUEST

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

**IN RE: INVOKANA (CANAGLIFLOZIN)
PRODUCTS LIABILITY LITIGATION**

:
: **MDL NO. 2750**
:
: **CASE NO. 3:16-cv-02750**
:
: **JUDGE BRIAN R. MARTINOTTI**
:

THIS DOCUMENT RELATES TO:

CASE NAME: _____

CASE NO: _____

DEFENDANT FACT SHEET

For each case, Defendants Janssen Research & Development, LLC, Janssen Ortho, LLC, Janssen Pharmaceuticals, Inc. (collectively “Janssen”) and Johnson & Johnson (“J&J”), who have relevant information, (collectively referred to as “Defendants”), must complete this Defendant Fact Sheet (“DFS”) and identify or provide documents and/or data responsive to the questions set forth below to the best of their knowledge. In the event the DFS does not provide you with enough space for you to complete your responses or answers, please attach additional sheets if necessary. Please identify any documents that you are producing as responsive to a question or request by bates number.

As set forth in the Implementing Order on Plaintiff and Defense Fact Sheets, Defendants must complete and serve this DFS on each Plaintiff’s counsel identified in the PFS as well as Plaintiffs’ Executive Committee by email, and identify or provide DOCUMENTS and/or data responsive to the questions set forth below for each such Plaintiff. Defendants must supplement their responses to the extent that additional information is provided by Plaintiff in a Substantially Completed supplemental PFS, within sixty (60) days of receiving the supplemental information.

DEFINITIONS & INSTRUCTIONS

As used herein, “YOU,” “YOUR,” or “YOURS” means the responding DEFENDANTS.

“DEFENDANTS” shall mean and refer to those companies involved in the development, manufacture and distribution of the drugs known as Invokana and/or Invokamet including Janssen

Pharmaceuticals, Inc., Janssen Research & Development LLC, Janssen Ortho LLC and Johnson & Johnson. Defendants who have relevant information shall each answer each document request and question that not only calls for YOUR knowledge, but also for all knowledge that is available to YOU by reasonable inquiry, including inquiry of YOUR "officers," "directors," "agents," and "employees."

"PRESCRIBING HEALTHCARE PROVIDER" means: the physician(s) or other individual healthcare provider(s) identified by full name and address in PFS Section III who prescribed Invokana and/or Invokamet to the Plaintiff as identified in Section III of the PFS:.

"TREATING HEALTHCARE PROVIDER" means: the physician(s) who diagnosed plaintiff with the alleged injuries in the PFS, as identified in PFS Section V and/or any physician(s) who treated plaintiff's injuries post hospitalization as identified in PFS Section V.

"REMUNERATION" means anything of monetary value above \$50.

As used herein, the term "DOCUMENT" shall, consistent with Federal Rule of Civil Procedure 34(a)(1)(A), refer to any "designated documents or electronically stored information – including writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations – stored in any medium form which information can be obtained either directly or, if necessary, after translation by the responding party into a reasonably usable form."

If YOU are aware that information within YOUR possession, custody or control that was, or is likely to have been, responsive to this DFS was lost or destroyed, you must notify the MDL Co-Lead counsel of the nature of the information and the circumstances of the loss or destruction.

As used herein, "KEY OPINION LEADER" or "THOUGHT LEADER" shall mean and refer to any doctors or medical professionals hired by, consulted with, or retained by DEFENDANTS to, amongst other things, consult, give lectures, respond to media inquiries, conduct clinical trials, write articles or abstracts, sign their names as authors to articles or abstracts written by others, sit on advisory boards and make presentations on their behalf at regulatory meetings or hearings.

The phrase "SAMPLES" refers to any medication or unit of a prescription drug not intended to be sold, which is given to promote the drug's sales. This includes any vouchers or coupons that provide for the PRESCRIBING HEALTHCARE PROVIDERS or patients access to the medication for a specified period of time.

The phrase "SALES REPRESENTATIVE" means any person presently or formerly engaged or employed by YOU whose job duties include calling on physicians or other health care professionals, healthcare facilities, hospitals, and/or physician practice groups; promoting drugs manufactured or licensed by YOU to physicians or other HEALTH CARE PROVIDERS; distributing drug SAMPLES to physicians or other HEALTH CARE PROVIDERS. "SALES REPRESENTATIVE" also includes those who occupy positions titled "Professional Sales Representative," "Sales Professional," "Specialty Sales Representative," "Senior Sales Representative," "Senior Health Care Representative," "Professional Representative," "Health Care Representative", "Institutional" or "Managed Care" sales representative, "Endocrinology Sales Representative" "Medical Service Representative", and "Medical Sales Representative" or

any other titles used by Defendants and any of its divisions SALES REPRESENTATIVE also includes any contract employees or SALES REPRESENTATIVES from other companies involved in the promotion or co-promotion of Invokana and/or Invokamet.

The phrase “MEDICAL SCIENCE LIAISON(S)” means any person presently or formerly engaged or employed by YOU for the purpose of sales support and direct field communication with physicians or other HEALTH CARE PROVIDERS about medical and science information related to Invokana and/or Invokamet, and opinion leader management. This includes employees with the titles of “Medical Science Liaison (MSL)”, “Clinical Education Consultant (CEC)” or any other titles YOU use or have used in the past for these employees.

The phrase “CALL NOTES” means database entries reflecting contacts with PRESCRIBING HEALTHCARE PROVIDERS, related to Invokana and/or Invokamet, diabetes, treatment of diabetes, and endocrinology.

“RELEVANT TIME PERIOD” means from May 25, 2007 through May 1, 2016.

For each chart included in the questions below, DEFENDANTS may fill out the chart, produce responsive information in a standard report from a structured database, or indicate that no data was found, if applicable.

DEFENDANTS’ searches shall be limited to the RELEVANT TIME PERIOD for information contained within structured databases and central repositories that can be queried using standard search techniques for the information requested by Plaintiffs.

I. CASE INFORMATION

This DFS pertains to the following case: _____

Case caption: _____

Civil Action No. _____

Date this DFS was completed: _____

II. COMMUNICATIONS AND CONTACTS WITH PLAINTIFF’S PRESCRIBING HEALTHCARE PROVIDER(S)

A. For each PRESCRIBING HEALTHCARE PROVIDER identified in Section III of the PFS:

1. State the total number of known contacts between any of DEFENDANTS’ Sales Representatives and each PRESCRIBING HEALTHCARE PROVIDER regarding Invokana and/or Invokamet.

Name of Prescribing Healthcare Provider	Total # of Contacts

2. Identify by name and current title DEFENDANTS' Sales Representatives included in the contacts referenced in question 1 above and state whether that individual is a current or former employee.

Name of Representative	Title	Current or Former Employee

3. Identify the time period during which the representative had any such contact with the PRESCRIBING HEALTHCARE PROVIDER.

Name of Representative	Prescribing Healthcare Provider	Dates of Each Contact with Prescribing Healthcare Provider

4. If the Representative is no longer an employee, Defendants will provide the dates of employment for the employee.

Name of Representative	Date of Termination

B. For each Defendant’s SALES REPRESENTATIVE, identified in this DFS please:

- i) produce his/her complete CALL NOTES for each such contact that relates to (a) Invokana and/or Invokamet.

C. Have Defendants or their representatives ever provided any Invokana and/or Invokamet samples to Plaintiff’s PRESCRIBING HEALTHCARE PROVIDER(s) identified in Section III of the PFS?

Yes _____ No _____ Not Applicable _____

If the answer is “Yes,” please provide the following information related to SAMPLES of Invokana and/or Invokamet:

1. The PRESCRIBING HEALTHCARE PROVIDER(s) who received the samples;
2. The date(s) on which such SAMPLES of Invokana and/or Invokamet were provided;
3. The amount, dosage, and lot numbers of such SAMPLES;
4. The name(s) of the DEFENDANT representative(s) and/or department who provided such SAMPLES of Invokana (canagliflozin);

PRESCRIBING HEALTHCARE PROVIDER	Date(s) Shipped and/or Provided	Amount and Dosage	Lot Number	Representative Who Provided

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D. Medical Information Request Letters (“MIR”):

1. Please indicate if any of the PRESCRIBING OR TREATING HEALTHCARE PROVIDER(S) ever initiated a MIR concerning Invokana and/or Invokamet by identifying the name and address of the sender of the MIR, the date it was sent; the name and address of the recipient; and whether or not a response to the MIR or similar document was sent.

Sender (Name and Address)	MIR Date	Recipient (Name and Address)	Response Sent? (Yes or No)

For each MIR in which a response was sent as indicated by a “Yes” above, please identify the format of the response; the date the response was sent; the name and address of the sender of the response; the name and address of the recipient of the response; and provide and identify by Bates number any and all documentation, including lists or database records, which demonstrates that the responsive documents were sent.

Original MIR or Request Document Date	Format of Response (Letter or otherwise)	Date Response Sent	Response Sender (Name and Address)	Response Recipient (Name and Address)	Bates Number of Supporting Documentation

E. Other Means of Information Requests by Physicians:

1. For the PRESCRIBING AND TREATING HEALTHCARE PROVIDER(S) identified by Plaintiff in Sections III and V of the PFS, did any such provider ever contact YOU by any other means not already addressed in Section D, *supra*, to request information concerning Invokana and/or Invokamet, its indications, potential side effects and or-other risks?

Yes _____ No _____

For each contact initiated by a PRESCRIBING OR TREATING HEALTHCARE PROVIDER(S) as indicated by a “Yes” above, please identify the name and address of the HEALTHCARE PROVIDER who requested the information; the date of the request; the format of the request; the name and address of the recipient of the request; whether a response was sent; and provide and identify by Bates number any and all documentation, including lists or database records, which demonstrates that the responsive documents were sent.

Provider Who Requested Information (Name and Address)	Date of Request	Format of Request (Phone Call or otherwise)	Recipient (Name and Address)	Response Sent? (Yes or No)	Bates Number of Supporting Documentation

G. Dear Doctor Letters:

- Please identify any “Dear Doctor,” “Dear Health Care Provider,” “Dear Colleague,” or any other similar type of document or letter sent to the PRESCRIBING HEALTHCARE PROVIDER(S) identified by Plaintiff in Section III of the PFS concerning Invokana and/or Invokamet.

Sender (Name and Address)	Letter or Document Date	Recipient (Name and Address)	Bates Number

III. CONSULTING WITH PLAINTIFF’S PRESCRIBING AND TREATING HEALTHCARE PROVIDER(S)

For each PRESCRIBING AND TREATING HEALTHCARE PROVIDER identified in Plaintiff’s PFS, please answer the following:

- If the HEALTHCARE PROVIDER has been consulted, retained, or compensated by

Defendants as a “KEY OPINION LEADER,” “THOUGHT LEADER,” member of a “speaker’s bureau,” “clinical investigator,” “consultant”, advisory board member or in a similar capacity or otherwise has or had a financial relationship with or has been provided REMUNERATION by DEFENDANTS as related to Invokana (canagliflozin), please state the following for each:

1. Identify the HEALTHCARE PROVIDER.
2. Identify the date(s) that the HEALTHCARE PROVIDER was consulted, retained, or compensated.
3. State the nature of the affiliation.
4. State the type and total amount of REMUNERATION provided to the HEALTHCARE PROVIDER.

HEALTHCARE PROVIDER	Date(s) Consulted, Retained, or Compensated	Nature of Affiliation	Compensation, Reimbursement, and/or Remuneration

IV. PLAINTIFF’S PRESCRIBING HEALTHCARE PROVIDER’S PRACTICES

A. Do you have or have you had access to any databases, documents, or other information that track or purport to track the prescribing or treating practices of PRESCRIBING HEALTHCARE PROVIDER with respect to Invokana?

_____ Yes _____ No

If the answer is “Yes,” state and produce all prescriber-level data designed to track prescribing or treating practices that YOU obtained on Plaintiff’s PRESCRIBING HEALTHCARE PROVIDER to the extent: 1) that information is in DEFENDANTS possession, custody or control (DEFENDANTS have no obligation to obtain and/or purchase additional data from IMS beyond that currently maintained in Defendant’s internal company data sources); 2) DEFENDANTS are able to obtain express approval from IMS to release the data (if there is a charge levied by IMS, then the parties will meet and confer regarding which party shall be responsible for paying the charge); and 3) Plaintiffs enter into a confidentiality or consent agreement with IMS prior to production

here (to the extent requested by IMS). Specifically, if available, DEFENDANTS will provide: 1) product(s) prescribed, 2) the number of new prescriptions, and 3) the number of total prescriptions identified in Section III of the PFS.

- B. For each PRESCRIBING HEALTHCARE PROVIDER, please state whether he/she attended any educational or promotional event, conference, lecture, luncheon, dinner or other meeting sponsored or co-sponsored by any of the Defendants regarding Invokana (canagliflozin)?

_____ Yes _____ No

If yes, please state as to each such PRESCRIBING HEALTHCARE PROVIDER:

1. The identity of the PRESCRIBING HEALTHCARE PROVIDER attendee.
2. The title, location, and date of the program attended.
3. The topic of the program attended.
4. All speakers at the program.
5. Please provide or identify by Bates-stamp all presentations, agendas, brochures, and other written materials for the program

VI. PLAINTIFF'S MEDICAL CONDITION

- A. Have you been contacted by Plaintiff, or anyone acting on behalf of Plaintiff (other than Plaintiff's counsel), concerning Plaintiff?

Yes _____ No _____

- B. Have you been contacted by anyone regarding a potential side effect or adverse event experienced by Plaintiff while on Invokana (canagliflozin), excluding contact/reporting by counsel for Plaintiff and/or submission in connection with this litigation?

Yes _____ No _____

- C. If you have been contacted by any person or entity concerning the Plaintiff (other than Plaintiff's counsel) for a reason other than reporting an adverse event, please state the name of the person(s) who contacted you and the name and address of the person(s) who responded to the contact on your behalf.

D. Please identify and produce all documents created before the filings of this lawsuit which reflect any communication between any person and you concerning Plaintiff.

E. Please produce a copy of any MedWatch form, other than documents initiated in the course of litigation, which refers or relates to Plaintiff. Any MedWatch form produced shall be redacted as necessary per federal law.

CERTIFICATION

I am employed by _____, one of the DEFENDANTS in this litigation. I am authorized by _____ [name of other DEFENDANTS] to execute this certification on each corporation's behalf. The foregoing answers were prepared with the assistance of a number of individual, including counsel for DEFENDANTS, upon whose advice and information I relied. I declare under penalty of perjury subject to 28 U.S.C. § 1746 that all of the information provided in this Defendant Fact Sheet is true and correct to the best of my knowledge upon information and belief.

Signature

Print Name

Date