

EXHIBIT A

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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 INTERROGATORIES**
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. 33, Plaintiffs propound the following General Causation
24 Interrogatories to Novo Nordisk, Inc. ("Defendant"). Each interrogatory shall be
25 answered separately and fully in writing under oath unless it is objected to, in which event
26 the reasons for the objection shall be stated. The answers are to be signed by the person
27 making them, and the objections signed by the attorney making them.

1 **PRECLINICAL, NONCLINICAL AND ANIMAL STUDIES**

2 **INTERROGATORY NO. 3:** For each preclinical, nonclinical and/or animal study
3 involving VICTOZA, separately identify the study protocols; data; researcher and/or
4 laboratory technician notebooks, notes, logs, bench notes, books, computer files and emails;
5 results; reports; and pancreatic specimens (e.g., histology slides, tissue samples, etc.)
6 provided to the FDA, and any 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.) not provided to the
9 FDA.

10 **ANSWER:**

11 **INTERROGATORY NO. 4:** For each preclinical, nonclinical and/or animal study
12 involving VICTOZA, separately identify the study protocols; data; researcher and/or
13 laboratory technician notebooks, notes, logs, bench notes, books, computer files and emails;
14 results; reports; and pancreatic specimens (e.g., histology slides, tissue samples, etc.)
15 provided to the EMA, and any study protocols; data; researcher and/or laboratory
16 technician notebooks, notes, logs, bench notes, books, computer files and emails; results;
17 reports; and pancreatic specimens (e.g., histology slides, tissue samples, etc.) not
18 provided to the EMA.

19 **ANSWER:**

20
21 **INTERROGATORY NO. 5:** If any preclinical, nonclinical and/or animal studies
22 involving VICTOZA are not yet started or completed, describe the nature and intended
23 purpose of each study, and identify the person(s) in charge of each.

24 **ANSWER:**

25 **HUMAN STUDIES**

26 **INTERROGATORY NO. 6:** For each human study involving VICTOZA, separately
27 identify the study protocols; data; researcher and/or laboratory technician notebooks, notes,
28

1 logs, bench notes, books, computer files and emails; results; reports; and pancreatic
2 specimens (e.g., histology slides, tissue samples, etc.) provided to the FDA, and any study
3 protocols; data; researcher and/or laboratory technician notebooks, notes, logs, bench notes,
4 books, computer files and emails; results; reports; and pancreatic specimens (e.g.,
5 histology slides, tissue samples, etc.) not provided to the FDA.

6 **ANSWER:**

7
8 **INTERROGATORY NO. 7:** For each human study involving VICTOZA, separately
9 identify the study protocols; data; researcher and/or laboratory technician notebooks, notes,
10 logs, bench notes, books, computer files and emails; results; reports; and pancreatic
11 specimens (e.g., histology slides, tissue samples, etc.) provided to the EMA, and any
12 study protocols; data; researcher and/or laboratory technician notebooks, notes, logs, bench
13 notes, books, computer files and emails; results; reports; and pancreatic specimens (e.g.,
14 histology slides, tissue samples, etc.) not provided to the EMA.

15 **ANSWER:**

16 **INTERROGATORY NO. 8:** If any human studies involving VICTOZA are not yet
17 started or completed, describe the nature and intended purpose of each study, and identify
18 the person(s) in charge of each.

19 **ANSWER:**

20
21 **OBSERVATIONAL STUDIES**

22 **INTERROGATORY NO. 9:** For each observational study (including, without limitation,
23 claims database studies, cohort studies and other epidemiological studies) involving
24 VICTOZA, separately identify the study protocols; data; researcher and/or laboratory
25 technician notebooks, notes, logs, bench notes, books, computer files and emails; results;
26 and reports provided to the FDA, and any study protocols; data; researcher and/or
27 laboratory technician notebooks, notes, logs, bench notes, books, computer files and emails;
28 results; and reports not provided to the FDA.

1 **ANSWER:**

2
3 **INTERROGATORY NO. 10:** For each observational study (including, without
4 limitation, claims database studies, cohort studies and other epidemiological studies)
5 involving VICTOZA, separately identify the study protocols; data; researcher and/or
6 laboratory technician notebooks, notes, logs, bench notes, books, computer files and emails;
7 results; and reports provided to the EMA, and any study protocols; data; researcher and/or
8 laboratory technician notebooks, notes, logs, bench notes, books, computer files and emails;
9 results; and reports not provided to the EMA.

10 **ANSWER:**

11 **INTERROGATORY NO. 11:** If any observational studies involving VICTOZA
12 (including, without limitation, claims database studies, cohort studies and other
13 epidemiological studies) are not yet started or completed, describe the nature and
14 intended purpose of each study, and identify the person(s) in charge of each.

15 **ANSWER:**

16
17 **STUDIES TO DETERMINE CAUSAL CONNECTION WITH PANCREATIC CANCER**

18 **INTERROGATORY NO. 12:** For each study, test, investigation, evaluation and/or
19 assessment undertaken by YOU for the purpose of determining, in whole or in part,
20 whether VICTOZA CAUSES and/or is capable of CAUSING pancreatic cancer,
21 separately identify the study protocols; data; researcher and/or laboratory technician
22 notebooks, notes, logs, bench notes, books, computer files and emails; results; and reports
23 provided to the FDA, and any study protocols; data; researcher and/or laboratory technician
24 notebooks, notes, logs, bench notes, books, computer files and emails; results; and reports
25 not provided to the FDA.

26 **ANSWER:**

1 **INTERROGATORY NO. 13:** For each study, test, investigation, evaluation and/or
2 assessment undertaken by YOU for the purpose of determining, in whole or in part,
3 whether VICTOZA CAUSES and/or is capable of CAUSING pancreatic cancer,
4 separately identify the study protocols; data; researcher and/or laboratory technician
5 notebooks, notes, logs, bench notes, books, computer files and emails; results; and reports
6 provided to the EMA, and any study protocols; data; researcher and/or laboratory
7 technician notebooks, notes, logs, bench notes, books, computer files and emails; results;
8 and reports not provided to the EMA.

9 **ANSWER:**

10 **INTERROGATORY NO. 14:** If any study, test, investigation, evaluation and/or
11 assessment undertaken by YOU for the purpose of determining, in whole or in part,
12 whether VICTOZA CAUSES and/or is capable of CAUSING pancreatic cancer has not
13 yet been started or completed, describe the nature and intended purpose of each such
14 study, test, investigation, evaluation and/or assessment, and identify the person(s) in
15 charge of each.

16 **ANSWER:**

17
18 **OTHER STUDIES**

19 **INTERROGATORY NO. 15:** For every other study, test, investigation, evaluation
20 and/or assessment YOU are aware of that bears, in whole or in part, on whether
21 VICTOZA CAUSES and/or is capable of CAUSING pancreatic cancer (whether such
22 study, test, investigation, evaluation and/or assessment involves VICTOZA, another
23 GLP-1 receptor or DPP-4 inhibitor, any other drug, or no drug), separately identify the
24 study protocols; data; researcher and/or laboratory technician notebooks, notes, logs, bench
25 notes, books, computer files and emails; results; reports; and pancreatic specimens (e.g.,
26 histology slides, tissue samples, etc.) provided to the FDA, and any study protocols; data;
27 researcher and/or laboratory technician notebooks, notes, logs, bench notes, books,
28

1 computer files and emails; results; reports; and pancreatic specimens (e.g., histology
2 slides, tissue samples, etc.) not provided to the FDA.

3 **ANSWER:**

4
5 **INTERROGATORY NO. 16:** For every other study, test, investigation, evaluation
6 and/or assessment YOU are aware of that bears, in whole or in part, on whether
7 VICTOZA CAUSES and/or is capable of CAUSING pancreatic cancer (whether such
8 study, test, investigation, evaluation and/or assessment involves VICTOZA, another
9 GLP-1 receptor or DPP-4 inhibitor, any other drug, or no drug), separately identify the
10 study protocols; data; researcher and/or laboratory technician notebooks, notes, logs, bench
11 notes, books, computer files and emails; results; reports; and pancreatic specimens (e.g.,
12 histology slides, tissue samples, etc.) provided to the EMA, and any study protocols; data;
13 researcher and/or laboratory technician notebooks, notes, logs, bench notes, books,
14 computer files and emails; results; reports; and pancreatic specimens (e.g., histology
15 slides, tissue samples, etc.) not provided to the EMA.

16 **ANSWER:**

17 **INTERROGATORY NO. 17:** If any such other study, test, investigation, evaluation
18 and/or assessment YOU are aware of that bears, in whole or in part, on whether
19 VICTOZA CAUSES and/or is capable of CAUSING pancreatic cancer (whether such
20 study, test, investigation, evaluation and/or assessment involves VICTOZA, another
21 GLP-1 receptor or DPP-4 inhibitor, any other drug, or no drug) has not yet been started or
22 completed, describe the nature and intended purpose of each such study, and identify the
23 person(s) in charge of each.

24 **ANSWER:**

25
26 **INTERROGATORY NO. 18:** Do YOU contend that any one study, test, investigation,
27 evaluation and/or assessment (whether such study, test, investigation, evaluation and/or
28 assessment involves VICTOZA, another GLP-1 receptor or DPP-4 inhibitor, any other

1 drug, or no drug), establishes that VICTOZA does not CAUSE and/or is not capable of
2 CAUSING pancreatic cancer? If so, explain your answer.

3 **ANSWER:**

4
5 **ADVERSE EVENTS**

6 **INTERROGATORY NO. 19:** Identify each pancreatitis and pancreatic cancer
7 ADVERSE EVENT that YOU are aware of with respect to VICTOZA (whether it arose
8 from pre-market or post-market use) that YOU deemed to be related to the patient's use
9 of VICTOZA, including its Bates number (if already produced), date, name of the
10 author/reporter, and the location from which the ADVERSE EVENT was reported.

11 **ANSWER:**

12 **INTERROGATORY NO. 20:** Identify each pancreatitis and pancreatic cancer
13 ADVERSE EVENT that YOU are aware of with respect to VICTOZA (whether it arose
14 from pre-market or post-market use) that YOU did not deem to be related to the patient's
15 use of VICTOZA, including its Bates number (if already produced), date, name of the
16 author/reporter, and the location from which the ADVERSE EVENT was reported.

17 **ANSWER:**

18
19 **INTERROGATORY NO. 21:** Identify each pancreatitis and pancreatic cancer
20 ADVERSE EVENT that YOU are aware of with respect to VICTOZA that involved a
21 participant in a human study who was diagnosed either while still participating in the
22 study or after withdrawing or otherwise being removed from the study, including its Bates
23 number (if already produced), date, name of the author/reporter, and the location from
24 which the ADVERSE EVENT was reported; and state whether or not YOU deemed such
25 ADVERSE EVENT related to the patient's use of VICTOZA.

26 **ANSWER:**

1 **INTERROGATORY NO. 22:** Identify each instance of pancreatitis and pancreatic
2 cancer that YOU are aware of with respect to VICTOZA that involved a participant in a
3 human study who was diagnosed either while still participating in the study or after
4 withdrawing or otherwise being removed from the study, and which YOU did not classify
5 as an ADVERSE EVENT, including its Bates number (if already produced), date, name
6 of the author/reporter, and the location from which the instance was reported; and state
7 whether or not YOU deemed such instance related to the patient's use of VICTOZA.

8 **ANSWER:**

9
10 **INTERROGATORY NO. 23:** Itemize and explain the criteria YOU use to determine
11 whether an ADVERSE EVENT is related to a patient's use of VICTOZA, and identify
12 the DOCUMENTS that list and/or explain those criteria.

13 **ANSWER:**

14 **LITERATURE REGARDING CAUSAL CONNECTION WITH PANCREATIC CANCER**

15 **INTERROGATORY NO. 24:** Identify all medical and/or scientific literature YOU are
16 aware of, including studies, editorials and/or peer-reviewed articles, that relates to the
17 association between VICTOZA or any other GLP-1 agonist or DPP-4 inhibitor and
18 pancreatitis and/or pancreatic cancer.

19 **ANSWER:**

20
21 **INTERROGATORY NO. 25:** Itemize and explain the criteria YOU use to determine
22 whether VICTOZA or any other GLP-1 agonist or DPP-4 inhibitor CAUSES and/or is
23 capable of CAUSING pancreatic cancer, and identify the DOCUMENTS that list and/or
24 explain those criteria.

25 **ANSWER:**

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

2 **INTERROGATORY NO. 30:** If any of YOUR employees, officers, directors, agents,
3 contractors, key opinion leaders, members of speakers' bureaus, advisory board members,
4 or scientific advisors have corresponded with or supplied information or data to any
5 scientific journal regarding whether VICTOZA or any other GLP-1 agonist or DPP-4
6 inhibitor CAUSES and/or is capable of CAUSING pancreatitis and/or pancreatic cancer,
7 identify: the person(s) involved; the scientific journal(s) involved; the date(s) on which
8 the correspondence took place or the information or data was supplied; and the
9 correspondence, information and/or data.

10 **ANSWER:**

11 **INTERROGATORY NO. 31:** If any of YOUR employees, officers, directors, agents,
12 contractors, key opinion leaders, members of speakers' bureaus, advisory board members,
13 or scientific advisors have submitted a manuscript, case report, article described as an
14 "advertisement," opinion piece or topic to any scientific journal regarding whether
15 VICTOZA or any other GLP-1 agonist or DPP-4 inhibitor CAUSES and/or is capable of
16 CAUSING pancreatitis and/or pancreatic cancer, identify: the person(s) involved; the
17 scientific journal(s) involved; the date(s) on which the material was submitted; and the
18 materials that were submitted.

19 **ANSWER:**

20
21 **INTERROGATORY NO. 32:** If any of YOUR employees, officers, directors, agents,
22 contractors, key opinion leaders, members of speakers' bureaus, advisory board members,
23 or scientific advisors have participated in or supplied information or data to any expert
24 meeting, panel or committee investigating or reviewing whether VICTOZA or any other
25 GLP-1 agonist or DPP-4 inhibitor CAUSES and/or is capable of CAUSING pancreatitis
26 and/or pancreatic cancer, identify: the person(s) involved; the name(s) and place(s) of the
27 meeting(s), panel(s) or committee proceedings; the date(s) on which the meeting(s),
28 panel(s) or committee proceedings took place; and the correspondence, data and other

1 DOCUMENTS supplied to, received from, or created by such meeting(s), panel(s) or
2 committee proceedings.

3 **ANSWER:**

4
5 **INTERROGATORY NO. 33:** If any of YOUR employees, officers, directors, agents,
6 contractors, key opinion leaders, members of speakers’ bureaus, advisory board members,
7 or scientific advisors corresponded with or supplied information or data to the European
8 Medicines Agency (EMA) about or in connection with any assessments of whether
9 VICTOZA or any other GLP-1 agonist or DPP-4 inhibitor CAUSES and/or is capable of
10 CAUSING pancreatitis and/or pancreatic cancer (including, without limitation, as
11 reflected in the EMA’s 2013 “Assessment report for GLP-1 based therapies” and its 2014
12 “Pancreatic Safety of Incretin-Based Drugs – FDA and EMA Assessment”), identify: the
13 person(s) involved; the name(s) of the person(s) with whom they corresponded or
14 supplied information or data to at the EMA; the date(s) on which the correspondence took
15 place or the information or data was supplied; and the correspondence, information or
16 data.

16 **ANSWER:**

17
18 **INTERROGATORY NO. 34:** If any of YOUR employees, officers, directors, agents,
19 contractors, key opinion leaders, members of speakers’ bureaus, advisory board members,
20 or scientific advisors corresponded with or supplied information or data to the FDA about
21 or in connection with any assessments of whether VICTOZA or any other GLP-1 agonist
22 or DPP-4 inhibitor CAUSES and/or is capable of CAUSING pancreatitis and/or
23 pancreatic cancer (including, without limitation, as reflected in the EMA’s 2013
24 “Assessment report for GLP-1 based therapies” and its 2014 “Pancreatic Safety of
25 Incretin-Based Drugs – FDA and EMA Assessment”), identify: the person(s) involved;
26 the name(s) of the person(s) with whom they corresponded or supplied information or
27 data to at the EMA; the date(s) on which the correspondence took place or the
28 information or data was supplied; and the correspondence, information or data.

1 **ANSWER:**

2
3 **INTERROGATORY NO. 35:** If any of YOUR employees, officers, directors, agents,
4 contractors, key opinion leaders, members of speakers' bureaus, advisory board members,
5 or scientific advisors corresponded with or supplied information or data to any scientific
6 journal about authors Dr. Peter C. Butler, Dr. Michael Elashoff, Dr. Robert Elashoff, Dr.
7 Alexandra E. Butler, Dr. Belinda Gier, Dr. Aleksey V. Matveyenko, Dr. Edwin Gale, or
8 Dr. Sonal Singh, and/or about any of the works they have authored on incretin
9 medications, identify: the person(s) involved; the scientific journal(s) involved; the
10 date(s) on which the correspondence took place or the information or data was supplied;
11 and the correspondence, information and/or data.

12 **ANSWER:**

13
14 DATED: April 8, 2014

PLAINTIFFS' COUNSEL



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