

EXHIBIT B

1 Michael K. Johnson
2 **JOHNSON BECKER, PLLC**
3 33 South 6th Street, Suite 4530
4 Minneapolis, MN 55402
5 Telephone: (612) 436-1800
6 Facsimile: (612) 436-1801
7 mjohnson@johnsonbecker.com

8 Ryan L. Thompson
9 **WATTS GUERRA LLP**
10 5250 Prue Road, Suite 525
11 San Antonio, Texas 78240
12 Telephone: (210) 448-0500
13 Facsimile: (210) 448-0501
14 rthompson@wattsguerra.com

Hunter J. Shkolnik
**NAPOLI, BERN, RIPKA &
SHKOLNIK LLP**
350 Fifth Avenue
New York, New York 10018
Telephone: (212)267-3700
Facsimile: (212)587-0031
hunter@napolibern.com

Tor A. Hoerman
TORHOERMAN LAW LLC
101 W. Vandalia Street, Suite 350
Edwardsville, Illinois 62025
Phone: (618) 656-4400
Facsimile: (618) 656-4401
thoerman@torhoermanlaw.com

12 **UNITED STATES DISTRICT COURT**
13 **SOUTHERN DISTRICT OF CALIFORNIA**

14 **IN RE: INCRETIN-BASED**
15 **THERAPIES PRODUCTS**
16 **LIABILITY LITIGATION**

17 **Relates to: ALL CASES**

**Master File No.: 3:13-md-02452-
AJB-MDD**

MDL – 2452

Judge: Hon. Anthony J. Battaglia

18
19 **PLAINTIFFS' GENERAL CAUSATION REQUESTS TO PRODUCE**
20 **TO DEFENDANT NOVO NORDISK, INC.**

21 To: Novo Nordisk, Inc. c/o DLA Piper LLP US
22 1251 Avenue of the Americas, New York NY 10020-1104

23 Pursuant to Fed. R. Civ. P. 34, Plaintiffs request that Defendant Novo Nordisk, Inc.
24 (“Defendant”) produce the documents and tangible things listed below. These requests
25 are continuing in nature pursuant to Fed. R. Civ. P. 26. Defendant is therefore required to
26 supplement its responses as new or different information becomes known.

1 **DEFINITIONS AND INSTRUCTIONS**

2 The following terms shall have the following meanings, unless the context requires
3 otherwise:

4 1. “YOU,” “YOUR,” or “DEFENDANT” – means Novo Nordisk, Inc., as well
5 as its divisions, parents, subsidiaries, and each of their present and former officers,
6 directors, employees, agents, and representatives.

7 2. “DOCUMENT” or “DOCUMENTS” or “DOCUMENTATION” – means any
8 document or tangible thing in the broadest sense of the term as defined in Fed. R. Civ. P.
9 26 and 34, including electronically stored information.

10 3. “IDENTIFY” – as it relates to a person, means that person’s name, address,
11 telephone number, and place of employment; as it relates to an entity other than a person,
12 means that entity’s name and any other information reasonably required to allow for
13 precise identification; as it relates to a DOCUMENT, means that DOCUMENT’S Bates
14 number (if it has been produced), or a description of the DOCUMENT sufficient to
15 permit meaningful discussion of that specific DOCUMENT by Court and counsel (if it
16 has not been produced); as it relates to oral communication, means a reasonably detailed
17 summary of the substance of the oral communication and the identities of those
18 participating in it.

19 4. “ADVERSE EVENT” – refers to pancreatitis and/or pancreatic cancer related
20 or potentially related to the use of VICTOZA. This includes all such instances
21 communicated to YOU by any source, regardless of whether YOU agree that the claimed
22 event occurred, and regardless of whether YOU determined that the claimed event was
23 related to VICTOZA.

24 5. “REPORTABLE EVENT” – means any information relating to an ADVERSE
25 EVENT that YOU believed YOU were required to report to the FDA.

26 6. Use of the term “VICTOZA” includes reference to the medication bearing that
27 trade name as well as the chemical compound liraglutide.

28 7. “CAUSE” or “CAUSES” or “CAUSING” – means that a substance is capable
of increasing the likelihood that an event will occur. In the context of a substance

1 “CAUSING” pancreatitis and/or pancreatic cancer, this includes: (a) the substance
2 playing any role in initiating or promoting any of the processes which initiate pancreatitis
3 or pancreatic cancer; and/or (b) the substance playing any role in initiating or promoting
4 any of the processes by which pancreatitis and/or pancreatic cancer progress; and/or (c)
5 the substance playing any role in the progression or spread of PanINs, tumors,
6 precancerous cells and/or cancerous cells.

7 8. Unless otherwise indicated, the “relevant period” for the information sought is
8 1995 to the present. If YOUR answer would vary for different timeframes within the
9 relevant period, specify those timeframes and provide separate answers for each.

10 **REQUESTS TO PRODUCE**

11 **REQUEST NO. 1:** The DOCUMENTS identified in YOUR answers to Plaintiffs’ General
12 Causation Interrogatories to Defendant Novo Nordisk, Inc.

13 **RESPONSE:**

14 **REQUEST NO. 2:** The IND/NDA and any SNDAs for VICTOZA in native electronic
15 searchable format as maintained by YOU.

16 **RESPONSE:**

17
18 **REQUEST NO. 3:** All other correspondence, data and other DOCUMENTS that YOU
19 provided to or received from the FDA related to the safety of VICTOZA with respect to
20 pancreatitis and/or pancreatic cancer, which are not part of the IND/NDA or any SNDAs for
21 VICTOZA.

22 **RESPONSE:**

23 **PERSONS WITH DISCOVERABLE INFORMATION ON GENERAL CAUSATION ISSUES**

24 **REQUEST NO. 4:** Corporate organization charts that identify the persons with
25 supervisory responsibility over scientific research into the safety of VICTOZA and those
26 working at their direction; the persons responsible for determining whether VICTOZA
27 CAUSES and/or is capable of CAUSING pancreatic cancer and those working at their
28

1 direction; the persons in charge of compiling and reporting pancreatitis and/or pancreatic
2 cancer ADVERSE EVENTS for VICTOZA and those working at their direction; and the
3 persons in charge of maintaining the source DOCUMENTS for pancreatitis and/or
4 pancreatic cancer ADVERSE EVENTS for VICTOZA and those working at their
5 direction.

6 **RESPONSE:**

7
8 **PRECLINICAL, NONCLINICAL AND ANIMAL STUDIES**

9 **REQUEST NO. 5:** A complete list of all VICTOZA preclinical, nonclinical and/or animal
10 studies performed, completed, designed, planned and/or contemplated, identifying them by
11 name, number or any other designation YOU use to identify them.

12 **RESPONSE:**

13 **REQUEST NO. 6:** For each VICTOZA preclinical, nonclinical and/or animal study
14 performed, completed, designed, planned and/or contemplated, produce the following:

- 15 a. The protocols; data; researcher and/or laboratory technician notebooks,
16 notes, logs, bench notes, books, computer files and emails; results;
17 reports; and pancreatic specimens (e.g. histology slides, tissue samples,
18 etc.) for that study;
- 19 b. The database(s) where the above information can be located; and
- 20 c. If an independent investigator, contract research organization, or other
21 third party was involved in the study, produce all documents relating to
22 the work performed, including but not limited to contracts and
23 communications between YOU and said independent investigator,
24 contract research organization, or other third party.

25 **RESPONSE:**

26

27

28

1 **REQUEST NO. 7:** The standard operating procedures and/or policy and procedures
2 manuals for VICTOZA preclinical, nonclinical and animal studies.

3 **RESPONSE:**

4
5 **REQUEST NO. 8:** Every DOCUMENT that addresses the significance of any
6 preclinical, nonclinical and/or animal study in relation to whether VICTOZA CAUSES
7 and/or is capable of CAUSING pancreatic cancer.

8 **RESPONSE:**

9
10 **REQUEST NO. 9:** The memoranda, reports and other similar DOCUMENTS that
11 describe the nature and intended purpose of any preclinical, nonclinical and/or animal
12 studies involving VICTOZA that are not yet started or completed and, to the extent such
13 DOCUMENTS exist, the protocols; data; researcher and/or laboratory technician
14 notebooks, notes, logs, bench notes, books, computer files and emails; results; reports; and
15 pancreatic specimens (e.g. histology slides, tissue samples, etc.) for each such preclinical,
16 nonclinical and/or animal study.

17 **RESPONSE:**

18 **HUMAN STUDIES**

19 **REQUEST NO. 10:** A complete list of all VICTOZA human studies performed,
20 completed, designed, planned and/or contemplated, identifying them by name, number or
21 any other designation YOU use to identify them.

22 **RESPONSE:**

23
24 **REQUEST NO. 11:** For each VICTOZA human study performed, completed, designed,
25 planned and/or contemplated, produce the following:

- 26 a. The protocols; data; researcher and/or laboratory technician notebooks,
27 notes, logs, bench notes, books, computer files and emails; results;

1 reports; and pancreatic specimens (e.g. histology slides, tissue samples,
2 etc.) for that study;

- 3 b. The database(s) where the above information can be located;
4 c. All documentation and/or communication regarding sponsorship of the
5 study; and
6 d. If an independent investigator, contract research organization, or other
7 third party was involved in the study, produce all documents relating to
8 the work performed, including but not limited to contracts and
9 communications between YOU and said independent investigator,
10 contract research organization, or other third party.

11 **RESPONSE:**

12 **REQUEST NO. 12:** The standard operating procedures and/or policy and procedures
13 manuals for VICTOZA human studies.

14 **RESPONSE:**

15
16 **REQUEST NO. 13:** Every DOCUMENT that records, analyzes or discusses information
17 about each person YOU are aware of who was a participant in a VICTOZA human study
18 and was diagnosed with pancreatitis and/or pancreatic cancer either while still participating
19 in the study or after withdrawing or otherwise being removed from the study.

20 **RESPONSE:**

21
22 **REQUEST NO. 14:** Every DOCUMENT that addresses the significance of any human
23 study in relation to whether VICTOZA CAUSES and/or is capable of CAUSING
24 pancreatic cancer.

25 **RESPONSE:**

26
27 **REQUEST NO. 15:** The memoranda, reports and other similar DOCUMENTS that
28 describe the nature and intended purpose of any human studies involving VICTOZA that

1 are not yet started or completed and, to the extent such DOCUMENTS exist, the study
2 protocols; data; researcher and/or laboratory technician notebooks, notes, logs, bench notes,
3 books, computer files and emails; results; reports; and pancreatic specimens (e.g. histology
4 slides, tissue samples, etc.) for each such human study.

5 **RESPONSE:**

6
7 **OBSERVATIONAL STUDIES**

8 **REQUEST NO. 16:** A complete list of all VICTOZA observational studies (including,
9 without limitation, claims database studies, cohort studies and other epidemiological
10 studies) performed, completed, designed, planned and/or contemplated, identifying them by
11 name, number or any other designation YOU use to identify them.

12 **RESPONSE:**

13 **REQUEST NO. 17:** For each VICTOZA observational study (including, without
14 limitation, claims database studies, cohort studies and other epidemiological studies)
15 performed, completed, designed, planned and/or contemplated, produce the following:

- 16 a. The protocols; data; researcher and/or laboratory technician notebooks,
17 notes, logs, bench notes, books, computer files and emails; results; and
18 reports for that study;
- 19 b. The database(s) where the above information can be located; and
- 20 c. If an independent investigator, contract research organization, or other
21 third party was involved in the study, produce all documents relating to
22 the work performed, including but not limited to contracts and
23 communications between YOU and said independent investigator,
24 contract research organization, or other third party.

25 **RESPONSE:**

26

27

28

1 **REQUEST NO. 18:** The standard operating procedures and/or policy and procedures
2 manuals for VICTOZA observational studies (including, without limitation, claims database
3 studies, cohort studies and other epidemiological studies).

4 **RESPONSE:**

5
6 **REQUEST NO. 19:** Every DOCUMENT that addresses the significance of any
7 observational studies (including, without limitation, claims database studies, cohort studies
8 and other epidemiological studies) in relation to whether VICTOZA CAUSES and/or is
9 capable of CAUSING pancreatic cancer.

10 **RESPONSE:**

11 **REQUEST NO. 20:** The memoranda, reports and other similar DOCUMENTS that
12 describe the nature and intended purpose of any observational studies (including, without
13 limitation, claims database studies, cohort studies and other epidemiological studies)
14 involving VICTOZA that are not yet started or completed and, to the extent such
15 DOCUMENTS exist, the study protocols; data; researcher and/or laboratory technician
16 notebooks, notes, logs, bench notes, books, computer files and emails; results; and reports
17 for each such study.

18 **RESPONSE:**

19
20 **STUDIES TO DETERMINE CAUSAL CONNECTION WITH PANCREATIC CANCER**

21 **REQUEST NO. 21:** The standard operating procedures and/or policy and procedures
22 manuals for VICTOZA studies undertaken to determine, in whole or in part, whether
23 VICTOZA CAUSES and/or is capable of CAUSING pancreatic cancer.

24 **RESPONSE:**

25
26 **REQUEST NO. 22:** The study protocols; data; researcher and/or laboratory technician
27 notebooks, notes, logs, bench notes, books, computer files and emails; results; and reports
28 that were provided to the FDA for each study, test, investigation, evaluation and/or

1 assessment undertaken by YOU for the purpose of determining, in whole or in part,
2 whether VICTOZA CAUSES and/or is capable of CAUSING pancreatic cancer.

3 **RESPONSE:**

4
5 **REQUEST NO. 23:** The study protocols; data; researcher and/or laboratory technician
6 notebooks, notes, logs, bench notes, books, computer files and emails; results; and reports
7 that were not provided to the FDA for each study, test, investigation, evaluation and/or
8 assessment undertaken by YOU for the purpose of determining, in whole or in part,
9 whether VICTOZA CAUSES and/or is capable of CAUSING pancreatic cancer.

10 **RESPONSE:**

11
12 **REQUEST NO. 24:** The study protocols; data; researcher and/or laboratory technician
13 notebooks, notes, logs, bench notes, books, computer files and emails; results; and reports
14 that were provided to the EMA for each study, test, investigation, evaluation and/or
15 assessment undertaken by YOU for the purpose of determining, in whole or in part,
16 whether VICTOZA CAUSES and/or is capable of CAUSING pancreatic cancer.

17 **RESPONSE:**

18
19 **REQUEST NO. 25:** The study protocols; data; researcher and/or laboratory technician
20 notebooks, notes, logs, bench notes, books, computer files and emails; results; and reports
21 that were not provided to the EMA for each study, test, investigation, evaluation and/or
22 assessment undertaken by YOU for the purpose of determining, in whole or in part,
23 whether VICTOZA CAUSES and/or is capable of CAUSING pancreatic cancer.

24 **RESPONSE:**

25
26 **REQUEST NO. 26:** Every DOCUMENT that addresses the significance of any study,
27 test, investigation, evaluation and/or assessment undertaken by YOU for the purpose of
28 determining, in whole or in part, whether VICTOZA CAUSES and/or is capable of

1 CAUSING pancreatic cancer, in relation to whether VICTOZA CAUSES and/or is
2 capable of CAUSING pancreatic cancer.

3 **RESPONSE:**

4
5 **REQUEST NO. 27:** The memoranda, reports and other similar DOCUMENTS that
6 describe the nature and intended purpose of any study, test, investigation, evaluation
7 and/or assessment undertaken by YOU for the purpose of determining, in whole or in
8 part, whether VICTOZA CAUSES and/or is capable of CAUSING pancreatic cancer, that
9 is not yet started or completed and, to the extent such DOCUMENTS exist, the study
10 protocols; data; researcher and/or laboratory technician notebooks, notes, logs, bench notes,
11 books, computer files and emails; results; and reports for each such study, test,
12 investigation, evaluation and/or assessment.

13 **RESPONSE:**

14 **OTHER STUDIES**

15 **REQUEST NO. 28:** The standard operating procedures and/or policy and procedures
16 manuals for all other studies YOU are aware of that bear, in whole or in part, on whether
17 VICTOZA CAUSES and/or is capable of CAUSING pancreatic cancer (whether such
18 study, test, investigation, evaluation and/or assessment involves VICTOZA, another
19 GLP-1 receptor or DPP-4 inhibitor, any other drug, or no drug).

20 **RESPONSE:**

21
22 **REQUEST NO. 29:** Every DOCUMENT that addresses the significance of any other
23 study, test, investigation, evaluation and/or assessment YOU are aware of that bears, in
24 whole or in part, on whether VICTOZA CAUSES and/or is capable of CAUSING
25 pancreatic cancer (whether such study, test, investigation, evaluation and/or assessment
26 involves VICTOZA, another GLP-1 receptor or DPP-4 inhibitor, any other drug, or no
27 drug), in relation to whether VICTOZA CAUSES pancreatic cancer.

28 **RESPONSE:**

1 **REQUEST NO. 30:** The memoranda, reports and other similar DOCUMENTS that
2 describe the nature and intended purpose of any other study, test, investigation, evaluation
3 and/or assessment YOU are aware of that bears, in whole or in part, on whether
4 VICTOZA CAUSES and/or is capable of CAUSING pancreatic cancer (whether such
5 study, test, investigation, evaluation and/or assessment involves VICTOZA, another
6 GLP-1 receptor or DPP-4 inhibitor, any other drug, or no drug) that is not yet started or
7 completed and, to the extent such DOCUMENTS exist, the study protocols; data;
8 researcher and/or laboratory technician notebooks, notes, logs, bench notes, books,
9 computer files and emails; results; reports; and pancreatic specimens (e.g., histology
10 slides, tissue samples, etc.) for each such other study, test, investigation, evaluation and/or
11 assessment.

12 **RESPONSE:**

13
14 **FDA AND EMA**

15 **REQUEST NO. 31:** The study protocols; data; researcher and/or laboratory technician
16 notebooks, notes, logs, bench notes, books, computer files and emails; results; reports; and
17 pancreatic specimens (e.g., histology slides, tissue samples, etc.) that were provided to the
18 FDA for any other study, test, investigation, evaluation and/or assessment YOU are aware
19 of that bears, in whole or in part, on whether VICTOZA CAUSES and/or is capable of
20 CAUSING pancreatic cancer (whether such study, test, investigation, evaluation and/or
21 assessment involves VICTOZA, another GLP-1 receptor or DPP-4 inhibitor, any other
22 drug, or no drug).

23 **RESPONSE:**

24 **REQUEST NO. 32:** The study protocols; data; researcher and/or laboratory technician
25 notebooks, notes, logs, bench notes, books, computer files and emails; results; reports; and
26 pancreatic specimens (e.g., histology slides, tissue samples, etc.) that were not provided to
27 the FDA for any other study, test, investigation, evaluation and/or assessment YOU are
28 aware of that bears, in whole or in part, on whether VICTOZA CAUSES and/or is

1 capable of CAUSING pancreatic cancer (whether such study, test, investigation,
2 evaluation and/or assessment involves VICTOZA, another GLP-1 receptor or DPP-4
3 inhibitor, any other drug, or no drug).

4 **RESPONSE:**

5
6 **REQUEST NO. 33:** The study protocols; data; researcher and/or laboratory technician
7 notebooks, notes, logs, bench notes, books, computer files and emails; results; reports; and
8 pancreatic specimens (e.g., histology slides, tissue samples, etc.) that were provided to the
9 EMA for any other study, test, investigation, evaluation and/or assessment YOU are
10 aware of that bears, in whole or in part, on whether VICTOZA CAUSES and/or is
11 capable of CAUSING pancreatic cancer (whether such study, test, investigation,
12 evaluation and/or assessment involves VICTOZA, another GLP-1 receptor or DPP-4
13 inhibitor, any other drug, or no drug).

14 **RESPONSE:**

15 **REQUEST NO. 34:** The study protocols; data; researcher and/or laboratory technician
16 notebooks, notes, logs, bench notes, books, computer files and emails; results; reports; and
17 pancreatic specimens (e.g., histology slides, tissue samples, etc.) that were not provided to
18 the EMA for any other study, test, investigation, evaluation and/or assessment YOU are
19 aware of that bears, in whole or in part, on whether VICTOZA CAUSES and/or is
20 capable of CAUSING pancreatic cancer (whether such study, test, investigation,
21 evaluation and/or assessment involves VICTOZA, another GLP-1 receptor or DPP-4
22 inhibitor, any other drug, or no drug).

23 **RESPONSE:**

24
25 **REQUEST NO. 35:** All emails, letters, reports, memoranda and other written
26 communications YOU have sent to or received from any governmental agency (including,
27 without limitation, the FDA and EMA) or any other entity or person regarding whether
28

1 VICTOZA or any other GLP-1 agonist or DPP-4 inhibitor CAUSES and/or is capable of
2 CAUSING pancreatitis and/or pancreatic cancer.

3 **RESPONSE:**

4
5 **REQUEST NO. 36:** If any of YOUR employees, officers, directors, agents, contractors,
6 key opinion leaders, members of speakers' bureaus, advisory board members, or scientific
7 advisors corresponded with or supplied information or data to the European Medicines
8 Agency (EMA) about or in connection with any assessments of whether VICTOZA or
9 any other GLP-1 agonist or DPP-4 inhibitor CAUSES and/or is capable of CAUSING
10 pancreatic cancer (including, without limitation, as reflected in the EMA's 2013
11 "Assessment report for GLP-1 based therapies" and its 2014 "Pancreatic Safety of
12 Incretin-Based Drugs – FDA and EMA Assessment"), produce the correspondence,
13 information or data provided to the EMA, and any correspondence or other
14 DOCUMENTS YOU received from the EMA in response.

15 **RESPONSE:**

16 **REQUEST NO. 37:** If any of YOUR employees, officers, directors, agents, contractors,
17 key opinion leaders, members of speakers' bureaus, advisory board members, or scientific
18 advisors corresponded with or supplied information or data to the FDA about or in
19 connection with any assessments of whether VICTOZA or any other GLP-1 agonist or
20 DPP-4 inhibitor CAUSES and/or is capable of CAUSING pancreatic cancer (including,
21 without limitation, as reflected in the FDA's 2014 "Pancreatic Safety of Incretin-Based
22 Drugs – FDA and EMA Assessment"), produce the correspondence, information or data,
23 and any correspondence or other DOCUMENTS YOU received from the FDA in
24 response.

25 **RESPONSE:**

1 **ADVERSE EVENTS**

2 **REQUEST NO. 38:** The standard operating procedures and/or policy and procedures
3 manuals for the handling of pancreatitis and pancreatic cancer ADVERSE EVENTS and
4 REPORTABLE EVENTS pertaining to VICTOZA.

5 **RESPONSE:**

6
7 **REQUEST NO. 39:** Produce in electronic format complete copies of all databases used
8 to track, trend, or record information regarding pancreatitis and pancreatic cancer
9 ADVERSE EVENTS that YOU associated with VICTOZA. To the extent that YOUR
10 databases incorporate the following information for pancreatitis and pancreatic cancer
11 ADVERSE EVENTS for VICTOZA, this request includes:

- 12 a. All DOCUMENTS and information in YOUR possession regarding each
ADVERSE EVENT;
- 13 b. Whether the ADVERSE EVENT was in the form of a MedWatch Report,
14 communication from a medical provider or consumer, an ADVERSE
EVENT REPORT (“AER”) or some other form;
- 15 c. All attempts YOU made to communicate with anyone to gather further
information regarding each ADVERSE EVENT;
- 16 d. All communications YOU made or received, including the substance of the
17 communications, the identities of any persons YOU communicated with
internally, and the identities of any persons YOU communicated with
18 externally regarding each ADVERSE EVENT;
- 19 e. The nature and results of any investigations YOU conducted to determine
the CAUSE of each ADVERSE EVENT, and/or the basis of any decisions
20 not to investigate;
- 21 f. Any experts and/or consultants whom YOU contacted regarding any
ADVERSE EVENT;
- 22 g. YOUR deliberations and decision-making processes used to determine
whether each ADVERSE EVENT was or was not a REPORTABLE
23 EVENT;
- 24 h. Any action YOU took as a result of each ADVERSE EVENT;
- 25 i. YOUR analysis and conclusions as to the nature, severity and frequency of
each ADVERSE EVENT;
- 26 j. All ADVERSE EVENT report forms, including supplemental reports and
related information, that were submitted to the FDA for each ADVERSE
27 EVENT;
- 28 k. The current status or final disposition of each ADVERSE EVENT; and

- 1 1. Any reporting rates analysis and/or trending analysis done regarding each
2 ADVERSE EVENT.

3 To the extent that YOUR databases do not incorporate some or all of the information
4 referenced above in subparts a-1, produce the equivalent information by reference to the
5 business records in which YOU store it.

6 **RESPONSE:**

7 **REQUEST NO. 40:** The complete file that YOU established and maintain in response to
8 each individual pancreatitis and pancreatic cancer ADVERSE EVENT for VICTOZA
9 (commonly known as “source files,” ADVERSE EVENT report files, backup files, or
10 files containing source documentation related to ADVERSE EVENTS). This request
11 seeks the production of all DOCUMENTS and information contained or discussed in the
12 source files for each ADVERSE EVENT, which should contain most or all of the
13 DOCUMENTS and information described in the preceding request in subparts a-1.

14 **RESPONSE:**

15
16 **REQUEST NO. 41:** To the extent not already produced in response to the preceding
17 requests, produce all DOCUMENTS for each pancreatitis and pancreatic cancer
18 REPORTABLE EVENT for VICTOZA, including the following:

- 19 a. All DOCUMENTS and information in YOUR possession regarding each
20 REPORTABLE EVENT;
21 b. Whether the REPORTABLE EVENT was in the form of a MedWatch
22 Report, communication from a medical provider or consumer, an
23 ADVERSE EVENT REPORT (“AER”) or some other form;
24 c. All attempts YOU made to communicate with anyone to gather further
25 information regarding each REPORTABLE EVENT;
26 d. All communications YOU made or received, including the substance of the
27 communications, the identities of any persons YOU communicated with
28 internally, and the identities of any persons YOU communicated with
externally regarding each REPORTABLE EVENT;
e. The nature and results of any investigations YOU conducted to determine
the CAUSE of each REPORTABLE EVENT, and/or the basis of any
decisions not to investigate;

- f. Any experts and/or consultants whom YOU contacted regarding any REPORTABLE EVENT;
- g. YOUR deliberations and decision-making processes used to determine whether each underlying ADVERSE EVENT was or was not a REPORTABLE EVENT;
- h. Any action YOU took as a result of each REPORTABLE EVENT;
- i. YOUR analysis and conclusions as to the nature, severity and frequency of each REPORTABLE EVENT;
- j. All REPORTABLE EVENT report forms, including supplemental reports and related information, that were submitted to the FDA for each REPORTABLE EVENT;
- k. The current status or final disposition of each REPORTABLE EVENT; and
- l. Any reporting rates analysis and/or trending analysis done regarding each REPORTABLE EVENT.

RESPONSE:

REQUEST NO. 42: All DOCUMENTS that state or discuss any request by the FDA that YOU conduct post-market surveillance of VICTOZA with respect to pancreatitis and pancreatic cancer. Include in your response any correspondence, plans, reports, or other DOCUMENTS submitted by YOU to the FDA in response.

RESPONSE:

REQUEST NO. 43: All charts, graphs, schematics, reports, memoranda and other similar DOCUMENTS analyzing, summarizing and/or reporting on pancreatitis and/or pancreatic cancer ADVERSE EVENTS for VICTOZA, including all such DOCUMENTS that compare VICTOZA to any other therapeutic agent(s) for the treatment of type 2 diabetes. To the extent that such DOCUMENTS were prepared in color, they should also be produced in color.

RESPONSE:

REQUEST NO. 44: All reports, memoranda and other DOCUMENTS that list and/or explain the criteria YOU use to determine whether any particular pancreatitis and/or pancreatic cancer ADVERSE EVENT is related to the patient's use of VICTOZA.

1 **RESPONSE:**

2
3 **LITERATURE REGARDING CAUSAL CONNECTION WITH PANCREATIC CANCER**

4 **REQUEST NO. 45:** All medical and scientific literature that YOUR company has
5 identified that relates to the association between VICTOZA or any other GLP-1 agonist or
6 DPP-4 inhibitor and pancreatitis and/or pancreatic cancer.

7 **RESPONSE:**

8
9 **REQUEST NO. 46:** All reports, analyses, presentations, memoranda and other
10 DOCUMENTS YOU are aware of that address, in whole or in part, whether VICTOZA or
11 any other GLP-1 agonist or DPP-4 inhibitor CAUSES and/or is capable of CAUSING
12 pancreatitis and/or pancreatic cancer.

13 **RESPONSE:**

14 **REQUEST NO. 47:** To the extent not already produced in response to the preceding
15 requests, all published and unpublished medical and scientific literature, reports, analyses,
16 presentations, memoranda and other DOCUMENTS YOU are aware of that address
17 whether VICTOZA or any other GLP-1 agonist or DPP-4 inhibitor CAUSES the
18 proliferation of abnormal or dysfunctional beta cells; the proliferation of abnormal or
19 dysfunctional alpha cells; the expansion of pancreatic ductal glands in rats; the formation of
20 dysplastic lesions and chronic pancreatitis in mice; increases in the weight and/or size of the
21 exocrine pancreas; the inhibition of apoptosis of pancreatic ductal cells; and the inhibition of
22 apoptosis of pancreatic islet cells.

23 **RESPONSE:**

24
25 **REQUEST NO. 48:** To the extent not already produced in response to the preceding
26 requests, all published and unpublished medical and scientific literature, reports, analyses,
27 presentations, memoranda and other DOCUMENTS YOU are aware of that address the
28 mechanism of action of VICTOZA or any other GLP-1 agonist or DPP-4 inhibitor.

1 **RESPONSE:**

2
3 **REQUEST NO. 49:** To the extent not already produced in response to the preceding
4 requests, all published and unpublished medical and scientific literature, reports, analyses,
5 presentations, memoranda and other DOCUMENTS YOU are aware of that address the
6 effect that VICTOZA or any other GLP-1 agonist or DPP-4 inhibitor has on the pancreas.

7 **RESPONSE:**

8
9 **REQUEST NO. 50:** All reports, memoranda and other DOCUMENTS that list and/or
10 explain the criteria YOU use to determine whether VICTOZA or any other GLP-1 agonist
11 or DPP-4 inhibitor CAUSES and/or is capable of CAUSING pancreatitis and/or pancreatic
12 cancer.

13 **RESPONSE:**

14 **REQUEST NO. 51:** All medical and/or scientific literature that YOU have reported to the
15 FDA or any other regulatory authorities that relates to the association between VICTOZA
16 and pancreatitis and/or pancreatic cancer, including, but not limited to, all PSURs,
17 PADERS/PAERS, and independent submissions.

18 **RESPONSE:**

19
20 **REQUEST NO. 52:** To the extent not already produced in response to the preceding
21 requests, produce all communications, analyses, expert analyses, safety board analyses,
22 independent analyses, and/or meta-analyses that pertain to, reference, or in any way
23 discuss any of the medical and scientific literature and/or the preclinical, nonclinical,
24 animal, human, observational and/or other studies referred to above with respect to
25 whether VICTOZA or any other GLP-1 agonist or DPP-4 inhibitor CAUSES and/or is
26 capable of CAUSING pancreatitis and/or pancreatic cancer.

27 **RESPONSE:**

1 **COMMUNICATIONS REGARDING CAUSAL CONNECTION WITH PANCREATIC CANCER**

2 **REQUEST NO. 53:** All communications YOU have had with the author(s) of the medical
3 and/or scientific literature referenced above with respect to whether VICTOZA or any other
4 GLP-1 agonist or DPP-4 inhibitor CAUSES and/or is capable of CAUSING pancreatic
5 cancer.

6 **RESPONSE:**

7
8 **REQUEST NO. 54:** All emails, letters, reports, memoranda and other written
9 communications YOU have had internally regarding whether VICTOZA or any other GLP-
10 1 agonist or DPP-4 inhibitor CAUSES and/or is capable of CAUSING pancreatic cancer.

11 **RESPONSE:**

12 **REQUEST NO. 55:** If YOU have made and/or requested label changes in the United
13 States or elsewhere to add or strengthen warnings about the risks of pancreatitis and/or
14 pancreatic cancer associated with VICTOZA at any time since YOU began to market
15 VICTOZA, provide all DOCUMENTS, including emails, letters, reports, memoranda and
16 other written communications, that YOU have sent to or received from the FDA and/or
17 any applicable foreign country's regulatory authority in connection with each label
18 change and/or request. This request to produce includes, without limitation, any PAS or
19 CBE submitted by YOU to the FDA, and any response YOU have received from the
20 FDA.

21 **RESPONSE:**

22
23 **REQUEST NO. 56:** All emails, letters, reports, memoranda and other written
24 communications to or from any source discussing or referring to physician monitoring
25 and/or testing for pancreatitis and/or pancreatic cancer associated with the use of
26 VICTOZA.

27 **RESPONSE:**

1 **REQUEST NO. 57:** The meeting minutes and any summaries of meeting minutes for each
2 internal meeting at which YOU discussed whether VICTOZA or any other GLP-1 agonist
3 or DPP-4 inhibitor CAUSES and/or is capable of CAUSING pancreatitis and/or pancreatic
4 cancer.

5 **RESPONSE:**

6
7 **REQUEST NO. 58:** All notes, recordings, handouts, materials and presentations YOU or
8 YOUR employees are aware of that were made or obtained in connection with any meeting,
9 conference or other event, internal or external, at which the subject of whether VICTOZA or
10 any other GLP-1 agonist or DPP-4 inhibitor CAUSES and/or is capable of CAUSING
11 pancreatitis and/or pancreatic cancer was discussed.

12 **RESPONSE:**

13 **REQUEST NO. 59:** If the sale of VICTOZA has ever been prohibited due to concerns
14 that it may CAUSE pancreatitis and/or pancreatic cancer, produce all emails, letters,
15 reports, memoranda and other written communications received by YOU addressing or
16 discussing those concerns, and all emails, letters, reports, memoranda and other written
17 communications prepared by YOU (whether sent or not sent) addressing or discussing
18 those concerns.

19 **RESPONSE:**

20 **INCRETIN SCIENCE AND SCIENTIFIC LITERATURE: BIAS/INFLUENCE/RELIABILITY**

21 **REQUEST NO. 60:** If any of YOUR employees, officers, directors, agents, contractors,
22 key opinion leaders, members of speakers' bureaus, advisory board members, or scientific
23 advisors have corresponded with or supplied information or data to any scientific journal
24 regarding whether VICTOZA or any other GLP-1 agonist or DPP-4 inhibitor CAUSES
25 and/or is capable of CAUSING pancreatitis and/or pancreatic cancer, produce the
26 correspondence, information and/or data.

27 **RESPONSE:**

1 **REQUEST NO. 61:** If any of YOUR employees, officers, directors, agents, contractors,
2 key opinion leaders, members of speakers' bureaus, advisory board members, or scientific
3 advisors have submitted a manuscript, case report, article described as an
4 "advertisement," opinion piece or topic to any scientific journal regarding whether
5 VICTOZA or any other GLP-1 agonist or DPP-4 inhibitor CAUSES and/or is capable of
6 CAUSING pancreatitis and/or pancreatic cancer, produce the material submitted.

7 **RESPONSE:**

8
9 **REQUEST NO. 62:** If any of YOUR employees, officers, directors, agents, contractors,
10 key opinion leaders, members of speakers' bureaus, advisory board members, or scientific
11 advisors have participated in or supplied information or data to any expert meeting, panel
12 or committee investigating or reviewing whether VICTOZA or any other GLP-1 agonist
13 or DPP-4 inhibitor CAUSES and/or is capable of CAUSING pancreatitis and/or
14 pancreatic cancer, produce the correspondence, data and other DOCUMENTS supplied
15 to, received from, or created by such meeting(s), panel(s) or committee proceedings.

16 **RESPONSE:**

17 **REQUEST NO. 63:** If any of YOUR employees, officers, directors, agents, contractors,
18 key opinion leaders, members of speakers' bureaus, advisory board members, or scientific
19 advisors corresponded with or supplied information or data to any authors, medical
20 journals, scientific journals, any other publications, any diabetes research or research-
21 funding organizations or persons affiliated with them, any scientific advisors, or any
22 consultants about Dr. Susan Bonner-Weir, Dr. Alexandra E. Butler, Dr. Peter C. Butler,
23 Dr. David D. Dore, Dr. Daniel J. Drucker, Dr. Michael Elashoff, Dr. Robert Elashoff, Dr.
24 Edwin Gale, Dr. Rajesh Garg, Dr. Belinda Gier, Dr. Fred Gorlick, Dr. Steven Kahn, Dr.
25 Jacqueline Koehler, Dr. Aleksey V. Matveyenko, Dr. Robert Ratner, Dr. Sonal Singh, or
26 Dr. Jay S. Skyler, and/or about any of the work they have done or authored regarding
27 incretin medications, produce the correspondence, information and/or data.

28 **RESPONSE:**

1 **REQUEST NO. 64:** To the extent not already produced in response to the preceding
2 requests, all emails, letters, reports, memoranda and other written communications with
3 authors, medical journals, scientific journals, any other publications, any diabetes research
4 or research-funding organizations or persons affiliated with them, any scientific advisors, or
5 any consultants about whether VICTOZA or any other GLP-1 agonist or DPP-4 inhibitor
6 CAUSES and/or is capable of CAUSING pancreatitis and/or pancreatic cancer.

7 **RESPONSE:**

8
9 **REQUEST NO. 65:** All DOCUMENTS that constitute or discuss compensation,
10 honoraria, grants, scholarships or gifts, whether offered or actually paid, to individuals or
11 institutions for work (including, without limitation, work done on preclinical studies,
12 nonclinical studies, animal studies, human studies, other research, or the authorship of
13 articles) concerning whether VICTOZA or any other GLP-1 agonist or DPP-4 inhibitor
14 CAUSES and/or is capable of CAUSING pancreatitis and/or pancreatic cancer. Include in
15 YOUR response, without limitation, all such DOCUMENTS pertaining to Dr. Susan
16 Bonner-Weir, Dr. David D. Dore, Dr. Daniel J. Drucker, Dr. Rajesh Garg, Dr. Fred
17 Gorlick, Dr. Steven Kahn, Dr. Jacqueline Koehler, Dr. Robert Ratner, Dr. Jay S. Skyler,
18 and/or the companies and/or organizations that employ them.

19 **RESPONSE:**

20 **DOCUMENT RETENTION, DESTRUCTION AND ARCHIVING**

21 **REQUEST NO. 66:** All of YOUR DOCUMENT retention, destruction and archiving
22 policies that apply to VICTOZA preclinical, nonclinical, animal, human and/or
23 observational studies; other studies addressing, in whole or in part, whether VICTOZA
24 CAUSES and/or is capable of CAUSING pancreatitis and/or pancreatic cancer;
25 VICTOZA ADVERSE EVENTS; and any other DOCUMENTS addressing whether
26 VICTOZA CAUSES and/or is capable of CAUSING pancreatitis and/or pancreatic
27 cancer.

28 **RESPONSE:**

1 PRIVILEGE LOG

2 REQUEST NO. 67: To the extent that YOU have withheld any DOCUMENTS
3 responsive to any of these requests under any claim of privilege, produce a privilege log
4 as required by Fed. R. Civ. P. 26.

5 **RESPONSE:**

6 DATED: April 8, 2014

7 
8 **PLAINTIFFS' COUNSEL**

9 Michael K. Johnson
10 **JOHNSON BECKER, PLLC**
11 33 South Sixth Street, Suite 4530
12 Minneapolis, Minnesota 55402
13 Telephone: (612) 436-1800
14 Facsimile: (612) 436-1801
15 mjohnson@johnsonbecker.com

16 Ryan L. Thompson
17 **WATTS GUERRA LLP**
18 5250 Prue Road, Suite 525
19 San Antonio, Texas 78240
20 Telephone: (210) 448-0500
21 Facsimile: (210) 448-0501
22 rthompson@wattsguerra.com

23 Hunter J. Shkolnik
24 **NAPOLI, BERN, RIPKA**
25 **& SHKOLNIK LLP**
26 350 Fifth Avenue
27 New York, New York 10018
28 Telephone: (212)267-3700
Facsimile: (212)587-0031
hunter@napolibern.com

Tor A. Hoerman
TORHOERMAN LAW LLC
101 W. Vandalia Street, Suite 350
Edwardsville, Illinois 62025
Phone: (618) 656-4400
Facsimile: (618) 656-4401
thoerman@torhoermanlaw.com