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UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF CALIFORNIA

IN RE INCRETIN-BASED THERAPIES  
PRODUCTS LIABILITY LITIGATION

Case No. 3:13-md-02452 AJB (MDD)

*This Document Relates to All Cases*

**EXHIBITS 1 - 12 TO JOINT  
MOTION FOR DETERMINATION  
OF DISPUTES RELATED TO THE  
SCOPE OF WRITTEN  
DISCOVERY RELATED TO  
GENERAL CAUSATION**

Hon. Mitchell D. Dembin

# **EXHIBIT 1**

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9 *Plaintiff Co-Liaison Counsel*

10 UNITED STATES DISTRICT COURT  
11 SOUTHERN DISTRICT OF CALIFORNIA

12 IN RE INCRETIN-BASED  
13 THERAPIES PRODUCTS  
14 LIABILITY LITIGATION

15 *As to All Related and Member Cases*

CASE NO. 13md2452-AJB (MDD)

MDL 2452

Magistrate: Hon. Mitchell D. Dembin  
Judge: Hon. Anthony J. Battaglia

17  
18 **PLAINTIFFS' FIRST SET OF INTERROGATORIES**

19 **TO DEFENDANT ELI LILLY AND COMPANY**

20 To: Eli Lilly and Company c/o Pepper Hamilton LLP  
21 620 Eighth Avenue, 37<sup>th</sup> Floor, New York, NY 10018

22  
23 Pursuant to Rule 33 Federal Rules of Civil Procedure, the Plaintiffs in the above  
24 referenced case, hereby propound the following First Set of Interrogatories to Eli Lilly  
25 and Company ("Defendant"). Plaintiffs request Defendant to permit the Plaintiffs to  
26 review and copy the answers listed below.  
27

1 Each interrogatory, as provided by law, shall be answered separately and fully in  
2 writing under oath, unless it is objected to, in which event the reasons for the objection  
3 shall be stated. The answers are to be signed by the person making them, and the  
4 objections signed by the attorney making them. Answers to these interrogatories, or  
5 objections in lieu thereof, shall be served within 30 days from the service of this  
6 document.  
7

8 Under Rule 33 Federal Rules of Civil Procedure, these Interrogatories are  
9 continuing in nature. Defendant, therefore, is required to supplement their responses as  
10 new or different information becomes known.  
11

### 12 DEFINITIONS

13  
14 1. "DOCUMENTS," "DOCUMENT," and "DOCUMENTATION" as used in  
15 this Request is coextensive with the meaning of the terms "DOCUMENTS" and "tangible  
16 things" in Rule 34 of the Federal Rules of Civil Procedure, and shall have the broadest  
17 possible meaning and interpretation ascribed to the terms "DOCUMENTS" and "tangible  
18 things" under Rule 34, and the applicable Local Rules. Consistent with the above  
19 definition, the term "DOCUMENT" shall include, without limitation, any database,  
20 written, printed, typed, photostatic, photographed, recorded, computer-generated,  
21 computer-stored, or otherwise maintained or reproduced communication or  
22 representation, any data compilation in any form, whether comprised of letters, words,  
23 numbers, pictures, sounds, bytes, e-mails, electronic signals or impulses, electronic data,  
24 active files, deleted files, file fragments, or any combination thereof including, without  
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1 limitation, all memoranda, notes, records, letters, envelopes, telegrams, messages, studies,  
2 analyses, contracts, agreements, projections, estimates, working papers, accounts,  
3 analytical records, reports and/or summaries of investigations, opinions or reports of  
4 consultants, opinions or reports of experts, opinions or reports of accountants, other  
5 reports, trade letters, press releases, comparisons, books, diaries, articles, magazines,  
6 newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, forecasts,  
7 drawings, diagrams, instructions, minutes of meetings, correspondence and  
8 communications (as defined below) of any type (including but not limited to video files,  
9 audio files, inter- and intra-office communications), questionnaires, surveys, charts,  
10 graphs, photographs, phonographs, films, tapes, discs, data cells, drums, printouts, all  
11 other compiled data which can be obtained (translated, if necessary, through intermediary  
12 or other devices into usable forms), DOCUMENTS maintained on, stored in or generated  
13 on any electronic transfer or storage system, any preliminary versions, drafts or revisions  
14 of any of the foregoing, and other writings or DOCUMENTS of whatever description or  
15 kind, whether produced or authorized by or on behalf of YOU or anyone else, and shall  
16 include all non-identical copies and drafts of any of the foregoing now in the possession,  
17 custody or control of YOU, or the former or present directors, officers, counsel, agents,  
18 employees, partners, consultants, principals, and/or persons acting on YOUR behalf.  
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24 2. "Communication", "communications" and/or "correspondence" shall mean  
25 and refer to any oral, written, spoken or electronic transmission of information, including  
26 but not limited to, meetings, discussions, conversations, telephone calls, memoranda,  
27  
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1 letters, emails, text messages, postings, instructions, conferences, or seminars or any other  
2 exchange of information between yourselves or between you and any other person or  
3 entity.

4  
5 3. "Electronic data" or "data" means the original (native electronic format),  
6 and any non-identical copies (whether non-identical because of notes made on copies or  
7 attached comments, annotations, marks, transmission notations, or highlighting of any  
8 kind) of writings of every kind and description whether inscribed by mechanical,  
9 facsimile, electronic, magnetic, digital, or other means. Electronic data includes, by way  
10 of example only, computer programs (whether private, commercial, or works-in-  
11 progress), programming notes or instructions, activity listings of electronic mail receipts  
12 and/or transmittals, output resulting from the use of any software program, including  
13 word processing documents, spreadsheets, database files, charts, graphs and outlines,  
14 electronic mail, operating systems, source code of all types, peripheral drivers, PIF files,  
15 batch files, ASCII files, and any and all miscellaneous files and/or file fragments,  
16 regardless of the media on which they reside and regardless of whether said electronic  
17 data consists of an active file, deleted file or file fragment. Electronic data includes any  
18 and all items stored on computer memories, hard disks, floppy disks, CD-ROMs,  
19 removable media such as zip drives, usb drives, storage cartridges, Bernoulli Boxes and  
20 their equivalent, magnetic tapes of all types, microfiche, punched cards, punched tape,  
21 computer chips, including, but not limited to EPROM, PROM, RAM and ROM, on or in  
22 any other vehicle for digital data storage and/or transmittal. The term electronic data also  
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1 includes the file, folder tabs and/or containers and labels appended to, or associated with,  
2 any physical storage device associated with each original and/or copy.

3 4. "Possession, custody or control" shall mean and refer to any documents in  
4 your possession, custody or control. A document is deemed to be in your "possession,  
5 custody or control" if it is in your physical custody, or if it is in the physical custody of  
6 another person or entity and you: (a) own such document in whole or in part; (b) have a  
7 right by contract, statute or otherwise to use, inspect, examine or copy such document on  
8 any terms; (c) have an understanding, express or implied, that you may use, inspect,  
9 examine or copy such document on any terms; or (d) have, as a practical matter, been able  
10 to use, inspect, examine or copy such document when you have sought to do so. Such  
11 documents shall include, without limitation, documents that are in the custody of your  
12 attorney(s), employees, staff, representatives and agents.

13 5. "Relating to," "relate to," "referring to," "refer to," "reflecting," "reflect,"  
14 "concerning," or "concern" shall mean evidencing, regarding, concerning, discussing,  
15 embodying, describing, summarizing, containing, constituting, showing, mentioning,  
16 reflecting, pertaining to, dealing with, relating to, referring to in any way or manner, or in  
17 any way logically or factually, connecting with the matter described in that paragraph of  
18 these demands, including DOCUMENTS attached to or used in the preparation of or  
19 concerning the preparation of the DOCUMENTS.

20 6. Unless otherwise indicated, the "relevant period" for the information sought  
21 is 1995 to the present.



1 c. Date of correspondence; and

2 d. Location of correspondence.

3 **Interrogatory No. 2:**

4 Has any employee, officer, director, agent, contractor, director, key opinion leader,  
5 member of speaker bureau, advisory board member, or scientific advisor of YOURS  
6 submitted a manuscript, case report, article described as an "advertisement," opinion  
7 piece or topic to any scientific journal on any of the following topics: incretin mimetic  
8 therapies, glucagon-like peptide 1 therapies, dipeptidyl peptidase-4 inhibitor therapies,  
9 exenatide, liraglutide, sitagliptin, saxagliptin, alogliptin, and linagliptin? If so, for each,  
10 please state:  
11  
12

- 13 a. Individual's name, title, address, phone number who submitted the  
14 manuscript, case report, article, opinion piece or topic;  
15  
16 b. Journal name(s) to which the manuscript, case report, article, opinion  
17 piece or topic was submitted;  
18  
19 c. Working title of manuscript, case report, article, opinion piece or  
20 topic;  
21  
22 d. Date of submission;  
23  
24 e. Location of the manuscript, case report, article, opinion piece or topic;  
25  
26 f. The amount paid for every manuscript, case report, article, opinion  
27 piece or topic for which payment was made by or on behalf of YOU  
28 for the publication of such document.

1 **Interrogatory No. 3:**

2 Has any employee, officer, director, agent, contractor, director, key opinion leader,  
3 member of speaker bureau, advisory board member, or scientific advisor of YOURS  
4 participated in or supplied information to any expert meeting, panel or committee  
5 anywhere in the world, investigating or reviewing glucagon-like peptide 1 based or  
6 dipeptidyl peptidase-4 inhibitor therapies? If so, for each, please state:  
7

- 8 a. Individual's name, title, address, phone number who participated in or  
9 supplied such information;  
10  
11 b. Name and place of meeting, panel or committee the individual  
12 participated or supplied information;  
13  
14 c. Date(s) of meeting, panel or committee proceedings; and  
15  
16 d. Location of all writings, data, correspondence and attachments  
17 supplied, received or created through such meeting, panel or  
18 committee.

19 **Interrogatory No. 4:**

20 Has any employee, officer, director, agent, contractor, director, key opinion leader,  
21 member of speaker bureau, advisory board member, or scientific advisor of YOURS  
22 corresponded with or supplied information or data to the European Medicines Agency  
23 ("EMA") about or in connection with its 2013 "Assessment report for GLP-1 based  
24 therapies." If so, for each, please state:  
25

- 26 a. Correspondent's name, title, address, phone number;  
27  
28

- 1 b. Journal name(s);  
2 c. Date of correspondence; and  
3 d. Location of correspondence.  
4

5 **Interrogatory No. 5:**

6 Has any employee, officer, director, agent, contractor, director, key opinion leader,  
7 member of speaker bureau, advisory board member, or scientific advisor of YOURS  
8 corresponded with or supplied information or data to any scientific journal about any of  
9 the following individuals: Dr. Peter C. Butler, Dr. Michael Elashoff, Dr. Robert Elashoff,  
10 Dr. Alexandra E. Butler, Dr. Belinda Gier, Dr. Aleksey V. Matveyenko, Dr. Edwin Gale,  
11 Dr. Sonal Singh? If so, for each, please state:  
12

- 13 a. Correspondent's name, title, address, phone number;  
14 b. Journal name(s);  
15 c. Date of correspondence; and  
16 d. Whereabouts of correspondence.  
17

18 Dated: November 21, 2013

19 RESPECTFULLY SUBMITTED,

20 By: Gay M. Blatt

21 **GAYLE M. BLATT**

22 CASEY GERRY SCHENK FRANCAVILLA

23 BLATT & PENFIELD, LLP

24 110 Laurel St.

25 San Diego, CA 92101

26 Phone: (619) 238-1811

27 Facsimile: (619) 544-9232

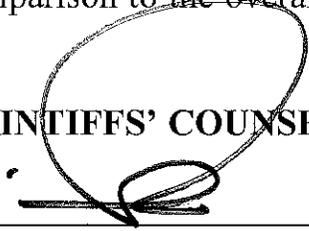
28 gmb@cglaw.com

*Plaintiff Co-Liaison Counsel*

- 1 (b) When the removal(s) occurred;  
2 (c) Whether the discontinuance(s) were permanent or temporary;  
3 (d) The primary motivations behind the discontinuance(s); and,  
4 (e) The rate of discontinuance in comparison to the overall prevalence of the  
5 drug(s) on the market.

6 DATED: January 30, 2014

**PLAINTIFFS' COUNSEL**

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# **EXHIBIT 2**

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15 **UNITED STATES DISTRICT COURT**  
16 **SOUTHERN DISTRICT OF CALIFORNIA**

17 **IN RE INCRETIN-BASED**  
18 **THERAPIES PRODUCTS**  
19 **LIABILITY LITIGATION**

20 **Relates to: ALL CASES**

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

**MDL – 2452**

**Judge: Hon. Anthony J. Battaglia**

21 **PLAINTIFFS' AMENDED SECOND SET OF INTERROGATORIES**

22 **TO DEFENDANT ELI LILLY AND COMPANY**

23 To: Eli Lilly and Company c/o Pepper Hamilton, LLP  
24 620 Eighth Avenue, 37<sup>th</sup> Floor, New York, NY 10018

25 Pursuant to Fed. R. Civ. P. 33, Plaintiffs propound the following Amended Second  
26 Set of Interrogatories to Eli Lilly and Company ("Defendant"). Each interrogatory shall  
27 be answered separately and fully in writing under oath unless it is objected to, in which  
28 event the reasons for the objection shall be stated. The answers are to be signed by the  
person making them, and the objections signed by the attorney making them. By

1 agreement of the parties, service of this amended Second Set of Interrogatories has not  
2 restarted the 30-day limit for responding, inasmuch as it is identical to the interrogatories  
3 served on January 7, 2014, but for deletion of interrogatories 7, 12, 15, 20, 26 and 38 of  
4 the prior set. Nonetheless, Defendant has requested a modest extension of time to  
5 respond, and the parties are currently negotiating the exact date on which Defendant's  
6 responses will be due.

7 These interrogatories are continuing in nature pursuant to Fed. R. Civ. P. 33.  
8 Defendant is therefore required to supplement its responses as new or different  
9 information becomes known.

### 10 **DEFINITIONS AND INSTRUCTIONS**

11 The following terms shall have the following meanings, unless the context requires  
12 otherwise:

13 1. "YOU," "YOUR," or "DEFENDANT" – means Eli Lilly and Company, as  
14 well as its divisions, parents, subsidiaries, and each of their present and former officers,  
15 directors, employees, agents, and representatives.

16 2. "ELECTRONIC STORAGE DEVICE" – means any device capable of storing  
17 ESI for any period of time, including without limitation, disks, including hard disks and  
18 floppy disks, CD-ROMs, DVDs, network servers, shared servers, computers, magnetic  
19 tape, back-up tape, voice-mail, temporary files, telephones, and PDAs, whether currently  
20 on Defendant's premises or otherwise (e.g. at an employee's home or remote office).

21 3. "ELECTRONICALLY STORED INFORMATION" or "ESI" – means any  
22 information stored in an electronic medium, and shall include, without limitation, any  
23 information, including files, documents, images, video, metadata or any combination  
24 thereof stored, created, or used on any ELECTRONIC STORAGE DEVICE, disk, tape  
25 (including backup tapes and other backup media), or other computer or digital storage  
26 medium, microfilm, microfiche, floppy, or any other storage or recording medium. ESI  
27 includes without limitation electronic mail messages, information stored on web pages or  
28 web servers, and database records.

1           4. "RELATE" – or any variant thereof, including, but not limited to, the term  
2 "RELATING TO," shall be understood to apply if the data or information evidences,  
3 mentions, constitutes, contains, summarizes, describes, concerns, refers to, supports,  
4 contradicts or addresses the subject matter described in this set of demands in which the  
5 term "relate," or any variant thereof, appears.

6           5. "DOCUMENT" or "DOCUMENTS" – means any handwriting, typewriting,  
7 printing, photostating, photographing, photocopying, transmitting by electronic mail or  
8 facsimile, and every other means of recording upon any tangible thing, any form of  
9 communication or representation, including letters, words, pictures, sounds, or symbols,  
10 or combinations thereof, and any record thereby created, regardless of the manner in  
11 which the record has been stored; and shall include, without limitation, the original (and  
12 absent the original then a copy thereof), and all file copies and copies not identical to the  
13 original of any writing or record of every type, form, and description that is in the  
14 possession, custody, or control of the responding party, or which is no longer in the  
15 responding party's possession but of which the responding party still has knowledge,  
16 whether or not said writings or records are claimed to be privileged or otherwise immune  
17 from discovery, including by way of illustration and not limitation, the following items:  
18 notes, correspondence, communications of any nature (including intra-company  
19 communications and correspondence), electronic mail messages, telegrams, cables,  
20 memoranda (including internal memoranda), notebooks of any nature, including  
21 laboratory and engineering reports; summaries, minutes, and records of telephone  
22 conversations, personal conversations or interviews; diaries, routing slips or memoranda,  
23 reports (including tests and analysis reports), books, manuals, publications, invoices,  
24 specifications, shipping papers, purchase orders, flow charts, schematics, diagrams,  
25 photographs of any nature, minutes or recordings of any meetings or conferences,  
26 including lists of persons attending meetings or conferences; transcripts of oral testimony  
27 or statements; labels, tags, fliers, brochures, pamphlets, advertisements, advertising  
28 layouts, circulars, trade letters, press releases, and translations; presentations, including  
boards, transparencies, storybooks and/or scripts; drafts of original or preliminary notes

1 on, and marginal comments appearing on, any DOCUMENTS; whether those writings or  
2 records are on paper, magnetic disk, tape or other computer or digital storage medium,  
3 microfilm, floppy, or any other storage media or recording media.

4 6. "ADVERSE EVENT" – refers to any harmful or undesired experience related  
5 or potentially related to the use of BYETTA, including, without limitation, disability  
6 caused by use of the drug, life-threatening adverse drug experience that caused or placed  
7 the patient at risk of death, or unexpected adverse drug experiences not previously  
8 observed or anticipated.

9 7. Use of the term "BYETTA" includes reference to the medication bearing that  
10 trade name as well as the chemical compound exenatide.

11 8. Unless otherwise indicated, the "relevant period" for the information sought is  
12 1995 to the present.

### 13 INTERROGATORIES

#### 14 **INTERROGATORY NO. 1:**

15 Please identify the name(s) of the company(ies) or other entities that manufactured,  
16 marketed, tested, created, distributed, packaged, promoted, and/or sold BYETTA during  
17 each year that BYETTA was manufactured, marketed, tested, created, distributed,  
18 packaged, promoted, and/or sold. If separate companies or other entities were responsible  
19 for different aspects of the manufacturing, marketing, testing, creating, distributing,  
20 packaging, promoting, and/or selling of BYETTA, then indicate which company or other  
21 entity was responsible for each of the above aspects for each year BYETTA was  
22 manufactured, marketed, tested, created, distributed, packaged, promoted, and/or sold, up  
through and including the present.

#### 23 **INTERROGATORY NO. 2:**

24 Describe in detail the relationship between and among Defendant and any other  
25 companies or other entities that manufactured, marketed, tested, created, distributed,  
26 packaged, promoted, and/or sold BYETTA. Provide with your answer any  
27 DOCUMENTS memorializing the agreements between and among Defendant and any  
28 such companies or other entities.

1 **INTERROGATORY NO. 3:**

2 Identify all license agreements and/or development agreements with any person  
3 and/or entity concerning BYETTA, and produce a copy of any written agreement.

4 **INTERROGATORY NO. 4:**

5 Identify the names and state the present and/or last known address(es) of the  
6 individual(s)/employee(s) with the most knowledge pertaining to BYETTA, including but  
7 not limited to:

- 8 (a) The Product managers at all times Defendant manufactured, produced,  
9 promoted, formulated, created, designed, sold and/or tested BYETTA,  
10 identifying the individuals by time period;
- 11 (b) The sales representatives (whether nationally, regionally, etc.) at all times  
12 Defendant manufactured, produced, promoted, formulated, created,  
13 designed, sold and/or tested BYETTA, identifying the individuals by time  
14 period;
- 15 i. If the sales representative was a regional position, please identify all  
16 regions that Defendant utilized and the person(s) most  
17 knowledgeable for each specific region, identifying the individuals  
18 by time period; and
- 19 ii. Describe the sales and marketing organizational structure utilized  
20 by YOU regarding BYETTA;
- 21 (c) The safety and compliance individuals in charge of reporting ADVERSE  
22 EVENTS and complaints of side effects to the FDA or any other agency,  
23 and investigating all ADVERSE EVENTS and complaints of side effects  
24 at all times Defendant manufactured, produced, promoted, formulated,  
25 created, designed, sold and/or tested BYETTA, identifying the  
26 individuals by time period;
- 27 (d) The person or persons at all times responsible for Quality Assurance with  
28 regard to BYETTA;
- (e) Defendant's liaison(s) to the FDA, whether or not part of the regulatory  
affairs department, with regard to BYETTA at all times Defendant  
manufactured, produced, promoted, formulated, created, designed, sold  
and/or tested BYETTA, identifying the individuals by time period;
- (f) Defendant's researcher(s) and developer(s) responsible for BYETTA at  
all times Defendant manufactured, produced, promoted, formulated,  
created, designed, sold and/or tested BYETTA, identifying the  
individuals by time period;

- 1 (g) Defendant's scientific researcher(s) of BYETTA at all times Defendant  
2 manufactured, produced, promoted, formulated, created, designed, sold  
3 and/or tested BYETTA, identifying the individuals by time period;
- 4 (h) The person or persons responsible for Defendant's marketing and/or  
5 detailing of BYETTA at all times Defendant manufactured, produced,  
6 promoted, formulated, created, designed, sold and/or tested BYETTA,  
7 identifying the individuals by time period;
- 8 (i) Defendant's Chief Medical Officer at all times Defendant manufactured,  
9 produced, promoted, formulated, created, designed, sold and/or tested  
10 BYETTA, identifying the individuals by time period;
- 11 (j) Defendant's Chief Executive Officer ("CEO") at all times Defendant  
12 manufactured, produced, promoted, formulated, created, designed, sold  
13 and/or tested BYETTA, identifying the individuals by time period;
- 14 (k) Defendant's President at all times Defendant manufactured, produced,  
15 promoted, formulated, created, designed, sold and/or tested BYETTA,  
16 identifying the individuals by time period;
- 17 (l) Defendant's Chief Financial Officer ("CFO") at all times Defendant  
18 manufactured, produced, promoted, formulated, created, designed, sold  
19 and/or tested BYETTA, identifying the individuals by time period;
- 20 (m) Defendant's Chief Information Officer ("CIO") at all times Defendant  
21 manufactured, produced, promoted, formulated, created, designed, sold  
22 and/or tested BYETTA, identifying the individuals by time period;
- 23 (n) The person responsible for regulatory affairs at all times Defendant  
24 manufactured, produced, promoted, formulated, created, designed, sold  
25 and/or tested BYETTA, identifying the individuals by time period;
- 26 (o) Defendant's liaison(s) with any subsidiary or affiliate located outside the  
27 United States that manufactured, produced, promoted, formulated,  
28 created, designed, sold and/or tested BYETTA, identifying the  
individuals by time period;
- (p) Defendant's General Counsel and/or the names of all associate general  
counsel at all times Defendant manufactured, produced, promoted,  
formulated, created, designed, sold and/or tested BYETTA, identifying  
the individuals by time period;
- (q) Defendant's Chief Operating Officer ("COO") at all times Defendant  
manufactured, produced, promoted, formulated, created, designed, sold  
and/or tested BYETTA, identifying the individuals by time period; and
- (r) Members of any International Product Team maintained or utilized by  
YOU at all times Defendant manufactured, produced, promoted,

1 formulated, created, designed, sold and/or tested BYETTA, identifying  
2 the individuals by time period.

3 **INTERROGATORY NO. 5:**

4 Identify all persons and/or entities paid by YOU for consulting services of any kind  
5 concerning BYETTA, and for each such person or entity state the nature of the consulting  
6 services rendered and the time frame(s) during which they were rendered.

7 **INTERROGATORY NO. 6:**

8 Did YOU or others acting on YOUR behalf ever consult with researchers,  
9 physicians, nurse scientists, public health advocates, governmental bodies, or others not  
10 on your own staff about whether BYETTA, JANUVIA, JANUMET and/or VICTOZA  
11 were effective and/or as effective as other therapeutic agents for the treatment of type 2  
12 diabetes? If so, state: (a) how efficacy was defined; (b) the method(s) by which efficacy  
13 was determined; (c) the name of each consultant; (d) the date or time periods of each  
14 consultation; (e) the amounts paid to each consultant; (f) the opinions and/or findings  
15 given to YOU by each consultant; (g) if those opinions and/or findings were ever  
16 published, identify the name(s) and location(s) of the publication(s); and (h) if those  
17 opinions and/or findings were not published, (1) explain why not, (2) state whether they  
18 were written anywhere, and (3) state the location of each such writing.

19 **INTERROGATORY NO. 7:**

20 Identify every country in which BYETTA is or has been marketed or sold by YOU  
21 and/or marketed or sold by other corporate entities pursuant to an agreement with YOU,  
22 whether it was marketed or sold under the brand name BYETTA or any other name.  
23 Include in your answer: (a) the date YOU or your agents first sought regulatory approval  
24 to market or sell BYETTA in each country; (b) the date on which approval to market or  
25 sell BYETTA was granted in each country; and (c) the date on which BYETTA first  
26 became commercially available in each country.

27 **INTERROGATORY NO. 8:**

28 Did Defendant ever sell, manufacture, market, promote, test, or issue warnings  
about side effects concerning BYETTA outside the United States, even if the product had

1 a different name or formulation? If so, please state the countries and the dates that  
2 BYETTA or the differently named and/or formulated product was and/or is sold,  
3 manufactured, marketed, promoted, or tested, and specify each country where the  
4 warnings were different than those issued in the United States.

5 **INTERROGATORY NO. 9:**

6 Identify the design used by YOU with respect to BYETTA, and any changes in the  
7 design of BYETTA from the time it was first developed until the present. Include in your  
8 answer the specific changes made to the design, the date of the changes, and why the  
9 changes were made.

10 **INTERROGATORY NO. 10:**

11 Identify each and every database that YOU or others acting on YOUR behalf  
12 maintain or have maintained that is likely to contain any data or information about  
13 BYETTA, JANUVIA, JANUMET, VICTOZA and/or any other GLP-1 agonist or DPP-4  
14 inhibitor. Include in your answer:

- 15 (a) The name of each database;
- 16 (b) The identity of the database administrators;
- 17 (c) The dates of use for each database;
- 18 (d) The hardware and software platforms each database utilized;
- 19 (e) The type of information about BYETTA, JANUVIA, JANUMET,  
20 VICTOZA, and/or any other GLP-1 agonist or DPP-4 inhibitor contained  
21 in each database;
- 22 (f) Whether each database was a transactional database;
- 23 (g) Whether each database was a warehouse database;
- 24 (h) The identity of all other databases that fed information into each database  
25 identified;
- 26 (i) The search capabilities of each database;
- 27 (j) The back-up schedule for each database;
- 28 (k) Whether each database has an audit trail feature that has been enabled;
- (l) The archival, retention and destruction policies with respect to each  
database; and,

1 (m) Whether any database has been discontinued and what was done with the  
2 data contained in any retired database.

3 **INTERROGATORY NO. 11:**

4 Have YOU ever had a document retention policy, document destruction policy, or  
5 document archiving policy? If so, describe each such policy, indicating the applicable  
6 time frames for each policy.

7 **INTERROGATORY NO. 12:**

8 Identify any and all insurance agreements under which any insurer may be liable to  
9 satisfy part or all of a judgment which may be entered against YOU in this litigation  
10 and/or any individual case, or to indemnify or reimburse YOU for payments made to  
11 satisfy a judgment, and with respect to each, please state:

- 12 (a) The name and address of each insurance company and the maximum  
13 amount of all liability coverage of each insurance company, indicating  
14 the amount per person, the amount for all persons, and the amount for  
15 each accident or occurrence;
- 16 (b) If there is excess or umbrella liability insurance coverage, state the name  
17 and address of each insurance carrier for such coverage and the amounts  
18 of coverage available from each, indicating the amount of such coverage,  
19 the aggregate limits and the amount of the underlying limits that must be  
20 exhausted prior to such policy being impacted;
- 21 (c) Set forth how the available insurance coverage identified in paragraphs  
22 (a) and (b) above have been impacted or diminished by any settlements,  
23 awards or judgments that have been paid by any insurance company  
24 identified in paragraph (a) or (b) above;
- 25 (d) If YOU are self-insured, identify the available amounts of such self-  
26 insurance per person for all persons, and the amount for each accident or  
27 occurrence; and
- 28 (e) Identify any entity that has made a reservation of rights.

29 **INTERROGATORY NO. 13:**

30 Have YOU performed or had performed on YOUR behalf any animal studies in  
31 which the safety, side effects, and/or efficacy of BYETTA was tested or otherwise  
32 documented? If so, please state the following:

- 33 (a) When was the first time such a study was made by or for YOU;

- 1 (b) How many studies were done by or for YOU, and state the inclusive dates  
2 of each study;
- 3 (c) Why each study was done;
- 4 (d) Identify the type(s) of animal(s) tested, and state the number of animals  
involved in each study;
- 5 (e) Why the particular test animal was selected for each study;
- 6 (f) What dosage of BYETTA was selected for each study;
- 7 (g) Why the particular dosage of BYETTA was selected for each study;
- 8 (h) What comparator drug or drugs, if any, were used for each study;
- 9 (i) Why the particular comparator drug or drugs, if any, were used for each  
study;
- 10 (j) Whether the studies were completed and whether the data was ever  
11 published; if the data was published, identify the date, publication, and  
authors; and if the data was not published, state why not; and
- 12 (k) Whether the study results were submitted to the FDA and, if so, state the  
13 date on which it was submitted and identify the Bates number of any  
cover letter accompanying the submission.

14 **INTERROGATORY NO. 14:**

15 Identify all pre-approval or post-approval clinical trials or other studies that were  
16 conducted by YOU or on YOUR behalf (whether completed or not) concerning  
17 BYETTA, pursuant to an Investigational New Drug (“IND”) Application, New Drug  
18 Application (“NDA”), Supplemental New Drug Application (“SNDA”), or Abbreviated  
19 New Drug Application (“ANDA”) or conducted for any other reason and, with respect to  
20 each such trial or study, state:

- 21 (a) The protocol number and study name;
- 22 (b) The names and addresses of all clinical investigation sites;
- 23 (c) The names and addresses of all clinical investigators, including any  
medical institution they are affiliated with;
- 24 (d) The names and addresses of all sponsor-investigators;
- 25 (e) The names and addresses of all contract research organizations;
- 26 (f) Whether the studies have been concluded;
- 27 (g) The duration of each study;
- 28

- 1 (h) The Bates number for each final study report and each study protocol;
- 2 (i) A description of what each study concerned, and the results of each
- 3 study;
- 4 (j) The identity of each person responsible for maintaining the records
- 5 regarding these studies;
- 6 (k) Whether any study was terminated before it was fully completed, and if
- 7 so state why;
- 8 (l) Whether any studies have been terminated at the request and/or the
- 9 demand of the FDA;
- 10 (m) Whether the study was submitted for publication and, if so, whether it
- 11 was accepted for publication;
- 12 (n) The citation to any published study;
- 13 (o) The date that the data from each study was "locked" and the date that the
- 14 data was unblended;
- 15 (p) The number of patients enrolled in each study and the number of patients
- 16 who completed each study;
- 17 (q) Identify those studies that were designed to test the safety of BYETTA;
- 18 (r) Identify those studies that were designed to test the efficacy of BYETTA;
- 19 (s) Whether the FDA has ever lodged any complaints, warnings, or
- 20 reprimands with respect to the conduct of any of the studies;
- 21 (t) All amendments to any study protocol and the reason why the protocol
- 22 was amended;
- 23 (u) Whether any human tissue was obtained as part of any study and, if so,
- 24 identify the study and state the location of the tissue;
- 25 (v) If an animal study, state the type of animal used in the study;
- 26 (w) Whether any animal tissue was obtained as part of any study and, if
- 27 so, identify the study and state the location of the tissue;
- 28 (x) Whether any animal pancreatic tissue was obtained as part of any study
- and, if so, identify the study and state the location of the tissue;
- (y) Whether any pancreatic islet cell hyperplasia was diagnosed in any
- animal study and, if so, identify the study and state the location of the
- tissue;
- (z) Whether any pancreatic duct inflammation was diagnosed in any animal
- study and, if so, identify the study and state the location of the tissue;

- 1 (aa) Whether any PanIN lesions were diagnosed in any animal study and,  
2 if so, identify the study and state the location of the tissue;
- 3 (bb) Whether any nesidioblastosis was diagnosed in any animal study and,  
4 if so, identify the study and state the location of the tissue;
- 5 (cc) Whether any animal thyroid tissue was obtained as part of any study  
6 and, if so, identify the study and state the location of the tissue;
- 7 (dd) The Bates number for all informed consent forms;
- 8 (ee) Identify who has custody of the protocols followed in each study;
- 9 (ff) Identify all records and data from, reflecting and/or relating to each  
10 such study; and,
- 11 (gg) Whether the study results were submitted to the FDA and, if so, the  
12 date on which they were submitted and the Bates number of any cover  
13 letter accompanying the submissions.

14 **INTERROGATORY NO. 15:**

15 Identify all clinical trials or other studies that were conducted by YOU or on  
16 YOUR behalf (whether completed or not) concerning any product (whether or not it was  
17 ever approved for marketing or submitted to any Regulatory Authority for such approval)  
18 containing exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or DPP-4  
19 inhibitor as one of its components and, with respect to each such trial or study, state:

- 20 (a) The names and addresses of all clinical investigation sites;
- 21 (b) The names and addresses of all clinical investigators;
- 22 (c) The names and addresses of all sponsor-investigators;
- 23 (d) The names and addresses of all contract research organizations;
- 24 (e) Whether such studies have been concluded;
- 25 (f) A description of what each study concerned, and the results of each such  
26 study;
- 27 (g) The identity of each person responsible for maintaining the records  
28 regarding these studies;
- (h) Whether any study was terminated before it was fully completed and, if  
so, state why;
- (i) Whether any studies have been terminated at the request and/or the  
demand of the FDA;

- 1 (j) Whether the FDA has ever lodged any complaints, warnings, or  
2 reprimands with respect to the conduct of any of the studies;
- 3 (k) Identify who has custody of the protocols followed in each study;
- 4 (l) Identify all records and data from, reflecting and/or relating to each such  
5 study; and,
- 6 (m) Whether the study results were submitted to the FDA and, if so, the date  
7 on which they were submitted and the Bates number of any cover letter  
8 accompanying the submissions.

9 **INTERROGATORY NO. 16:**

10 Please identify and describe all tests, investigations, studies, evaluations and/or  
11 assessments conducted by YOU or on YOUR behalf, and/or relied upon by YOU either in  
12 whole or in part, relating in any way to BYETTA, JANUVIA, JANUMET and/or  
13 VICTOZA and pancreatitis and/or pancreatic cancer, including:

- 14 (a) If published, the exact title, author, publisher, place of publication, and  
15 year of publication of any such test, investigation, study, evaluation  
16 and/or assessment;
- 17 (b) The dates that each such test, investigation, study, evaluation and/or  
18 assessment was conducted;
- 19 (c) The name and job title of each of YOUR employees, agents and/or  
20 servants, if any, who were responsible for the performance and/or  
21 evaluation of, and/or were in any way involved with the performance  
22 and/or evaluation of, each such test, investigation, study, evaluation  
23 and/or assessment;
- 24 (d) Whether the individuals identified in sub-paragraph (c) above are still  
25 employed by YOU and, if not, their last known address;
- 26 (e) A step-by-step description of the methodology of each such test,  
27 investigation, study, evaluation and/or assessment;
- 28 (f) The purpose of each such test, investigation, study, evaluation and/or  
assessment;
- (g) The full and complete verbatim results of each such test, investigation,  
study, evaluation and/or assessment;
- (h) All raw data for each such test, investigation, study, evaluation and/or  
assessment;
- (i) The date, manner, and means by which YOU first became aware of each  
such test, investigation, study, evaluation and/or assessment; and,

1 (j) Whether such data from each such test, investigation, study, evaluation  
2 and/or assessment was submitted to the FDA, and if so, on what date.

3 **INTERROGATORY NO. 17:**

4 From the date YOU first developed, designed, manufactured, distributed, sold,  
5 and/or made BYETTA available to consumers up through the present, identify all studies  
6 YOU relied on, if any, as proof of the safety and/or efficacy of BYETTA, and/or the  
7 relative safety and/or efficacy of BYETTA compared to other diabetes medications. As  
8 to each such published study, identify the study by title, author, publication, and year of  
9 publication. If any unpublished study was involved, state the title of such unpublished  
10 study and the date YOU received its results. For each study, also provide:

- 11 (a) If the study was not published, explain why not;
- 12 (b) For studies undertaken by YOU, the date YOU first undertook each such  
13 study;
- 14 (c) The name and title of each of YOUR employee(s) and/or agent(s) who  
15 were responsible and/or involved with each such study, and state whether  
16 they are still employed by YOU, and if not, provide their last known  
17 addresses and phone numbers; and
- 18 (d) Produce all raw data for each study in native electronic format.

19 **INTERROGATORY NO. 18:**

20 From the date YOU first developed, designed, manufactured, distributed, sold,  
21 and/or made BYETTA available to consumers up through the present, identify all studies  
22 YOU relied on, if any, as proof that the use of the exenatide, sitagliptin, liraglutide and/or  
23 any other GLP-1 agonist or DPP-4 inhibitor in BYETTA is as safe as other diabetes  
24 medications, specifically indicating which studies, if any, show the following:

- 25 (a) That exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or  
26 DPP-4 inhibitor is safe;
- 27 (b) That exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or  
28 DPP-4 inhibitor does not cause cancer at a higher rate than any other  
therapeutic agents for the treatment of type 2 diabetes;
- (c) That exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or  
DPP-4 inhibitor does not cause pancreatitis at a higher rate than any other  
therapeutic agents for the treatment of type 2 diabetes;

- 1 (d) That exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or  
2 DPP-4 inhibitor does not cause pancreatic cancer at a higher rate than any  
3 other therapeutic agents for the treatment of type 2 diabetes;
- 4 (e) That exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or  
5 DPP-4 inhibitor does not cause death at a higher rate than any other  
6 therapeutic agents for the treatment of type 2 diabetes; and
- 7 (f) That exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or  
8 DPP-4 inhibitor does not cause any other severe personal injuries at a  
9 higher rate than any other therapeutic agents for the treatment of type 2  
10 diabetes.

11 As to each such study YOU identify in response to this interrogatory, if the study was  
12 published, state the study's exact title, author, publisher, place of publication, and year of  
13 publication; if the study was not published, explain why not and state the title of such  
14 unpublished study and the date you received its results; state the date YOU first  
15 undertook each such study; state the name and title of each of YOUR employee(s) and/or  
16 agent(s) who were responsible for and/or involved with each study, and if such employees  
17 are not still employed by YOU, provide their last known addresses and phone numbers;  
18 and provide all raw data for each study in native electronic format.

19 **INTERROGATORY NO. 19:**

20 Identify all testing that was done by YOU or on YOUR behalf, and/or relied upon  
21 by YOU either in whole or in part, which indicated the following:

- 22 (a) That BYETTA, JANUVIA, JANUMET, and/or VICTOZA is safe;
- 23 (b) That BYETTA, JANUVIA, JANUMET and/or VICTOZA does not  
24 cause cancer at a higher rate than any other therapeutic agents for the  
25 treatment of type 2 diabetes;
- 26 (c) That BYETTA, JANUVIA, JANUMET and/or VICTOZA does not cause  
27 pancreatitis at a higher rate than any other therapeutic agents for the  
28 treatment of type 2 diabetes;
- (d) That BYETTA, JANUVIA, JANUMET and/or VICTOZA does not  
cause pancreatic cancer at a higher rate than any other therapeutic agents  
for the treatment of type 2 diabetes;
- (e) That BYETTA, JANUVIA, JANUMET and/or VICTOZA does not cause  
death at a higher rate than any other therapeutic agents for the treatment  
of type 2 diabetes; and

1 (f) That BYETTA, JANUVIA, JANUMET and/or VICTOZA does not cause  
2 any other severe personal injuries at a higher rate than any other  
3 therapeutic agents for the treatment of type 2 diabetes.

4 As to each such test, attach copies of all test results and indicate whether they were ever  
5 published and/or submitted to the FDA.

6 **INTERROGATORY NO. 20:**

7 Please identify and describe all tests, investigations, studies, evaluations and/or  
8 assessments conducted by YOU or on YOUR behalf, and/or relied upon by YOU either in  
9 whole or in part, relating in any way to BYETTA, JANUVIA, JANUMET and/or  
10 VICTOZA, including the following information:

- 11 (a) If published, the exact title, author, publisher, place of publication, and  
12 year of publication of any such test, investigation, study, evaluation  
13 and/or assessment;
- 14 (b) The dates that each such test, investigation, study, evaluation and/or  
15 assessment was conducted;
- 16 (c) The name and job title of each of YOUR employees, agents and/or  
17 servants who were responsible for the performance and/or evaluation of,  
18 and/or were in any way involved with the performance and/or evaluation  
19 of, each such test, investigation, study, evaluation and/or assessment;
- 20 (d) Whether the individuals identified in sub-paragraph (c) above are still  
21 employed by YOU, and if not, their last known addresses and phone  
22 numbers;
- 23 (e) A step-by-step description of the methodology of each such test,  
24 investigation, study, evaluation and/or assessment;
- 25 (f) The purpose of each such test, investigation, study, evaluation and/or  
26 assessment;
- 27 (g) The full and complete verbatim results of each such test, investigation,  
28 study, evaluation and/or assessment;
- (h) All raw data for each such test, investigation, study, evaluation and/or  
assessment;
- (i) The date, manner, and means by which YOU first became aware of each  
such test, investigation, study, evaluation and/or assessment; and
- (j) Whether such data was submitted to the FDA, and if so, on what date.

1 **INTERROGATORY NO. 21:**

2 Identify any third parties utilized by YOU in the regulatory process either pre-  
3 launch or post-launch, whether in the United States regulatory process or the regulatory  
4 process in any other country (identifying each such country). Provide copies of any  
5 contracts, agreement, or communications between YOU and any such third party.

6 **INTERROGATORY NO. 22:**

7 Did YOU or YOUR BYETTA advisory board ever send or receive any oral or  
8 written correspondence with the FDA and/or have any communication with the FDA,  
9 whether in person, telephonic, or otherwise, concerning BYETTA? If yes, then identify  
10 and describe fully (a) all of the correspondence and/or communications; and (b) the date  
11 all correspondence was sent and/or received by YOU and/or the date when the  
12 communications occurred. Attach copies of all such correspondence and any recordings  
13 (written or otherwise) of such communications. If the correspondence exists in electronic  
14 format, produce it in its native electronic format.

15 **INTERROGATORY NO. 23:**

16 Did the FDA or any advisory committee or sub-committee of the FDA or any other  
17 governmental body ever hold any hearings as to the safety and/or efficacy of BYETTA,  
18 JANUVIA, JANUMET and/or VICTOZA? If yes, identify the date(s), time(s), place(s),  
19 and participants in the hearings; state whether YOU or anyone acting on YOUR behalf  
20 provided testimony at any such hearings (including but not limited to hearings by the  
21 FDA, CDC, NIH, USDA, U.S. Congress, and/or U.S. Senate); state the outcome of the  
22 hearings; attach all transcripts of such hearings in native electronic form; and state  
23 whether the FDA and/or any other governmental body ever suggested, requested, or  
24 required YOU to provide further information and/or perform further tests as to the safety  
25 of BYETTA, JANUVIA, JANUMET and/or VICTOZA.

26 **INTERROGATORY NO 24:**

27 Identify all governmental agencies in all countries worldwide that declined to  
28 approve, challenged, asked for additional study, or sought additional warnings before

1 approving YOUR application to market BYETTA for any indication. Include in your  
2 answer:

- 3 (a) The country and agency;
- 4 (b) The date approval was sought;
- 5 (c) The date approval was denied, challenged, declined, or additional study  
6 or warnings were sought;
- 7 (d) The indication involved;
- 8 (e) The reason for denial, challenge, decline, or seeking additional study or  
9 warnings regarding the application;
- 10 (f) The specifics of any additional study requested; and
- 11 (g) The specifics of any additional warnings requested.

12 **INTERROGATORY NO. 25:**

13 State whether BYETTA was marketed, promoted, and/or advertised in the  
14 following manners, indicating yes or no for each:

- 15 (a) To doctors and/or other healthcare professionals via trade journals;
- 16 (b) To doctors and/or other healthcare professionals via a direct sales force;
- 17 (c) To doctors and/or other healthcare professionals by mailings;
- 18 (d) To doctors and/or other healthcare professionals by email;
- 19 (e) To doctors and/or other healthcare professionals by newsletter;
- 20 (f) To doctors and/or other healthcare professionals via CMS database;
- 21 (g) To consumers via outdoors marketing, promotion, and/or advertising;
- 22 (h) To consumers via magazine;
- 23 (i) To consumers via television;
- 24 (j) To consumers via newspaper;
- 25 (k) To consumers via radio;
- 26 (l) To consumers via newsletter;
- 27 (m) To consumers via e-mail; and/or
- 28 (n) To consumers via internet advertising/marketing.

1 **INTERROGATORY NO. 26:**

2 Identify all direct-to-consumer advertising, promotional, marketing, sales and/or  
3 public relations efforts or campaigns planned and/or implemented by YOU or on YOUR  
4 behalf concerning BYETTA, whether in writing or communicated by any other media  
5 and/or medium. For all such direct-to-consumer advertising, promotional, marketing,  
6 sales and/or public relations efforts or campaigns, please identify:

- 7 (a) The names and addresses of all persons and/or entities responsible for all  
8 such direct-to-consumer advertising, promotional, marketing, sales and/or  
9 public relations efforts or campaigns;
- 10 (b) The dates that YOU conducted such direct-to-consumer advertising,  
11 promotional, marketing, sales and/or public relations efforts or  
12 campaigns;
- 13 (c) The specific media vehicles by which the direct-to-consumer advertising,  
14 promotional, marketing, sales and/or public relations efforts or campaigns  
15 were conducted (i.e., print, television, radio, outdoor, etc.);
- 16 (d) All documents pertaining to the development of marketing strategies or  
17 programs for the sale and/or distribution of BYETTA;
- 18 (e) All documents pertaining to the implementation of marketing strategies  
19 or marketing programs concerning BYETTA;
- 20 (f) All documents describing all marketing strategies or programs concerning  
21 BYETTA;
- 22 (g) All documents pertaining to the intended "market" for BYETTA,  
23 including documents pertaining to sales targets, distribution and/or survey  
24 data;
- 25 (h) All drafts of any advertising and/or promotional literature concerning  
26 BYETTA;
- 27 (i) All documents reflecting pricing for BYETTA;
- 28 (j) All documents pertaining to sums of money that YOU budgeted in order  
to advertise, promote and/or market BYETTA;
- (k) All press releases prepared in connection with BYETTA; and
- (l) All press kits prepared in connection with BYETTA.

26 **INTERROGATORY NO. 27:**

27 State whether YOU hired, employed, consulted, and/or retained any advertising  
28 agency, public relations firm, and/or any other entity paid to assist in the marketing and/or

1 promotion of BYETTA. If so, provide the names and addresses of all advertising  
2 agencies utilized by YOU in selling, marketing, and/or promoting BYETTA during the  
3 entire period of time YOU manufactured, marketed, promoted, distributed, and/or sold  
4 BYETTA, up through and including the present.

5 **INTERROGATORY NO. 28:**

6 State whether YOU and/or any advertising agency hired, employed, consulted,  
7 and/or retained by YOU to market, advertise, and/or promote BYETTA conducted direct-  
8 to consumer advertising. If so, provide the following information:

- 9 (a) The dates that YOU conducted the direct-to-consumer advertising;
- 10 (b) The specific media vehicles by which the direct to consumer advertising  
11 was conducted (i.e., print, television, outdoor, etc.) and the names of all  
12 vehicles that carried the direct-to-consumer ads;
- 13 (c) The specific media vehicles by which the direct to consumer advertising  
14 was conducted (i.e., print, television, outdoor, etc.) and the names of all  
15 vehicles that carried the direct-to-consumer ads;
- 16 (d) The names and addresses of all outside entities hired by YOU that  
17 worked on any Direct-To-Consumer marketing and/or advertising  
18 campaigns relating to BYETTA, and state the location(s) at which each  
19 respective entity did work for YOU on Direct-To-Consumer marketing  
20 and/or advertising campaigns relating to BYETTA;
- 21 (e) The identities of all individuals employed by YOU who worked on any  
22 Direct-To-Consumer marketing and/or advertising campaigns relating to  
23 BYETTA, and with respect to each, state the job title and location at  
24 which each respective individual worked on any Direct-To-Consumer  
25 marketing and/or advertising campaigns relating to BYETTA;
- 26 (f) Whether YOU or any advertising agency hired, employed, consulted,  
27 and/or retained by YOU targeted in its advertising and/or marketing  
28 and/or promotion of BYETTA any specific sub-demographic(s) within  
the demographic of potential BYETTA users; and
- (g) If any specific condition was targeted in YOUR Direct-to-Consumer  
advertising:
- (1) Identify each condition targeted;
  - (2) Explain why each condition was targeted;
  - (3) Identify how each condition was determined to be targeted by  
YOU; and

1 (4) Provide the names and addresses of all advertising agencies  
2 utilized by YOU that were or are involved in targeting each  
3 specific condition listed.

4 **INTERROGATORY NO. 29:**

5 Identify all advertising, promotional, marketing, sales and/or public relations  
6 efforts or campaigns directed to health care providers planned and/or implemented by  
7 YOU or others on YOUR behalf concerning BYETTA, whether in writing or  
8 communicated by any other media and/or medium. For all such advertising, promotional,  
9 marketing, sales and/or public relations efforts or campaigns directed to health care  
10 providers, please identify:

- 11 (a) The names and addresses of all persons and/or entities responsible for all  
12 such advertising, promotional, marketing, sales and/or public relations  
13 efforts or campaigns;
- 14 (b) The dates that such advertising, promotional, marketing, sales and/or  
15 public relations efforts or campaigns were conducted;
- 16 (c) The specific media vehicles by which the advertising, promotional,  
17 marketing, sales and/or public relations efforts or campaigns were  
18 conducted (i.e., print, television, radio, outdoor, etc.);
- 19 (d) All documents pertaining to the development of marketing strategies or  
20 programs for the sale and/or distribution of BYETTA;
- 21 (e) All documents pertaining to the implementation of marketing strategies or  
22 marketing programs in connection with BYETTA;
- 23 (f) All documents describing all marketing strategies and/or programs  
24 concerning BYETTA;
- 25 (g) All documents pertaining to the intended "market" for BYETTA, including  
26 documents pertaining to sales targets, distribution and/or survey data;
- 27 (h) All drafts of any advertising and/or promotional literature concerning  
28 BYETTA;
- (i) All documents reflecting pricing for BYETTA;
- (j) All documents pertaining to sums of money that YOU budgeted in order to  
advertise, promote and/or market BYETTA;
- (k) All press releases prepared in connection with BYETTA; and
- (l) All press kits prepared in connection with BYETTA.

1 **INTERROGATORY NO. 30:**

2 Identify all forms of Internet marketing employed by YOU or others on YOUR  
3 behalf with regard to BYETTA, and identify the person with the most knowledge about  
4 such Internet marketing.

5 **INTERROGATORY NO. 31:**

6 Identify all conferences and/or events sponsored by YOU where BYETTA was  
7 referred to, including in your response the title, date and location of the conferences  
8 and/or events; a description of the materials provided at each conference and/or event,  
9 including but not limited to any brochures for the conferences and/or events; and describe  
10 any agenda for each such conference and/or event.

11 **INTERROGATORY NO. 32:**

12 Did the FDA or any advisory committee or sub-committee of the FDA or any other  
13 governmental body ever request that YOU cease dissemination of promotional materials  
14 for BYETTA for any of the following reasons:

- 15 (a) Broadening of the BYETTA indication;
- 16 (b) Overstating the efficacy of BYETTA;
- 17 (c) Minimizing serious risks associated with the use of BYETTA; or
- 18 (d) Any other reasons not included in a-c.

19 If so, identify any and all ways in which the promotional materials were deemed to be  
20 misleading; and identify any and all submissions, corrections and/or plans of action to  
21 correct the misleading promotional materials.

22 **INTERROGATORY NO. 33:**

23 Identify all reports of adverse reactions, injuries, and/or ADVERSE EVENTS in  
24 humans that YOU ever became aware from any source, including but not limited to the  
25 medical community, the press, and/or peer reviewed medical and/or scientific articles,  
26 domestic or international, with respect to exenatide, sitagliptin, liraglutide and/or any  
27 other GLP-1 agonist or DPP-4 inhibitor. As to each report, if published, identify the  
28 author(s), date of publication, place(s) of publications, and title; and identify YOUR  
action(s), if any, with respect to the continued sales, distribution, and/or marketing of an

1 exenatide, sitagliptin, liraglutide, and/or any other GLP-1 agonist or DPP-4 inhibitor-  
2 containing diabetes medication upon learning of each report. Provide copies of all such  
3 reports, and if these reports exist in electronic format, please produce them in their native  
4 electronic format.

5 **INTERROGATORY NO. 34:**

6 Beginning with the time when YOU first began to design, develop, manufacture,  
7 market, distribute, and/or sell BYETTA, up through and including the present, was  
8 BYETTA ever listed in the Physicians' Desk Reference ("PDR")? If so, please state  
9 whether YOU or others on YOUR behalf indicated a use for BYETTA in the PDR or in  
10 any other source and, if so, describe with particularity the information provided by YOU  
11 or others on YOUR behalf to the PDR, including but not limited to all correspondence,  
12 cover letters, attachments and other documents, as well as all information actually  
13 published in the PDR.

14 **INTERROGATORY NO. 35:**

15 During the period when YOU first began to develop, design, manufacture, market,  
16 distribute and/or sell BYETTA, up through the present, please state the following as to  
17 the BYETTA package insert:

- 18 (a) The indications for use during each year;
- 19 (b) The contraindications each year;
- 20 (c) The warnings each year;
- 21 (d) The adverse reactions each year; and,
- 22 (e) The dosage amounts each year.

23 Identify any and all changes made during this time period in each of the above categories,  
24 stating the date when each change was made, why each change was made, and who  
25 ordered each change. Please also state, if and when any changes were made, whether  
26 there were any drafts and/or other proposals prior to the final and/or ultimate change. If  
27 YOUR answer is in the affirmative, please identify each draft and/or proposal and provide  
28 copies of same. If each draft and/or proposal exists in electronic format, please produce  
them in their native electronic format.

1 **INTERROGATORY NO. 36:**

2 Identify all medical literature, including articles, studies, editorials, and/or any peer  
3 reviewed material in YOUR possession that mentions, identifies or sets forth any elevated  
4 hazards, risks, side effects, adverse reactions and/or dangers from the use of BYETTA,  
5 JANUVIA, JANUMET and/or VICTOZA, and with respect to each, please identify the  
6 date, manner, and means by which YOU first became aware of same.

7 **INTERROGATORY NO. 37:**

8 State whether BYETTA subjected users to any adverse effects and/or side effects  
9 that a user of BYETTA may experience at a higher rate than they would as a user of any  
10 other therapeutic agents for the treatment of type 2 diabetes. If YOUR answer is in the  
11 affirmative, please describe any and all adverse effects and/or side effects that a user of  
12 BYETTA may experience from the use of BYETTA at a higher rate than as a user of any  
13 other therapeutic agents for the treatment of type 2 diabetes. Please also identify the  
14 means by which these adverse effects and/or side effects and the rate at which they are  
15 likely to occur are made known to the patient and/or user of BYETTA, whether by any  
16 writing, instructional video, package insert, poster, letter, and/or any other means. Please  
17 also provide copies of all the writing(s), instructional video(s), package insert(s),  
18 poster(s), letter(s), and/or any other means referred to above, including copies of any and  
19 all change(s), drafts, revision(s), and/or modification(s) made to same.

20 **INTERROGATORY NO. 38:**

21 State whether YOU have ever received any complaint(s), domestic or international,  
22 of any of the following ADVERSE EVENTS: (a) cancer; (b) pancreatic cancer; (c)  
23 pancreatitis; and (d) death, from any consumer, BYETTA user, doctors, physicians and/or  
24 healthcare professionals concerning BYETTA, beginning in the year YOU first started  
25 developing, designing, manufacturing, marketing, distributing, promoting, and/or selling  
26 BYETTA, up through and including the present. If YOUR answer is in the affirmative,  
27 then identify and explain the process by which YOU receive complaints regarding  
28 BYETTA from consumers, as well as doctors, physicians and/or healthcare professionals.  
Please also state the total number of complaints YOU have received for each type of

1 complaint, (a) through (d), from consumers, doctors, physicians and/or healthcare  
2 professionals concerning BYETTA, and state the number of each type of complaint, (a)  
3 through (d), by year. Please provide copies of all such complaints or reports of  
4 complaints. If the complaints or reports of complaints exist in electronic format, produce  
5 them in their native electronic format.

6 **INTERROGATORY NO. 39:**

7 Identify each person acting on YOUR behalf who has been responsible for: (a)  
8 receiving any complaints, inquiries, letters and other documents pertaining to BYETTA;  
9 (b) evaluating any complaints, inquiries, letters, and other documents pertaining to  
10 BYETTA; (c) investigating any complaints, inquiries, letters or other documents  
11 pertaining to BYETTA; and (d) responding to any complaints, inquiries, letters and other  
12 documents pertaining to BYETTA.

13 **INTERROGATORY NO. 40:**

14 Identify each of YOUR employees, independent contractors or other agents,  
15 whether in the United States or abroad, who at any time expressed any concerns regarding  
16 the safety of BYETTA, JANUVIA, JANUMET and/or VICTOZA, including, without  
17 limitation, concerns about the risks of cancers, including but not limited to pancreatic  
18 cancer, pancreatitis, and/or death from the use of BYETTA, JANUVIA, JANUMET  
19 and/or VICTOZA. Include in your response any concerns expressed about matters before  
20 the FDA, or matters that arose during clinical studies, testing, or post-market surveillance.  
21 With respect to each matter for which concerns were expressed regarding the safety of  
22 BYETTA, JANUVIA, JANUMET and/or VICTOZA as described above, state the  
23 substance of the concerns expressed by each person identified; identify all documents that  
24 state or discuss such concerns; and describe in detail what action, if any, YOU took in  
25 response to those concerns.

26 **INTERROGATORY NO. 41:**

27 State whether exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or  
28 DPP-4 inhibitor subjects users to any potential adverse effects and/or side effects. If  
YOUR answer is in the affirmative, please describe any and all adverse effects and/or

1 side effects that a user of exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist  
2 or DPP-4 inhibitor could experience. Please also identify the means by which those  
3 adverse effects and/or side effects are made known by YOU to the users of exenatide,  
4 sitagliptin, liraglutide and/or any other GLP-1 agonist or DPP-4 inhibitor, whether by any  
5 writing, instructional video, package insert, poster, letter, and/or any other means. Please  
6 also provide copies of all writing(s), instructional video(s), package insert(s), poster(s),  
7 letter(s), and/or any other means employed by YOU, including copies of any and all  
8 change(s), drafts, revision(s), and/or modification(s) made to same.

9 **INTERROGATORY NO. 42:**

10 State whether exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or  
11 DPP-4 inhibitor subjects users to any potential adverse effects and/or side effects at a  
12 higher rate than they would experience as a user of a therapeutic agent for the treatment  
13 of type 2 diabetes containing an active ingredient other than exenatide, sitagliptin,  
14 liraglutide and/or any other GLP-1 agonist or DPP-4 inhibitor. If YOUR answer is in the  
15 affirmative, please describe any and all adverse effects and/or side effects that a user of  
16 exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or DPP-4 inhibitor  
17 would experience at a higher rate than they would experience as a user of a therapeutic  
18 agent for the treatment of type 2 diabetes containing an active ingredient other than  
19 exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or DPP-4 inhibitor.  
20 Please also identify the means by which the higher rates of those adverse effects and/or  
21 side effects are made known by YOU to the users of exenatide, sitagliptin, liraglutide  
22 and/or any other GLP-1 agonist or DPP-4 inhibitor, whether by any writing, instructional  
23 video, package insert, poster, letter, and/or any other means. Please also provide copies  
24 of all writing(s), instructional video(s), package insert(s), poster(s), letter(s), and/or any  
25 other means employed by YOU, including copies of any and all change(s), drafts,  
26 revision(s), and/or modification(s) made to same.  
27  
28

1 **INTERROGATORY NO. 43:**

2 Identify all instructions and/or warnings that accompanied BYETTA and all drafts  
3 of instructions and/or warnings regarding BYETTA at any time that BYETTA was  
4 marketed or sold in any country. Please also:

- 5 (a) Provide the content of any such instruction and/or warning and/or draft of  
6 such instruction and/or warning;
- 7 (b) State the manner each instruction and/or warning was attached to and/or  
8 accompanied BYETTA;
- 9 (c) Identify the name(s) of the person(s) responsible for creating each such  
10 instruction and/or warning and/or draft of such instruction and/or  
11 warning, and state whether they are still employed by YOU, and if not,  
12 then provide their last known addresses and phone numbers;
- 13 (d) Identify the name(s) of the person(s) who approved each such instruction  
and/or warning, and state whether they are still employed by YOU, and if  
not, then provide their last known addresses and phone numbers; and
- (e) State the purpose of each such warning and instruction.

14 **INTERROGATORY NO. 44:**

15 State whether any changes, revisions and/or modifications were made to any  
16 warning and/or instruction that accompanied BYETTA at any time that BYETTA was  
17 marketed or sold in any country. If YOUR answer is in the affirmative, please:

- 18 (a) Identify the change(s), revision(s) and/or modification(s);
- 19 (b) State the date(s) of any change(s), revision(s), and/or modification(s);
- 20 (c) State the reason for the change(s), revision(s), and/or modification(s); and
- 21 (d) Identify the name(s) of the person(s) who approved the change(s),  
22 revision(s) and/or modification(s), and state whether they are still  
employed by YOU, and if not, then provide their last known addresses  
and phone numbers.

23 Please also attach copies of all documents pertaining to the changes, revisions and/or  
24 modifications made to the instructions and/or warnings, as well as copies of all  
25 communications (written or otherwise), both internal and/or with the FDA, concerning  
26 any changes, revisions and/or modification concerning BYETTA.

1 **INTERROGATORY NO. 45:**

2 Have YOU ever issued a warning letter and/or “Dear Doctor” and/or “Dear  
3 healthcare provider” letter to the medical community either in the United States or in any  
4 other country regarding BYETTA? If YOUR answer is in the affirmative, please state:

- 5 (a) Who first suggested sending such letter;  
6 (b) Who composed each letter;  
7 (c) The date of each letter;  
8 (d) To whom the letter was sent;  
9 (e) How the identities and addresses of the recipients of each letter were  
10 determined; and  
11 (f) Whether subsequent letter(s) were sent and, if so, please identify:  
12 1. Who suggested sending the subsequent letter(s);  
13 2. Who composed the letter(s);  
14 3. The dates of the letter(s); and  
15 4. To whom the letter(s) were sent.

16 Please also attach copies of all letters sent to medical professionals and/or “Dear Doctor”  
17 and/or “Dear healthcare provider” letters.

18 **INTERROGATORY NO. 46:**

19 Did YOU or anyone on YOUR behalf communicate with any physician concerning  
20 BYETTA and its potential for ADVERSE EVENTS, including but not limited to cancers,  
21 pancreatitis, other severe personal injuries and/or death ? If so, provide:

- 22 (a) The date of the communication(s);  
23 (b) The manner by which the communication(s) took place;  
24 (c) The substance of the communication(s);  
25 (d) Why the communication(s) were made; and  
26 (e) The identity of the person(s) acting on YOUR behalf who made and/or  
27 issued the communication(s).

28 Please provide copies of all such communications. If the communications exist in  
electronic format, produce them in their native electronic format.

1 **INTERROGATORY NO. 47:**

2 Please state whether there have been any changes or discussions of changes to the  
3 warnings associated with BYETTA within the last year. If YOUR answer is in the  
4 affirmative, please specify:

- 5 (a) The areas in which any changes were implemented;
- 6 (b) The reason behind any changes;
- 7 (c) The dates of any changes;
- 8 (d) The studies, if any, that supported and/or prompted the changes;
- 9 (e) Any and all other information that supported and/or prompted the  
changes; and
- 10 (f) As to discussions of changes to warnings, describe in detail the nature of  
11 the changes considered, and specifically state whether there have been  
any references to potentially placing a black box warning on BYETTA.

12 **INTERROGATORY NO. 48:**

13 At any time since BYETTA became publicly available in the United States, have  
14 YOU discussed or considered withdrawing it from the market due to reports of  
15 ADVERSE EVENTS or for any other reason? If YOUR answer is in the affirmative,  
16 please state:

- 17 (a) When withdrawal was discussed or considered;
- 18 (b) Who was involved in any discussions regarding withdrawal;
- 19 (c) What prompted any discussions regarding withdrawal;
- 20 (d) Whether any studies were undertaken or reviewed in discussing or  
considering withdrawal and, if so, identify which ones; and
- 21 (e) Why it was determined not to withdraw BYETTA from the United States  
22 market.

23 **INTERROGATORY NO. 49:**

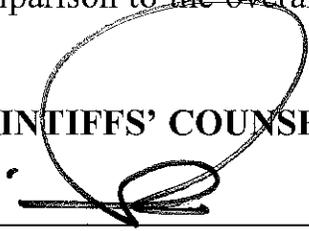
24 Has there ever been a discontinuance, either temporary or otherwise, of any  
25 exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or DPP-4 inhibitor -  
26 containing medication in the United States or any other country? If YOUR answer is in  
27 the affirmative, indicate the following:

- 28 (a) Which drug(s) were removed from the market;

- 1 (b) When the removal(s) occurred;  
2 (c) Whether the discontinuance(s) were permanent or temporary;  
3 (d) The primary motivations behind the discontinuance(s); and,  
4 (e) The rate of discontinuance in comparison to the overall prevalence of the  
5 drug(s) on the market.

6 DATED: January 30, 2014

**PLAINTIFFS' COUNSEL**

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# **EXHIBIT 3**

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9 *Plaintiff Co-Liaison Counsel*

10 UNITED STATES DISTRICT COURT  
11 SOUTHERN DISTRICT OF CALIFORNIA

12 IN RE INCRETIN-BASED  
13 THERAPIES PRODUCTS  
14 LIABILITY LITIGATION

15 *As to All Related and Member Cases*

CASE NO. 13md2452-AJB (MDD)

MDL 2452

Magistrate: Hon. Mitchell D. Dembin  
Judge: Hon. Anthony J. Battaglia

16  
17  
18 **PLAINTIFFS' FIRST SET OF REQUESTS TO PRODUCE**

19 **TO DEFENDANT ELI LILLY AND COMPANY**

20 To: Eli Lilly and Company c/o Pepper Hamilton LLP  
21 620 Eighth Avenue, 37<sup>th</sup> Floor, New York, NY 10018  
22

23 Pursuant to Rule 34 of the Federal Rules of Civil Procedure, Plaintiff in the above-  
24 referenced case requests Defendant Eli Lilly and Company to produce and permit the  
25 Plaintiff to inspect and copy the documents listed below.  
26  
27  
28

## DEFINITIONS

1  
2           1.     “DOCUMENTS,” “DOCUMENT,” and “DOCUMENTATION” as used in  
3 this Request is coextensive with the meaning of the terms “DOCUMENTS” and “tangible  
4 things” in Rule 34 of the Federal Rules of Civil Procedure, and shall have the broadest  
5 possible meaning and interpretation ascribed to the terms “DOCUMENTS” and “tangible  
6 things” under Rule 34, and the applicable Local Rules. Consistent with the above  
7 definition, the term “DOCUMENT” shall include, without limitation, any database,  
8 written, printed, typed, photostatic, photographed, recorded, computer-generated,  
9 computer-stored, or otherwise maintained or reproduced communication or  
10 representation, any data compilation in any form, whether comprised of letters, words,  
11 numbers, pictures, sounds, bytes, e-mails, electronic signals or impulses, electronic data,  
12 active files, deleted files, file fragments, or any combination thereof including, without  
13 limitation, all memoranda, notes, records, letters, envelopes, telegrams, messages, studies,  
14 analyses, contracts, agreements, projections, estimates, working papers, accounts,  
15 analytical records, reports and/or summaries of investigations, opinions or reports of  
16 consultants, opinions or reports of experts, opinions or reports of accountants, other  
17 reports, trade letters, press releases, comparisons, books, diaries, articles, magazines,  
18 newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, forecasts,  
19 drawings, diagrams, instructions, minutes of meetings, correspondence and  
20 communications (as defined below) of any type (including but not limited to video files,  
21 audio files, inter- and intra-office communications), questionnaires, surveys, charts,  
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1 graphs, photographs, phonographs, films, tapes, discs, data cells, drums, printouts, all  
2 other compiled data which can be obtained (translated, if necessary, through intermediary  
3 or other devices into usable forms), DOCUMENTS maintained on, stored in or generated  
4 on any electronic transfer or storage system, any preliminary versions, drafts or revisions  
5 of any of the foregoing, and other writings or DOCUMENTS of whatever description or  
6 kind, whether produced or authorized by or on behalf of YOU or anyone else, and shall  
7 include all non-identical copies and drafts of any of the foregoing now in the possession,  
8 custody or control of YOU, or the former or present directors, officers, counsel, agents,  
9 employees, partners, consultants, principals, and/or persons acting on YOUR behalf.  
10  
11

12 2. "Communication", "communications" and/or "correspondence" shall mean  
13 and refer to any oral, written, spoken or electronic transmission of information, including  
14 but not limited to, meetings, discussions, conversations, telephone calls, memoranda,  
15 letters, emails, text messages, postings, instructions, conferences, or seminars or any other  
16 exchange of information between yourselves or between you and any other person or  
17 entity.  
18  
19

20 3. "Electronic data" or "data" means the original (native electronic format),  
21 and any non-identical copies (whether non-identical because of notes made on copies or  
22 attached comments, annotations, marks, transmission notations, or highlighting of any  
23 kind) of writings of every kind and description whether inscribed by mechanical,  
24 facsimile, electronic, magnetic, digital, or other means. Electronic data includes, by way  
25 of example only, computer programs (whether private, commercial, or works-in-  
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27  
28

1 progress), programming notes or instructions, activity listings of electronic mail receipts  
2 and/or transmittals, output resulting from the use of any software program, including  
3 word processing documents, spreadsheets, database files, charts, graphs and outlines,  
4 electronic mail, operating systems, source code of all types, peripheral drivers, PIF files,  
5 batch files, ASCII files, and any and all miscellaneous files and/or file fragments,  
6 regardless of the media on which they reside and regardless of whether said electronic  
7 data consists of an active file, deleted file or file fragment. Electronic data includes any  
8 and all items stored on computer memories, hard disks, floppy disks, CD-ROMs,  
9 removable media such as zip drives, usb drives, storage cartridges, Bernoulli Boxes and  
10 their equivalent, magnetic tapes of all types, microfiche, punched cards, punched tape,  
11 computer chips, including, but not limited to EPROM, PROM, RAM and ROM, on or in  
12 any other vehicle for digital data storage and/or transmittal. The term electronic data also  
13 includes the file, folder tabs and/or containers and labels appended to, or associated with,  
14 any physical storage device associated with each original and/or copy.  
15  
16  
17

18 4. "Possession, custody or control" shall mean and refer to any documents in  
19 your possession, custody or control. A document is deemed to be in your "possession,  
20 custody or control" if it is in your physical custody, or if it is in the physical custody of  
21 another person or entity and you: (a) own such document in whole or in part; (b) have a  
22 right by contract, statute or otherwise to use, inspect, examine or copy such document on  
23 any terms; (c) have an understanding, express or implied, that you may use, inspect,  
24 examine or copy such document on any terms; or (d) have, as a practical matter, been able  
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1 to use, inspect, examine or copy such document when you have sought to do so. Such  
2 documents shall include, without limitation, documents that are in the custody of your  
3 attorney(s), employees, staff, representatives and agents.

4  
5 5. "Relating to," "relate to," "referring to," "refer to," "reflecting," "reflect,"  
6 "concerning," or "concern" shall mean evidencing, regarding, concerning, discussing,  
7 embodying, describing, summarizing, containing, constituting, showing, mentioning,  
8 reflecting, pertaining to, dealing with, relating to, referring to in any way or manner, or in  
9 any way logically or factually, connecting with the matter described in that paragraph of  
10 these demands, including DOCUMENTS attached to or used in the preparation of or  
11 concerning the preparation of the DOCUMENTS.

12  
13 6. Unless otherwise indicated, the "relevant period" for the information sought  
14 is 1995 to the present.

15  
16 7. "YOU," "YOUR," "YOURS," or "Defendants" refer to Defendants (both  
17 collectively and individually) as well as all of their partners, directors, officers,  
18 employees, servants, agents, attorneys, joint venturers, third-party contractors or other  
19 representatives, including all corporations and entities affiliated with Defendants. The  
20 terms "YOU" or "YOUR" or "YOURS" shall also include all predecessor business  
21 entities, as well as any predecessor's partners, directors, officers, employees, servants,  
22 agents, attorneys, joint venturers, third-party contractors or other representatives. The  
23 terms "YOU" or "YOUR" or "YOURS" shall also include all foreign subsidiaries or  
24 foreign parent companies, as well as any foreign subsidiaries' or parent companies'

1 partners, directors, officers, employees, servants, agents, attorneys, joint ventures or other  
2 representatives.

### 3 4 REQUESTS FOR PRODUCTION

#### 5 Request to Produce No. 1:

6 Produce any and all correspondence and DOCUMENTS, including but not limited  
7 to attachments, data and articles, submitted by YOU or anyone on YOUR behalf to the  
8 FDA in connection with the FDA's evaluation of "findings by a group of researchers that  
9 suggest an increased risk of pancreatitis and pre-cancerous cellular changes called  
10 pancreatic duct metaplasia," as noted in the FDA's Drug Safety Communication posted  
11 March 14, 2013. This request extends to correspondence and attachments before and  
12 after the FDA's evaluation.  
13  
14

#### 15 Request to Produce No. 2:

16 Produce any and all correspondence and DOCUMENTS, including but not limited  
17 to attachments, data and articles, submitted by YOU or anyone on YOUR behalf to any  
18 scientific journal on any of the following topics: incretin mimetic therapies, glucagon-  
19 like peptide 1 therapies, dipeptidyl peptidase-4 inhibitor therapies, exenatide, liraglutide,  
20 sitagliptin, saxagliptin, alogliptin, and linagliptin?  
21  
22

#### 23 Request to Produce No. 3:

24 Produce any and all correspondence and DOCUMENTS submitted by YOU or  
25 anyone on YOUR behalf to any scientific journal on any of the following topics:  
26

- 27 a. Pancreatic cancer in patients with Type 2 Diabetes Mellitus;

- 1 b. Pancreatic cancer in animals following administration of any GLP-1 or DPP-  
2 4 inhibitor based therapy; and  
3 c. Pancreatic cancer in humans following treatment with any GLP-1 or DPP-4  
4 inhibitor based therapy.  
5

6 **Request to Produce No. 4:**

7 Produce any and all correspondence and DOCUMENTS, including but not limited  
8 to attachments, data and articles, submitted by YOU or anyone on YOUR behalf to the  
9 European Medicines Agency (“EMA”) in connection with its 2013 “Assessment report  
10 for GLP-1 based therapies.”  
11

12 **Request to Produce No. 5:**

13 Produce any and all notes, minutes, recordings, made at or in connection with, and  
14 any DOCUMENTS received at, the “ad hoc expert meeting” referred to by the EMA in its  
15 2013 Assessment report for GLP-1 based therapies.  
16

17 **Request to Produce No. 6:**

18 Produce any and all notes, minutes, recordings, made at or in connection with, and  
19 any DOCUMENTS received at, the “Committee for Medicinal Products for Human Use”  
20 referred to by the EMA in its 2013 Assessment report for GLP-1 based therapies.  
21

22 **Request to Produce No. 7:**

23 Produce any and all notes, minutes, recordings, made at or in connection with, and  
24 any DOCUMENTS received at, the “Pharmacovigilance Risk Assessment Committee”  
25 referred to by the EMA in its 2013 Assessment report for GLP-1 based therapies.  
26  
27  
28

1 **Request to Produce No. 8:**

2 Produce any and all correspondence, communications or other DOCUMENTS that  
3 refer in any way to the Global Technology Communities Diabetes Summit held in  
4 Boston, Massachusetts April 29-30, 2013.  
5

6 **Request to Produce No. 9:**

7 Produce all correspondence and DOCUMENTS, including but not limited to  
8 attachments, data and articles, submitted by YOU or anyone on YOUR behalf related to  
9 presentations made at the Global Technology Communities Diabetes Summit held in  
10 Boston, Massachusetts April 29-30, 2013.  
11

12 **Request to Produce No. 10:**

13 Produce any and all correspondence, communications or other DOCUMENTS that  
14 refer in any way to the NIDDK-NCI Workshop on Pancreatitis-Diabetes-Pancreatic  
15 Cancer held on June 12-13, 2013 in Bethesda, Maryland.  
16

17 **Request to Produce No. 11:**

18 Produce any and all correspondence and DOCUMENTS, including but not limited  
19 to attachments, data and articles, submitted by YOU or anyone on YOUR behalf related  
20 to presentations made at the NIDDK-NCI Workshop on Pancreatitis-Diabetes-Pancreatic  
21 Cancer held on June 12-13, 2013 in Bethesda, Maryland.  
22

23 **Request to Produce No. 12:**

24 Produce any and all correspondence, communications and DOCUMENTS that  
25 refer to GLP-1 or DPP-4 inhibitor therapies, sent by YOU or anyone on YOUR behalf to,  
26  
27  
28

1 or received by YOU, regarding any of the following individuals:

- 2 a. Dr. Peter Butler
- 3 b. Dr. Daniel J. Drucker
- 4 c. Dr. David D. Dore
- 5 d. Dr. Robert Elashoff
- 6 e. Dr. Michael Elashoff
- 7 f. Dr. Rajesh Garg
- 8 g. Dr. Belinda Gier
- 9 h. Dr. Fred Gorlick
- 10 i. Dr. Jacqueline Koehler
- 11 j. Dr. Aleksey Matveyenko
- 12 k. Dr. Robert Ratner
- 13 l. Dr. Sonal Singh
- 14 m. Dr. Jay S. Skyler
- 15 n. Dr. Susan Bonner-Weir

16  
17  
18  
19 **Request to Produce No. 13:**

20  
21 Produce any and all correspondence, communications and DOCUMENTS,  
22 including but not limited to any and all emails, that refer to any of the following  
23 individuals:

- 24 a. Dr. Peter Butler
- 25 b. Dr. Daniel J. Drucker

1 c. Dr. David D. Dore

2 d. Dr. Robert Elashoff

3 e. Dr. Michael Elashoff

4 f. Dr. Rajesh Garg

5 g. Dr. Belinda Gier

6 h. Dr. Fred Gorlick

7 i. Dr. Jacqueline Koehler

8 j. Dr. Aleksey Matveyenko

9 k. Dr. Robert Ratner

10 l. Dr. Sonal Singh

11 m. Dr. Jay S. Skyler

12 n. Dr. Susan Bonner-Weir

13 **Request to Produce No. 14:**

14 Produce any and all DOCUMENTS reflecting any payment or compensation paid  
15 by YOU or on YOUR behalf to any of the following individuals, or the organization or  
16 company employing them:

17 a. Dr. Daniel J. Drucker

18 b. Dr. David D. Dore

19 c. Dr. Rajesh Garg

20 d. Dr. Fred Gorelick

21 e. Dr. Jacqueline Koehler

1 f. Dr. Robert Ratner

2 g. Dr. Jay S. Skyler

3 h. Dr. Susan Bonner-Weir

4 **Request to Produce No. 15:**

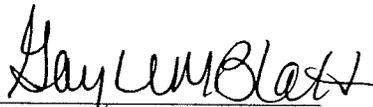
5 Produce any and all correspondence, communications and DOCUMENTS,  
6 including but not limited to attachments, data and articles, that refer to GLP-1 or DPP-4  
7 inhibitor therapies, sent by YOU or anyone on YOUR behalf to, or received by YOU  
8 from, the American Diabetes Association, or any of its officers, directors, advisors or  
9 staff.  
10  
11

12 **Request to Produce No. 16:**

13 Produce any and all DOCUMENTS reflecting YOUR communications to or from  
14 the pharmaceutical regulatory of Japan regarding GLP-1 or DPP-4 inhibitor therapies.  
15  
16

17 Dated: November 21, 2013

18 RESPECTFULLY SUBMITTED,

19 By: 

20 **GAYLE M. BLATT**

21 CASEY GERRY SCHENK FRANCAVILLA

22 BLATT & PENFIELD, LLP

23 110 Laurel St.

24 San Diego, CA 92101

25 Phone: (619) 238-1811

26 Facsimile: (619) 544-9232

27 gmb@cglaw.com

28 *Plaintiff Co-Liaison Counsel*

# **EXHIBIT 4**

1 Michael K. Johnson  
2 **JOHNSON BECKER, PLLC**  
3 33 South Sixth Street, Suite 4530  
4 Minneapolis, Minnesota 55402  
5 Telephone: (612) 436-1800  
6 Facsimile: (612) 436-1801  
7 **Email:** [mjohnson@johnsonbecker.com](mailto: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 Email: [rthompson@wattsguerra.com](mailto:rthompson@wattsguerra.com)

Hunter J. Shkolnik  
**NAPOLI, BERN, RIPKA &  
SHKOLNIK LLP**  
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Tor A. Hoerman  
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Facsimile: (618) 656-4401  
[thoerman@torhoermanlaw.com](mailto:thoerman@torhoermanlaw.com)

14 UNITED STATES DISTRICT COURT

15 SOUTHERN DISTRICT OF CALIFORNIA

17 IN RE INCRETIN-BASED  
18 THERAPIES PRODUCTS  
19 LIABILITY LITIGATION

20 *As to All Related and Member Cases*

CASE NO. 13md2452-AJB (MDD)

MDL 2452

Magistrate: Hon. Mitchell D. Dembin  
Judge: Hon. Anthony J. Battaglia

22 **PLAINTIFFS' SECOND SET OF REQUESTS TO PRODUCE**

23 **TO DEFENDANT ELI LILLY AND COMPANY**

24  
25 To: Eli Lilly and Company c/o Pepper Hamilton, LLP  
26 620 Eighth Avenue, 37<sup>th</sup> Floor, New York, NY 10018  
27  
28

1 Pursuant to Rule 34 of the Federal Rules of Civil Procedure, Plaintiff in the above-  
2 referenced case requests Defendant Eli Lilly and Company to produce and permit the  
3 Plaintiff to inspect and copy the documents listed below.

#### 4 DEFINITIONS

5 The following terms shall have the following meanings, unless the context requires  
6 otherwise:

7 1. "YOU," "YOUR," or "DEFENDANT" – means Eli Lilly and Company, as  
8 well as its divisions, parents, subsidiaries, and each of their present and former officers,  
9 directors, employees, agents, and representatives.

10 2. "ELECTRONIC STORAGE DEVICE" – means any device capable of storing  
11 ESI for any period of time, including without limitation, disks, including hard disks and  
12 floppy disks, CD-ROMs, DVDs, network servers, shared servers, computers, magnetic  
13 tape, back-up tape, voice-mail, temporary files, telephones, and PDAs, whether currently  
14 on Defendant's premises or otherwise (e.g. at an employee's home or remote office).

15 3. "ELECTRONICALLY STORED INFORMATION" or "ESI" – means any  
16 information stored in an electronic medium, and shall include, without limitation, any  
17 information, including files, documents, images, video, metadata or any combination  
18 thereof stored, created, or used on any ELECTRONIC STORAGE DEVICE, disk, tape  
19 (including backup tapes and other backup media), or other computer or digital storage  
20 medium, microfilm, microfiche, floppy, or any other storage or recording medium. ESI  
21 includes without limitation electronic mail messages, information stored on web pages or  
22 web servers, and database records.

23 4. "RELATE" – or any variant thereof, including, but not limited to, the term  
24 "RELATING TO," shall be understood to apply if the data or information evidences,  
25 mentions, constitutes, contains, summarizes, describes, concerns, refers to, supports,  
26 contradicts or addresses the subject matter described in this set of demands in which the  
27 term "relate," or any variant thereof, appears.

1           5. "EVIDENCE" – or any variant thereof, including, but not limited to, the term  
2 "EVIDENCING," shall be understood to apply if the data or information mentions,  
3 discusses, constitutes, concerns, supports, contradicts, or refers to the subject matter  
4 described in this set of demands in which the term "EVIDENCE," or any variant thereof,  
5 appears.

6           6. "DOCUMENT" or "DOCUMENTS" – means any handwriting, typewriting,  
7 printing, photostating, photographing, photocopying, transmitting by electronic mail or  
8 facsimile, and every other means of recording upon any tangible thing, any form of  
9 communication or representation, including letters, words, pictures, sounds, or symbols,  
10 or combinations thereof, and any record thereby created, regardless of the manner in  
11 which the record has been stored; and shall include, without limitation, the original (and  
12 absent the original then a copy thereof), and all file copies and copies not identical to the  
13 original of any writing or record of every type, form, and description that is in the  
14 possession, custody, or control of the responding party, or which is no longer in the  
15 responding party's possession but of which the responding party still has knowledge,  
16 whether or not said writings or records are claimed to be privileged or otherwise immune  
17 from discovery, including by way of illustration and not limitation, the following items:  
18 notes, correspondence, communications of any nature (including intra-company  
19 communications and correspondence), electronic mail messages, telegrams, cables,  
20 memoranda (including internal memoranda), notebooks of any nature, including  
21 laboratory and engineering reports; summaries, minutes, and records of telephone  
22 conversations, personal conversations or interviews; diaries, routing slips or memoranda,  
23 reports (including tests and analysis reports), books, manuals, publications, invoices,  
24 specifications, shipping papers, purchase orders, flow charts, schematics, diagrams,  
25 photographs of any nature, minutes or recordings of any meetings or conferences,  
26 including lists of persons attending meetings or conferences; transcripts of oral testimony  
27 or statements; labels, tags, fliers, brochures, pamphlets, advertisements, advertising

1 layouts, circulars, trade letters, press releases, and translations; presentations, including  
2 boards, transparencies, storybooks and/or scripts; drafts of original or preliminary notes  
3 on, and marginal comments appearing on, any DOCUMENTS; whether those writings or  
4 records are on paper, magnetic disk, tape or other computer or digital storage medium,  
5 microfilm, floppy, or any other storage media or recording media.

6 7. "ADVERSE EVENT" – refers to any harmful or undesired experience related  
7 or potentially related to the use of BYETTA, including, without limitation, disability  
8 caused by use of the drug, life-threatening adverse drug experience that caused or placed  
9 the patient at risk of death, or unexpected adverse drug experiences not previously  
10 observed or anticipated.

11 8. "REPORTABLE EVENT" – means any information that YOU received or  
12 otherwise became aware of, from any source, that YOU believed that YOU were required  
13 to report to the Food and Drug Administration relating to an ADVERSE EVENT.

#### 14 **REQUESTS FOR PRODUCTION OF DOCUMENTS**

##### 15 **REQUEST FOR PRODUCTION NO. 1:**

16 Produce in electronic format complete copies of all Databases that YOU use(d) to  
17 track, trend, or record information regarding any ADVERSE EVENT that YOU  
18 associated with BYETTA, and attach source and other related documentation. This  
19 request includes, to the extent that the databases incorporate this information, any and all  
20 information regarding the nature and type of ADVERSE EVENTS; when they were  
21 received by YOU; what action YOU took in response to the ADVERSE EVENTS; who  
22 YOU contacted or communicated with regarding the ADVERSE EVENTS; any follow-  
23 up efforts or investigation YOU made to obtain further information regarding the  
24 ADVERSE EVENTS; if and when YOU and the Food and Drug Administration ("FDA")  
25 communicated regarding the ADVERSE EVENTS; whether the ADVERSE EVENT was  
26 in the form of a Medwatch Report, communication from a medical provider or consumer,  
27 an ADVERSE EVENT REPORT ("AER") or other form; what YOUR conclusions were



1 communications YOU made or received regarding each ADVERSE EVENT for  
2 BYETTA, including internal communications; the results of any investigations regarding  
3 each ADVERSE EVENT for BYETTA and/or the basis for the decision to not  
4 investigate; and what YOUR conclusions were as to each ADVERSE EVENT; and the  
5 current status or final disposition of the ADVERSE EVENT.

6 **REQUEST FOR PRODUCTION NO. 4:**

7 Produce all DOCUMENTS AND ESI EVIDENCING or RELATING to any  
8 ADVERSE EVENTS YOU received related to any PLAINTIFF in this matter, including  
9 all DOCUMENTS and ESI EVIDENCING or RELATING to what the ADVERSE  
10 EVENT consisted of; when it was received by YOU; what action YOU took in response  
11 to the ADVERSE EVENT; any and all communications YOU made or received regarding  
12 the ADVERSE EVENT, including internal communications; any follow-up efforts YOU  
13 made to obtain further information regarding the ADVERSE EVENT; whether and on  
14 what basis YOU decided to not investigate; whether the ADVERSE EVENT was in the  
15 form of a Medwatch Report, communication from a medical provider or consumer, an  
16 Adverse Event Report or other form; what YOUR conclusions were as to the ADVERSE  
17 EVENT; and the current status or final disposition of the ADVERSE EVENT.

18 **REQUEST FOR PRODUCTION NO. 5:**

19 To the extent not produced in response to the preceding request for production,  
20 produce all DOCUMENTS AND ESI EVIDENCING or RELATING to the following  
21 information for each individual REPORTABLE EVENT for BYETTA:

- 22 a. any information in YOUR possession or references to information in YOUR  
23 possession related to the REPORTABLE EVENT;
- 24 b. any attempts YOU made to communicate with anyone to gather further  
25 information regarding the ADVERSE EVENT;
- 26 c. any communications YOU made or received, including internal  
27 communications, regarding the REPORTABLE EVENT;

- d. YOUR deliberations and decision-making processes used to determine whether the ADVERSE EVENT was or was not a REPORTABLE EVENT;
- e. any investigations YOU conducted to determine the cause of the event;
- f. any action YOU took as a result of the REPORTABLE EVENT to prevent recurrence of the REPORTABLE EVENT;
- g. experts and/or consultants whom YOU contacted regarding the ADVERSE EVENT;
- h. copies of all adverse event report forms, including supplemental reports, and other information submitted to the FDA;
- i. analysis of nature, severity and frequency of the ADVERSE EVENT;
- j. reporting rates analysis and trending of the ADVERSE EVENT.

**REQUEST FOR PRODUCTION NO. 6:**

Produce all DOCUMENTS AND ESI EVIDENCING or RELATING to any request by the Food and Drug Administration for YOU to conduct post-market surveillance of BYETTA; and any plans, reports, or other information YOU submitted to the Food and Drug Administration in response.

**REQUEST FOR PRODUCTION NO. 7:**

Produce all DOCUMENTS AND ESI EVIDENCING or referring to any and all data analysis or trends of adverse events that were reported to, or conducted by, YOU regarding BYETTA, including any studies, research or documents prepared to reflect any analysis or trend.

**REQUEST FOR PRODUCTION NO. 8:**

Produce all DOCUMENTS AND ESI EVIDENCING or referring to any and all written policies, procedures or standard operating procedures YOU had in place at the time YOU first began to market or distribute BYETTA regarding receiving, reviewing, investigating, evaluating, and/or documenting ADVERSE EVENTS YOU received for drugs that YOU marketed or distributed, including BYETTA. This includes for example,

1 any questionnaires or follow-up procedure YOU developed to deal with specific types of  
2 injuries related to BYETTA such as, but not limited to, pancreatitis, pancreatic and  
3 thyroid cancers.

4 **REQUEST FOR PRODUCTION NO. 9:**

5 Produce all DOCUMENTS AND ESI EVIDENCING any and all written policies,  
6 procedures, or standard operating procedures YOU had in place during the entire period  
7 of time since BYETTA was first marketed anywhere regarding the timely identification,  
8 communication, investigation, and evaluation of ADVERSE EVENTS that may  
9 constitute REPORTABLE EVENTS; the review process for determining when an  
10 ADVERSE EVENT meets the criteria for being a REPORTABLE EVENT; the  
11 documentation and recordkeeping requirements for information YOU evaluated to  
12 determine whether ADVERSE EVENTS YOU received constituted REPORTABLE  
13 EVENTS, the documentation and recordkeeping requirements for all REPORTABLE  
14 EVENTS and information related thereto actually submitted to the FDA; and the  
15 documentation and recordkeeping requirements regarding any information that was  
16 evaluated for the purpose of preparing the submission of annual reports, PADERs and  
17 PSURs.

18 **REQUEST FOR PRODUCTION NO. 10:**

19 Produce all DOCUMENTS AND ESI EVIDENCING or RELATING to any and/or  
20 all changes or additions YOU made to the procedures and standards identified in the  
21 preceding request for production from January 2003 through the present.

22 **REQUEST FOR PRODUCTION NO. 11:**

23 To the extent not already produced, produce all DOCUMENTS AND ESI  
24 EVIDENCING or referring to any information provided to any of YOUR employees or  
25 agents who were responsible for following up with or communicating with health care  
26 providers regarding adverse events associated with BYETTA regarding the following:  
27 the potential for BYETTA to cause pancreatitis, pancreatic and/or thyroid cancer, any  
28

1 information that these persons were to communicate to and/or obtain from the health care  
2 provider(s), and any training materials, scripts, questionnaires, and instructions that were  
3 to guide interactions with health care providers regarding adverse events for BYETTA.

4 **REQUEST FOR PRODUCTION NO. 12:**

5 Produce all DOCUMENTS AND ESI EVIDENCING any and/or all written  
6 policies, procedures or standard operating procedures YOU had in place during the entire  
7 period of time since BYETTA was first marketed anywhere regarding establishing and  
8 maintaining files for each ADVERSE EVENT that would contain any and/or all  
9 information in YOUR possession or references to information in YOUR possession  
10 related to the underlying ADVERSE EVENT, including all documentation of YOUR  
11 deliberations and decision-making processes used to determine if a drug-related death,  
12 serious injury, or injury of special interest was or was not a REPORTABLE EVENT, and  
13 copies of all adverse event report forms and other information submitted to the FDA.

14 **REQUEST FOR PRODUCTION NO. 13:**

15 Produce all DOCUMENTS AND ESI EVIDENCING or RELATING to any and/or  
16 all changes or additions YOU made to the procedures and standards identified in the  
17 preceding request for production during the entire period of time since BYETTA was first  
18 marketed anywhere.

19 **REQUEST FOR PRODUCTION NO. 14:**

20 Produce all DOCUMENTS AND ESI EVIDENCING or RELATING to  
21 communications and/or correspondence known as “Dear Doctor” or “Dear Healthcare  
22 Professional” letters prepared, generated, authored, and/or sent by YOU to health care  
23 professionals, including physicians, hospitals, pharmacies and clinics, in the United States  
24 and other countries, including any and all preliminary and final drafts of such letters, all  
25 minutes from company, departmental or directors meetings in which revisions or  
26 amendments to such communications and letters were discussed, as well as all editions or  
27 notations made by YOU, concerning BYETTA.

1 **REQUEST FOR PRODUCTION NO. 15:**

2 Produce all DOCUMENTS AND ESI EVIDENCING or RELATING to the  
3 organization of any division, segment, or office of DEFENDANT that participates in the  
4 receipt, collection, evaluation, analysis, trending, and/or reporting of information to any  
5 regulatory agency regarding ADVERSE EVENTS regarding BYETTA.

6 **REQUEST FOR PRODUCTION NO. 16:**

7 Produce all DOCUMENTS AND ESI EVIDENCING or RELATING to entities  
8 with whom YOU contract regarding the collection, processing, evaluating, investigation,  
9 follow-up, analysis, reporting and/or publication of ADVERSE EVENTS for BYETTA  
10 including but not limited to Functional Service Providers, Contract Research  
11 Organizations, vendors, and/or consultants.

12 Dated: December 13, 2013

13 RESPECTFULLY SUBMITTED,

14  
15 By: 

16 Michael K. Johnson  
17 **JOHNSON BECKER, PLLC**  
18 33 South Sixth Street, Suite 4530  
19 Minneapolis, Minnesota 55402  
20 Telephone: (612) 436-1800  
21 Facsimile: (612) 436-1801  
22 **Email:** [mjohnson@johnsonbecker.com](mailto:mjohnson@johnsonbecker.com)

23 Ryan L. Thompson  
24 **WATTS GUERRA LLP**  
25 5250 Prue Road, Suite 525  
26 San Antonio, Texas 78240  
27 Telephone: (210) 448-0500  
28 Facsimile: (210) 448-0501  
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Hunter J. Shkolnik  
**NAPOLI, BERN, RIPKA & SHKOLNIK**

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# **EXHIBIT 5**

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8 Ryan L. Thompson  
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11 San Antonio, Texas 78240  
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13 Facsimile: (210) 448-0501  
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Edwardsville, Illinois 62025  
Phone: (618) 656-4400  
Facsimile: (618) 656-4401  
[thoerman@torhoermanlaw.com](mailto:thoerman@torhoermanlaw.com)

15 **UNITED STATES DISTRICT COURT**  
16 **SOUTHERN DISTRICT OF CALIFORNIA**

17 **IN RE: INCRETIN-BASED**  
18 **THERAPIES PRODUCTS**  
19 **LIABILITY LITIGATION**

20 **Relates to: ALL CASES**

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

**MDL – 2452**

**Judge: Hon. Anthony J. Battaglia**

21 **PLAINTIFFS' AMENDED THIRD SET OF REQUESTS TO PRODUCE**  
22 **TO DEFENDANT ELI LILLY AND COMPANY**

23 To: Eli Lilly and Company c/o Pepper Hamilton, LLP  
24 620 Eighth Avenue, 37<sup>th</sup> Floor, New York, NY 10018

25 Pursuant to Rule 34 of the Federal Rules of Civil Procedure, Plaintiffs request  
26 Defendant Eli Lilly and Company to produce and permit the Plaintiffs to inspect and copy  
27 the documents listed below. By agreement of the parties, service of this amended Third  
28 Set of Requests to Produce has not restarted the 30-day limit for responding, inasmuch as  
it is identical to the requests served on January 7, 2014, but for deletion of requests 4, 10,

1 29, 33, 96 and 100 of the prior set. Nonetheless, Defendant has requested a modest  
2 extension of time to respond, and the parties are currently negotiating the exact date on  
3 which Defendant's responses will be due.

#### 4 DEFINITIONS AND INSTRUCTIONS

5 1. "YOU," "YOUR," or "DEFENDANT" – means Eli Lilly and Company, as  
6 well as its divisions, parents, subsidiaries, and each of their present and former officers,  
7 directors, employees, agents and representatives.

8 2. "ELECTRONIC STORAGE DEVICE" – means any device capable of  
9 storing ESI for any period of time, including without limitation, disks, including hard  
10 disks and floppy disks, CD-ROMs, DVDs, network servers, shared servers, computers,  
11 magnetic tape, back-up tape, voice-mail, temporary files, telephones, and PDAs, whether  
12 currently on Defendant's premises or otherwise (e.g. at an employee's home or remote  
13 office).

14 3. "ELECTRONICALLY STORED INFORMATION" or "ESI" – means any  
15 information stored in an electronic medium, and shall include, without limitation, any  
16 information, including files, documents, images, video, metadata or any combination  
17 thereof stored, created, or used on any ELECTRONIC STORAGE DEVICE, disk, tape  
18 (including backup tapes and other backup media), or other computer or digital storage  
19 medium, microfilm, microfiche, floppy, or any other storage or recording medium. ESI  
20 includes without limitation electronic mail messages, information stored on web pages or  
21 web servers, and database records.

22 4. "RELATE" – or any variant thereof, including, but not limited to, the term  
23 "RELATING TO," shall be understood to apply if the data or information evidences,  
24 mentions, constitutes, contains, summarizes, describes, concerns, refers to, supports,  
25 contradicts or addresses the subject matter described in this set of demands in which the  
26 term "relate," or any variant thereof, appears.

27 5. "DOCUMENT" or "DOCUMENTS" – means any handwriting, typewriting,  
28 printing, photostating, photographing, photocopying, transmitting by electronic mail or  
facsimile, and every other means of recording upon any tangible thing, any form of

1 communication or representation, including letters, words, pictures, sounds, or symbols,  
2 or combinations thereof, and any record thereby created, regardless of the manner in  
3 which the record has been stored; and shall include, without limitation, the original (and  
4 absent the original then a copy thereof), and all file copies and copies not identical to the  
5 original of any writing or record of every type, form, and description that is in the  
6 possession, custody, or control of the responding party, or which is no longer in the  
7 responding party's possession but of which the responding party still has knowledge,  
8 whether or not said writings or records are claimed to be privileged or otherwise immune  
9 from discovery, including by way of illustration and not limitation, the following items:  
10 notes, correspondence, communications of any nature (including intra-company  
11 communications and correspondence), electronic mail messages, telegrams, cables,  
12 memoranda (including internal memoranda), notebooks of any nature, including  
13 laboratory and engineering reports; summaries, minutes, and records of telephone  
14 conversations, personal conversations or interviews; diaries, routing slips or memoranda,  
15 reports (including tests and analysis reports), books, manuals, publications, invoices,  
16 specifications, shipping papers, purchase orders, flow charts, schematics, diagrams,  
17 photographs of any nature, minutes or recordings of any meetings or conferences,  
18 including lists of persons attending meetings or conferences; transcripts of oral testimony  
19 or statements; labels, tags, fliers, brochures, pamphlets, advertisements, advertising  
20 layouts, circulars, trade letters, press releases, and translations; presentations, including  
21 boards, transparencies, storybooks and/or scripts; drafts of original or preliminary notes  
22 on, and marginal comments appearing on, any DOCUMENTS; whether those writings or  
23 records are on paper, magnetic disk, tape or other computer or digital storage medium,  
microfilm, floppy, or any other storage media or recording media.

24 6. "ADVERSE EVENT" – refers to any harmful or undesired experience  
25 related or potentially related to the use of BYETTA, including, without limitation,  
26 disability caused by use of the drug, life-threatening adverse drug experience that caused  
27 or placed the patient at risk of death, or unexpected adverse drug experiences not  
28 previously observed or anticipated.



1 organization of the various departments, divisions and subdivisions, and the heads and/or  
2 employees of each such department, division or subdivision, and the relationship and/or  
3 overlap, if any, among and between departments, divisions and subdivisions.

4 8. All DOCUMENTS identifying the role of DEFENDANT with regard to  
5 BYETTA, including any agreements among and between YOU and any other entity  
6 relating to the manufacturing, marketing and/or sale of BYETTA, and all DOCUMENTS  
7 concerning any potential purchase of the rights to manufacture, market, and/or sell  
8 BYETTA by any entity, including, but not limited to, any communications with the  
9 potential purchaser and any internal communications regarding the potential purchase.

10 9. All DOCUMENTS concerning YOUR annual sales revenue and profits  
11 derived from BYETTA in the United States and broken down by State for every year  
12 since BYETTA was first marketed and sold in the United States.

13 10. All databases maintained by or on behalf of YOU that contain data  
14 concerning the number of prescriptions written by any physician relating to BYETTA.

15 11. All DOCUMENTS sufficient to identify any pharmaceutical product  
16 developed by or for YOU containing exenatide, other than BYETTA, whether or not  
17 ultimately submitted to a regulatory agency or marketed in any country.

18 12. All DOCUMENTS that comprise or reflect the policies and procedures that  
19 were or are in place for the storage, deletion, and back-up of DOCUMENTS, including  
20 emails, generated by YOUR employees and agents regarding BYETTA, and all  
21 DOCUMENTS concerning the steps taken by YOU to preserve all DOCUMENTS  
22 concerning, regarding, or pertaining to BYETTA.

23 13. All insurance policies, excess coverage policies, and any other type of  
24 insurance coverage, that YOU believe may potentially cover claims related to BYETTA  
25 for policy years 1995 until the present.

26 14. All DOCUMENTS identifying which clinical research companies and  
27 individuals were used to study BYETTA, together with any contracts whereby YOU  
28 engaged the services of such companies and individuals along with any study protocols

1 given to, used, or developed by such clinical research companies, and any study  
2 summaries and results provided by such clinical research companies.

3 15. All DOCUMENTS comprising or relating to any standard operating  
4 procedure and/or policy and procedure manuals relating to YOUR clinical and pre-  
5 clinical trials for BYETTA from 1995 until the present.

6 16. All DOCUMENTS that identify or list (including in summary format) any  
7 completed, proposed, planned, considered, or conceived pre-clinical studies as well as  
8 clinical trials that assess the association between BYETTA and cancers, including but not  
9 limited to pancreatic cancer and pancreatitis, as well as any other cancer.

10 17. All DOCUMENTS that identify any and all notebooks and electronic  
11 notebooks provided to clinical investigators or scientists that pertain to past, present, and  
12 future pre-clinical and clinical studies of BYETTA.

13 18. All DOCUMENTS comprising or concerning data collected during all  
14 phases of the BYETTA clinical and pre-clinical trials, including, but not limited to, all  
15 data concerning animal studies, *in vitro* studies, competitive studies, scientific studies,  
16 head-to-head studies, same assay studies, parallel studies, and double blind studies.

17 19. All study protocols developed by YOU or others on YOUR behalf relating to  
18 BYETTA, regardless of whether the study was ever completed, published or  
19 discontinued, or whether human patients were ever enrolled.

20 20. All DOCUMENTS from physicians and/or investigators concerning all  
21 BYETTA clinical or pre-clinical trials provided to YOU, whether provided to the FDA or  
22 not.

23 21. All DOCUMENTS containing any data or information relating to  
24 unpublished and discontinued studies (whether sponsored by YOU or not sponsored by  
25 YOU) involving BYETTA.

26 22. All DOCUMENTS containing any data or information relating to ongoing,  
27 past, future, or potential studies (whether sponsored by YOU or not sponsored by YOU)  
28 involving BYETTA.

1 23. All DOCUMENTS constituting minutes from meetings, summaries of the  
2 minutes of such meetings, agendas for such meetings, presentations made at any such  
3 meetings (in their native format) and/or summaries of such meetings with any and all  
4 physicians and investigators involved with clinical and pre-clinical trials for BYETTA.

5 24. All DOCUMENTS concerning any analysis or sub-analysis of clinical trial  
6 data and/or other safety and/or efficacy data used to determine specialty populations  
7 and/or other population criteria for the marketing, advertising, promotion, and/or  
8 targeting of BYETTA users.

9 25. All DOCUMENTS relating to BYETTA that were submitted to the FDA or  
10 received from the FDA.

11 26. All DOCUMENTS concerning any inquiries or investigations by  
12 governmental or regulatory organizations within the United States (either state or federal)  
13 related to BYETTA, including all DOCUMENTS submitted to or received from such  
14 organizations.

15 27. All correspondence or communications to or from any domestic or foreign  
16 regulatory agency and/or government relating to BYETTA and any English translations  
17 that exist.

18 28. All DOCUMENTS that concern or involve discussion about the potential or  
19 actual submission of BYETTA for approval and/or the approval of BYETTA in any  
20 country including, but not limited to, the U.S. This request includes, but is not limited to,  
21 communications regarding foreign governmental agencies and their drug approval  
22 procedures, rules and/or standards, any English translations that exist if the  
23 DOCUMENTS are written in any language other than English, and all DOCUMENTS  
24 pertaining to safety, adverse events, problems, and complications regarding BYETTA,  
25 including, but not limited to, adverse event reports and responses thereto, and post-  
26 approval clinical trials and any English translations that exist if the DOCUMENTS are  
27 written in any language other than English.

28 29. All DOCUMENTS concerning deferred approval to market, declined  
approval to market, declined approval for any indication, or approvals conditioned on

1 providing additional warnings with respect to BYETTA in any country. This request  
2 includes, but is not limited to, communications between the sponsor of BYETTA and the  
3 governmental agency involved, and any English translations that exist if the  
4 DOCUMENTS are written in any language other than English.

5 30. All DOCUMENTS pertaining to planned future IND (Investigational New  
6 Drug Application), NDA (New Drug Application), SNDA (Supplemental New Drug  
7 Application) and ANDA (Abbreviated New Drug Application) applications or  
8 submissions, or submissions for foreign regulatory agencies, related to BYETTA.

9 31. All DOCUMENTS comprising or regarding YOUR internal communications  
10 pertaining to BYETTA's past, present, and future anticipated market share and/or sales in  
11 the United States and/or worldwide.

12 32. All DOCUMENTS relating to, submitted to, created by, or concerning any  
13 committee that reviews and approves any advertising, sales and marketing materials  
14 relating to BYETTA.

15 33. All contracts or agreements with others relating to the promotion of  
16 BYETTA, including DOCUMENTS sufficient to identify all advertising agencies or  
17 public relations firms utilized by YOU in connection with BYETTA in the United States,  
18 and all DOCUMENTS concerning the relationship between YOU and any outside person  
19 or entity involved in the market analysis, marketing, advertising, or promotion of  
20 BYETTA.

21 34. All DOCUMENTS, including contracts, communications, invoices for  
22 services rendered, and any other DOCUMENTS relating to, demonstrating, or showing  
23 YOUR direct or indirect contact with third party contractors and/or vendors who provide  
24 computerized or other data on drug patient instructions for use by pharmacies. This  
25 request includes, but is not limited to, all records relating to, demonstrating, or showing  
26 whether YOU sought to ascertain what the third party contractors and/or vendors were  
27 stating about BYETTA, and any and all efforts to change any statements about BYETTA  
28 contained in patient information handouts generated by pharmacies using information  
generated by the third party contractors and/or vendors.

1 35. Video files (in video format) of all television advertisements, including  
2 drafts, for BYETTA, produced on DVD, and audio files (in audio format) of all radio  
3 advertisements, including drafts, for BYETTA on CD or DVD, as well as all  
4 DOCUMENTS showing or proving that a BYETTA advertisement was run on either  
5 television or radio, including but not limited to affidavits received from the media outlets,  
6 media buyers, or YOUR advertising agencies or public relations firms, and all  
7 DOCUMENTS that demonstrate what city, date and time each television or radio  
8 advertisement relating to BYETTA ran on television or radio.

9 36. All DOCUMENTS relating to point-of-purchase advertisement of whatever  
10 format for BYETTA, including copies of all print advertisements, including drafts, for  
11 BYETTA, all draft and final BYETTA question and answer brochures, copies of all  
12 outdoor advertisements for BYETTA, all DOCUMENTS relating to event advertising for  
13 BYETTA, and all DOCUMENTS relating to coupon programs for BYETTA.

14 37. Screenshots of all Internet based advertisements (including but not limited to  
15 Web sites, blogs, bulletin boards, and pod-casts) and e-commerce information relating to  
16 BYETTA sponsored by or on behalf of YOU, including every screen within any Website,  
17 copies of any Internet website (in a searchable format that can be navigated as if the site  
18 was operating live) tracking data relating to BYETTA, all DOCUMENTS or information  
19 relating to the marketing of BYETTA through any internet-based website, email  
20 campaign, or any other use of the internet or electronic communication, and copies in  
21 electronic/navigable format of any Web page or Website maintained by or on behalf of  
22 YOU that contains any content relating to BYETTA.

23 38. All DOCUMENTS relating to any Direct-to-Consumer marketing and/or  
24 advertising campaigns relating to BYETTA, relating to grassroots sponsorship for  
25 BYETTA, and all DOCUMENTS sufficient to identify YOUR thought leaders and/or key  
26 opinion leaders including, but not limited to, doctors and healthcare providers who were  
27 offered and/or received payment or honoraria from YOU for preparation of scientific  
28 papers, posters, medical articles, speeches, lectures, and/or presentations regarding  
BYETTA.

1           39. All DOCUMENTS that identify former and/or present sales representatives  
2 or detail persons responsible for, or involved with, the marketing or selling of BYETTA,  
3 including the territory each was responsible for.

4           40. All DOCUMENTS used in the training of YOUR sales force, sales  
5 representatives or detail persons who promoted or sold BYETTA at any point in time, and  
6 all DOCUMENTS concerning or regarding the training of YOUR sales force, sales  
7 representatives or detail persons who worked on BYETTA.

8           41. All audio files and video files (in native format) used in the training of your  
9 sales force, sales representatives or detail persons relating to BYETTA, produced on  
10 separate DVD, and all transcripts of any audio files and video files used in the training of  
11 your sales force, sales representatives or detail persons relating to BYETTA.

12           42. All audio communications (both in audio file format and a transcript of the  
13 same) between YOU and YOUR sales force, sales representatives or detail persons  
14 relating to BYETTA, and all email or other written communications between YOU and  
15 YOUR sales force relating to BYETTA.

16           43. All DOCUMENTS that reflect written procedures or guidelines for sales  
17 persons, sales representatives or detail people for recording information about doctor and  
18 healthcare provider detail visits relating to BYETTA.

19           44. All DOCUMENTS that contain information created by any sales  
20 representative or detail person concerning BYETTA that were created in relation to a  
21 meeting or conversation with any doctor, pharmacist or healthcare professional.

22           45. All databases maintained by or on behalf of YOU that contain sales call  
23 notes relating to BYETTA, including but not limited to all DOCUMENTS relating to the  
24 creation of and additions to “drop-down menus” in the call notes database(s) that are to be  
25 used by the sales force, sales representatives or detail persons instead of a data entry field  
26 to be entered by them.

27           46. All DOCUMENTS intended to be provided to prescribing physicians  
28 regarding BYETTA and its intended use, contraindications, potential complications,  
dosage, and potential need for patient monitoring and/or testing, including all

1 DOCUMENTS relating to materials left or intended to be left by sales representatives or  
2 detail persons in the offices of healthcare professionals relating to BYETTA, and all  
3 DOCUMENTS that were provided to physicians or other healthcare professionals that  
4 were intended for distribution to patients concerning the risks of BYETTA causing  
5 cancers, including but not limited to pancreatic cancer, and pancreatitis.

6 47. All DOCUMENTS that reflect warnings, objections or criticisms by any  
7 United States or foreign governmental or regulatory entity of YOUR marketing and/or  
8 promotional materials or practices for BYETTA, specifically including, but not limited to,  
9 all DDMAC letters received by YOU relating to BYETTA, and all internal  
10 communications relating to any DDMAC letter received by YOU relating to BYETTA.

11 48. All consulting agreements, engagement agreements, employment  
12 agreements, or any other agreement, however titled, relating in any way to the testing,  
13 research, development, and/or evaluation of BYETTA, including all DOCUMENTS  
14 regarding any post-marketing studies, seeding studies, cohort studies, case control studies,  
15 randomized studies, protocols, or surveillance conducted in the United States and  
16 worldwide pertaining to BYETTA; all DOCUMENTS regarding any on-going and future  
17 proposed post-marketing studies regarding BYETTA; and all DOCUMENTS comprising  
18 or regarding the retention and/or use of any third-parties who have analyzed or re-  
19 analyzed BYETTA and its causal connection or association with cancers, including but  
20 not limited to pancreatic cancer, and pancreatitis.

21 49. All DOCUMENTS relating to any Standard Operating Procedure (“SOP”)  
22 and policy and procedure manuals relating to YOUR pharmacovigilance group and its  
23 composition and responsibilities, and all DOCUMENTS relating to any SOP and policy  
24 and procedure manuals relating to YOUR post-marketing surveillance for BYETTA from  
25 1995 to the present.

26 50. All charts (to be produced in color) and other DOCUMENTS created by  
27 YOU relating to adverse event reports for BYETTA, including all charts and other  
28 DOCUMENTS that compare BYETTA to other therapeutic agents for the treatment of  
type 2 diabetes.

1           51. All DOCUMENTS concerning or relating to any studies, including but not  
2 limited to all phases, drafts, protocols, notes, comments, interim reports, final reports, and  
3 versions thereof, whether published or not, that raise questions about, suggest, indicate or  
4 demonstrate BYETTA's safety in relation to another drug(s).

5           52. All scientific, clinical, and medical literature concerning the potential  
6 association between therapeutic agents for the treatment of type 2 diabetes and any  
7 cancers, including but not limited to pancreatic cancer, and pancreatitis.

8           53. All DOCUMENTS comprising or regarding any communication with  
9 journals, authors, or publications about any articles or studies assessing a relationship or  
10 association between BYETTA and cancers, including but not limited to pancreatic cancer,  
11 and pancreatitis.

12           54. All DOCUMENTS comprising or regarding compensation, honoraria,  
13 grants, scholarships or gifts, offered or paid, to individuals or institutions for work  
14 associated with BYETTA, including, but not limited to, the promotion, marketing,  
15 research, pre-clinical and clinical trial investigation, and the authorship of articles related  
16 to or concerning BYETTA.

17           55. All DOCUMENTS and/or databases comprising, regarding, generated by, or  
18 sent to any committee, task force, or group YOU created or participated in to address or  
19 handle questions or concerns related to the potential association or causal connection  
20 between BYETTA and cancers, including but not limited to pancreatic cancer, and  
21 pancreatitis.

22           56. All internal communications and related DOCUMENTS concerning what  
23 information should be provided to consumers, physicians or other healthcare  
24 professionals concerning the risk of BYETTA causing cancers, including but not limited  
25 to pancreatic cancer, and pancreatitis, such DOCUMENTS including, but not limited to,  
26 approved informed consent forms; all correspondence and/or other communications  
27 prepared and/or sent in response to communications received from doctors, pharmacists,  
28 hospitals, healthcare providers and/or BYETTA users regarding complaints with  
BYETTA and/or adverse events with BYETTA, including any and all internal

1 communications; and all DOCUMENTS and/or information received or obtained from  
2 any source that relate in any way to any potential causal connection or association of  
3 BYETTA with cancers, including but not limited to pancreatic cancer, and pancreatitis.

4 57. All DOCUMENTS which were provided by YOU to or received by YOU  
5 from the FDA or any other regulatory agency that relate in any way to any potential  
6 causal connection or association of BYETTA with cancers, including but not limited to  
7 pancreatic cancer, and pancreatitis.

8 58. All labels or labeling, final and draft, for use on or in the box used to  
9 package BYETTA, whether submitted to the FDA or not.

10 59. All internal communications regarding final or draft labeling for use on or in  
11 the box used to package BYETTA

12 60. All communications between YOU and the FDA regarding labels or  
13 labeling, final and draft, for use on or in the box used to package BYETTA.

14 61. All DOCUMENTS relating to any SOP and policy and procedure manuals  
15 relating to the content and format of labeling for BYETTA from 1995 to the present.

16 62. All draft package inserts pertaining to BYETTA, whether submitted to the  
17 FDA or not, from 1995 to the present.

18 63. All internal communications regarding package inserts for BYETTA, from  
19 1995 to the present.

20 64. All communications between YOU and the FDA regarding any and all  
21 BYETTA package inserts, from 1995 to the present.

22 65. All final package inserts approved to be placed within the BYETTA  
23 package, from 1995 to the present.

24 66. All package inserts intended for dissemination in any country other than the  
25 U.S. for BYETTA, including any English translations that exist.

26 67. All draft Core Data Sheets pertaining to BYETTA, whether submitted to the  
27 FDA or not, from 1995 to the present.

28 68. All internal communications regarding Core Data Sheets for BYETTA, from  
1995 to the present.

1 69. All communications between YOU and the FDA regarding any and all  
2 BYETTA Core Data Sheets, from 1995 to the present.

3 70. All final Core Data Sheets relating to BYETTA approved to be distributed,  
4 from 1995 to the present.

5 71. All DOCUMENTS relating to any SOP and policy and procedure manuals  
6 relating to the content and format of package inserts, patient information sheets, and other  
7 information pertaining to or concerning BYETTA that was or is intended for physicians  
8 and patients.

9 72. All draft patient information sheets and/or consumer information sheets  
10 pertaining to BYETTA, whether submitted to the FDA or not.

11 73. All internal communications regarding final or draft BYETTA patient  
12 information sheets and/or consumer information sheets, all communications between  
13 YOU and the FDA regarding any and all BYETTA patient information sheets and/or  
14 consumer information sheets.

15 74. All final patient information sheets and/or consumer information sheets  
16 regarding BYETTA intended for dissemination to patients.

17 75. All draft package inserts or patient information sheets pertaining to  
18 BYETTA that were prepared for any country other than the U.S. and any English  
19 translations that exist.

20 76. All final patient information sheets intended for dissemination in any country  
21 other than the U.S. regarding BYETTA and any English translations that exist.

22 77. All DOCUMENTS and/or information received or obtained from any source  
23 that relate in any way to any causal connection or association of BYETTA with cancers,  
24 including but not limited to pancreatic cancer, and pancreatitis, which were disclosed by  
25 YOU to consumers, potential consumers and YOUR customers.

26 78. All DOCUMENTS concerning and/or explaining YOUR relationship with  
27 retail pharmacies as it relates to BYETTA.

28 79. All DOCUMENTS and/or information received or obtained from any source  
that relate in any way to any causal connection or association of BYETTA with cancers,

1 including but not limited to pancreatic cancer, and pancreatitis, which were disclosed by  
2 YOU to Pharmacies for distribution to consumers, potential consumers and YOUR  
3 customers.

4 80. All DOCUMENTS and/or information received or obtained from any source  
5 that relate in any way to any causal connection or association of BYETTA with cancers,  
6 including but not limited to pancreatic cancer, and pancreatitis, which were provided by  
7 YOU to YOUR sales force, sales representatives, detail persons or any other of YOUR  
8 employees involved in any way in the sale or marketing of BYETTA.

9 81. All DOCUMENTS relating to any SOP and policy and procedure manuals  
10 relating to Dear Doctor or Health Advisory Letters concerning or regarding BYETTA,  
11 from 1995 to the present.

12 82. All draft Dear Doctor/Healthcare Provider Letters relating to BYETTA,  
13 whether or not ever sent.

14 83. All internal communications regarding final or draft Dear Doctor/Healthcare  
15 Provider Letters regarding BYETTA.

16 84. All communications between YOU and the FDA regarding any draft or final  
17 BYETTA Dear Doctor/Healthcare Provider Letter, and all final form Dear  
18 Doctor/Healthcare Provider Letters approved for dissemination to doctors and/or  
19 healthcare providers regarding BYETTA.

20 85. All DOCUMENTS and/or information received or obtained from any source  
21 that relate in any way to any causal connection or association of BYETTA with cancers,  
22 including but not limited to pancreatic cancer, and pancreatitis, which were disclosed by  
23 YOU to the medical community.

24 86. All Dear Doctor/Healthcare Provider Letters intended for dissemination in  
25 any country other than the U.S. regarding BYETTA and any English translations that  
26 exist.

27 87. All DOCUMENTS comprising or regarding YOUR internal communications  
28 pertaining to BYETTA and any label changes and/or decisions whether to send Dear  
Doctor/Healthcare Provider Letters.

1 88. All DOCUMENTS comprising or regarding YOUR internal communications  
2 pertaining to BYETTA and the need for physician monitoring and/or testing for cancers,  
3 including but not limited to pancreatic cancer, and pancreatitis.

4 89. All DOCUMENTS relating to, demonstrating, or showing that YOU or  
5 YOUR consultants contemplated or considered recommending that healthcare  
6 professionals test patients' renal and/or gastrointestinal health prior to placing a patient on  
7 BYETTA, and all DOCUMENTS relating to, demonstrating, or showing the outcome of  
8 any such considerations or discussions.

9 90. The IND/NDA and any SNDAs for BYETTA in native electronic searchable  
10 format as maintained by YOU.

11 91. YOUR Regulatory File as it relates to BYETTA, in the format and manner in  
12 which YOU maintain it.

13 92. All DOCUMENTS comprising or regarding correspondence with any  
14 regulatory agency and/or governmental entity in any country, including the United States,  
15 pertaining to safety, adverse events, problems, or complications that reference or relate in  
16 any way to pancreatic cancer with respect to BYETTA, including, but not limited to,  
17 adverse event reports and responses thereto, or post-approval clinical trials and any  
18 English translations that exist if the DOCUMENTS are written in any language other than  
19 English.

20 93. All internal communications and DOCUMENTS regarding adverse events  
21 related to BYETTA and pancreatic cancer.

22 94. All DOCUMENTS prepared but not filed with the FDA, as well as all  
23 information pertaining to planned or potential future IND, NDA, SNDA and ANDA  
24 applications or submissions for BYETTA.

25 95. ALL DOCUMENTS stating or discussing any document retention and/or  
26 document destruction and/or document archiving policy or policies maintained by YOU  
27 from 1995 to the present, including, but not limited to, the policies themselves and any  
28 communications regarding the policies and/or changes or potential changes thereto.

1           96. All DOCUMENTS related to any third party with whom YOU contracted or  
2 otherwise utilized to distribute BYETTA to doctors, pharmacies, retailers, health care  
3 providers, or patients in the United States, including DOCUMENTS sufficient to identify  
4 the nature of YOUR relationship with said third party, the extent of their distribution  
5 network and assigned territory, the document(s) controlling or otherwise guiding YOUR  
6 relationship with said third party, and all communications by and/or between YOU and  
7 said third party related to BYETTA.

8           97. All correspondence or DOCUMENTS comprising or referring to  
9 communications to or from the European Medicine Agency or any members of the  
10 European Medicine Agency regarding BYETTA.

11           98. All correspondence or DOCUMENTS comprising or referring to  
12 communications to or from the European Association for the Study of Diabetes or any  
13 members of the European Association for the Study of Diabetes regarding BYETTA.

14           99. All correspondence or DOCUMENTS comprising or referring to  
15 communications to or from the International Diabetes Foundation or any members of the  
16 International Diabetes Foundation regarding BYETTA.

17           100. All correspondence or DOCUMENTS comprising or referring to  
18 communications to or from the American Diabetes Association or any members of the  
19 American Diabetes Association regarding BYETTA.

20           101. All correspondence or DOCUMENTS comprising or referring to  
21 communications to or from the American Academy of Clinical Endocrinologists or any  
22 members of the American Academy of Clinical Endocrinologists regarding BYETTA.

23           102. All DOCUMENTS submitted to or received from any foreign regulatory  
24 agency and/or government concerning any inquiries or investigations by the regulatory  
25 agency or government related to the safety of BYETTA.

26           103. All DOCUMENTS comprising or referring to communications to or from  
27 laboratories or researchers that have conducted studies in any animal model regarding  
28 exenatide, AC2993, BYETTA, BYDUREON, JANUVIA, JANUMET, VICTOZA and/or  
any other GLP-1 agonist or DPP-4 inhibitor, including, but not limited to, all writings

1 pertaining to the protocols for each such study, amendments to protocols, status reports  
2 on studies, drafts of study reports and all other writings transmitted to or from YOU in  
3 connection with the laboratories or researchers conducting those studies.

4 104. All raw data, including cageside observations; necropsy notes, data and  
5 format; pathology notes; assistants' notes, data and forms; animal and organ weight  
6 records; consumption records; physical and palpation records; histology, serology and  
7 pathology records; photographs; transcripts; recordings in native format; scanning  
8 electron micrographs; and all drafts for each animal study undertaken for any purpose  
9 with respect to BYETTA. This includes, but is not limited to every primate study, every  
10 rodent study, and every other animal and cell system, in vivo and in vitro, studied by  
11 YOU.

12 105. All DOCUMENTS and raw data for each study of the effect of exenatide,  
13 sitagliptin, liraglutide and/or any other GLP-1 agonist or DPP-4 inhibitor on the human  
14 pancreas, undertaken or sponsored by YOU.

15 106. If not included in the foregoing, all Global Safety/Pharmacovigilance  
16 DOCUMENTS, raw data, summaries of data, commentary, correspondence, notes,  
17 memoranda, emails, and internal DOCUMENTS relating to YOUR compliance with  
18 postmarketing requirements in conjunction with post-approval FDA mandated clinical  
19 study where measurements of lipase and amylase were obtained and summarized.

20 107. All raw data from all published epidemiological studies dealing with or  
21 commenting on the risk of pancreatitis that were sponsored in whole or in part by YOU,  
22 including but not limited to pre-study design, bio-statistical issues such as statistical  
23 power, and pre-publication internal analysis of findings.

24 108. All DOCUMENTS, memoranda, notes, emails, and correspondence however  
25 designated that discuss the subject of exenatide, sitagliptin, liraglutide and/or any other  
26 GLP-1 agonist or DPP-4 inhibitor and the proliferation of abnormal or dysfunctional Beta  
27 cells.

28 109. All correspondence, communications or other DOCUMENTS between YOU  
or any of YOUR agents, employees, consultants or representatives and *JAMA Intern.*

1 *Med.* referring in any way to publication of articles that address the risk of acute  
2 pancreatitis in connection with GLP-1 and/or DPP-4 based therapies, including but not  
3 limited to an article authored by Dr. Sonal Singh, *et al.*

4 110. All DOCUMENTS referring in any way to publication in *JAMA Intern. Med.*  
5 of articles that address the risk of acute pancreatitis in connection with GLP-1 and/or  
6 DPP-4 based therapies, including but not limited to an article authored by Dr. Sonal  
7 Singh, *et al.*

8 111. All correspondence, communications or other DOCUMENTS between YOU  
9 or any of YOUR agents, employees, consultants or representatives and *JAMA Intern.*  
10 *Med.* referring in any way to publication of commentaries that address the risk of acute  
11 pancreatitis in connection with GLP-1 and/or DPP-4 based therapies, including but not  
12 limited to a commentary authored by Dr. Peter Butler.

13 112. All DOCUMENTS referring in any way to publication in *JAMA Intern.*  
14 *Med.* of commentaries that address the risk of acute pancreatitis in connection with GLP-  
15 1 and/or DPP-4 based therapies, including but not limited to a commentary authored by  
16 Dr. Peter Butler.

17 113. All correspondence, communications or other DOCUMENTS between YOU  
18 or any of YOUR agents, employees, consultants or representatives and *Gastroenterology*,  
19 and all DOCUMENTS referring in any way to publication of articles that address the risk  
20 of Pancreatitis, and Pancreatic and Thyroid Cancers With Glucagon-Like Peptide-I-Based  
21 Therapies, including but not limited to an article authored by Dr. Michael Elashoff, *et al.*

22 114. All correspondence, communications or other DOCUMENTS between YOU  
23 or any of YOUR agents, employees, consultants or representatives and *Diabetes*, and all  
24 DOCUMENTS referring in any way to publication of articles that address GLP-I receptor  
25 activation by exendin-4, expansion of pancreatic duct glands in rats and/or formation of  
26 dysplastic lesions and chronic pancreatitis in mice, including but not limited to an article  
27 authored by Belinda Gier, *et al.*

28 115. All correspondence, communications and other DOCUMENTS that refer to  
GLP-1 and/or DPP-4 based therapies, sent by YOU or others on YOUR behalf to, or

1 received from, Dr. Steven Kahn; the Diabetes Research Institute Foundation, University  
2 of Miami; the Lunenfield-Tanenbaum Research Institute; and/or the Joslin Diabetes  
3 Clinic.

4 116. All DOCUMENTS comprising or referring to any compensation in any form  
5 paid by YOU or others on YOUR behalf to Dr. Steven Kahn; the Diabetes Research  
6 Institute Foundation, University of Miami; the Lunenfield-Tanenbaum Research Institute;  
7 and/or the Joslin Diabetes Clinic.

8 117. All DOCUMENTS, including without limitation correspondence, contracts,  
9 consulting agreements, invoices, receipts and all other forms of payment information  
10 related to research on GLP-1 and/or DPP-4 based therapies funded in whole or in part by  
11 YOU or others on YOUR behalf, or for which YOU or others on YOUR behalf supplied  
12 products, facilities or other support, that was supervised or conducted by or on behalf of  
13 Dr. Steven Kahn; the Diabetes Research Institute Foundation, University of Miami; the  
14 Lunenfield-Tanenbaum Research Institute; and/or the Joslin Diabetes Clinic.

15 118. All DOCUMENTS, memoranda, notes, emails, and correspondence however  
16 designated that discuss the subject of exenatide, sitagliptin, liraglutide and/or any other  
17 GLP-1 agonist or DPP-4 inhibitor and the proliferation of abnormal or dysfunctional  
18 alpha ( $\alpha$ ) cells.

19 119. All DOCUMENTS and raw data including histology slides from a 1999  
20 rodent study with alpha-cells hyperplasia, undertaken or sponsored by YOU.

21 120. All DOCUMENTS and raw data including histology slides from any rodent  
22 study which showed increased ductal proliferation and acinar to ductal metaplasia.

23 121. All DOCUMENTS and raw data including histology slides from any non-  
24 human primate study which showed increased ductal proliferation and acinar to ductal  
25 metaplasia.

26 122. All DOCUMENTS and raw data including histology slides from any rodent  
27 study which showed a hemorrhagic pancreas with apoptosis-like necrosis.

28 123. All DOCUMENTS and raw data including histology slides from any non-  
human primate study which showed a hemorrhagic pancreas with apoptosis-like necrosis.

1 124. All DOCUMENTS and study records from any rodent study which recorded  
2 amylase levels.

3 125. All DOCUMENTS and study records from any rodent study which recorded  
4 lipase levels.

5 126. All DOCUMENTS and study records from any non-human primate study  
6 which recorded amylase levels.

7 127. All DOCUMENTS and study records from any non-human study which  
8 recorded lipase levels.

9 128. All DOCUMENTS, including but not limited to internal communications,  
10 grant applications and proposals, grant funding decisions and meetings or hearings about  
11 the same, phases, drafts, protocols, interim reports, final reports, and versions thereof,  
12 whether published or not, regarding the effect(s) of exenatide, sitagliptin, liraglutide  
and/or any other GLP-1 agonist or DPP-4 inhibitor on glucagon suppression.

13 129. All DOCUMENTS, including but not limited to internal communications,  
14 grant applications and proposals, grant funding decisions and meetings or hearings about  
15 the same, phases, drafts, protocols, interim reports, final reports, and versions thereof,  
16 whether published or not, regarding the short- and long-term effect(s) of glucagon  
17 suppression.

18 130. All DOCUMENTS, including but not limited to internal communications,  
19 grant applications and proposals, grant funding decisions and meetings or hearings about  
20 the same, phases, drafts, protocols, interim reports, final reports, and versions thereof,  
21 whether published or not, regarding a 2008 presentation regarding a “likely” causal  
22 connection between exenatide and pancreatitis.

23 131. All pre-clinical and clinical study results obtained by YOU or others on  
24 YOUR behalf relating to BYETTA, documenting calcitonin levels, regardless of whether  
25 the study was ever completed, published or discontinued, or whether human patients were  
ever enrolled.

26 132. All pre-clinical and clinical study results obtained by YOU or others on  
27 YOUR behalf relating to BYETTA, documenting thyroid histology, regardless of whether  
28

1 the study was ever completed, published or discontinued, or whether human patients were  
2 ever enrolled.

3 133. All correspondence, communications and other DOCUMENTS that refer to  
4 GLP-1 and/or DPP-4 based therapies, sent by YOU or others on YOUR behalf to, or  
5 received from, Professor Michael Nauck, Head of the Diabeteszentrum Bad Lauterberg,  
6 Harz, Germany.

7 134. All DOCUMENTS, memoranda, notes, emails, PowerPoint presentations,  
8 lists of attendees and correspondence, however designated, from a June 2009 meeting  
9 held at the American Diabetes Association's annual conference in New Orleans which  
10 discussed that acinar to ductal metaplasia and chronic pancreatitis seen in the Matveyenko  
11 study could suggest an increased risk of pancreatic cancer.

12 135. All DOCUMENTS, memoranda, notes, emails, PowerPoint presentations,  
13 lists of attendees and correspondence, however designated, from a September 2008  
14 pancreatitis working group which discussed, *inter alia*, external messaging and included a  
15 presentation which pointed to the mounting reports of pancreatitis in patients taking  
16 exenatide and the strengthening biological plausibility of exocrine pancreatic effects.

17 136. All DOCUMENTS concerning or relating to any studies, including but not  
18 limited to all phases, drafts, protocols, notes, comments, interim reports, final reports, and  
19 versions thereof, whether published or not, that raise questions about, suggest, indicate or  
20 demonstrate that GLP-1 receptors occur on pancreatic duct cells.

21 137. All DOCUMENTS concerning or relating to any studies, including but not  
22 limited to all phases, drafts, protocols, notes, comments, interim reports, final reports, and  
23 versions thereof, whether published or not, that raise questions about, suggest, indicate or  
24 demonstrate that GLP-1 agonists and/or DPP-4 inhibitors induce ductal cell proliferation  
25 in addition to Beta cell proliferation.

26 138. All DOCUMENTS concerning or relating to any studies, including but not  
27 limited to all phases, drafts, protocols, notes, comments, interim reports, final reports, and  
28 versions thereof, whether published or not, that raise questions about, suggest, indicate or  
demonstrate that GLP-1 agonists and/or DPP-4 inhibitors inhibit apoptosis of ductal cells.

1 139. All DOCUMENTS concerning or relating to any studies, including but not  
2 limited to all phases, drafts, protocols, notes, comments, interim reports, final reports, and  
3 versions thereof, whether published or not, that raise questions about, suggest, indicate or  
4 demonstrate that GLP-1 agonists and/or DPP-4 inhibitors inhibit apoptosis of islet cells.

5 140. All DOCUMENTS, memoranda, notes, emails, PowerPoint presentations,  
6 lists of attendees and correspondence, however designated, from an August 2012  
7 American Statistical Association meeting presentation by William DuMouchel, chief  
8 statistical scientist at Oracle Health Sciences.

9 141. All correspondence, communications and other DOCUMENTS that refer to  
10 GLP-1 and/or DPP-4 based therapies, sent by YOU or others on YOUR behalf to, or  
11 received from, chief medical officer Pia Caduff of the WHO's Uppsala Monitoring  
12 Centre.

13 142. All DOCUMENTS concerning or relating to any studies, including but not  
14 limited to all phases, drafts, protocols, notes, comments, interim reports, final reports, and  
15 versions thereof, whether published or not, that raise questions about, suggest, indicate or  
16 demonstrate an association between increased pancreatic weight and/or increased size of  
17 the exocrine pancreas with increasing dosage of BYETTA or exenatide, sitagliptin,  
18 liraglutide and/or any other GLP-1 agonist or DPP-4 inhibitor.

19 143. All DOCUMENTS, raw data and other evidence on which YOU and YOUR  
20 pathologists relied to conclude that hyperplasia of pancreatic ductal epithelium was not  
21 test article-related, as was concluded in Study No. 0997-139 Sponsor study No. REST  
22 00120.

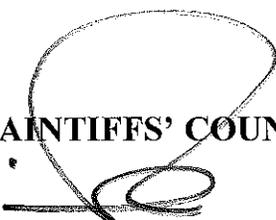
23 144. If not included in the foregoing, all DOCUMENTS, photographs, images,  
24 recordings in any format, and things maintained by Charles River Company pertaining to  
25 every primate study, including but not limited to, necropsy findings, and cage side  
26 observations of monkeys during the 273-day evaluation performed by employees of  
27 Sierra Biomedical.

28 145. If not included in the foregoing, all DOCUMENTS, photographs, images,  
recordings in any format, and things maintained by YOU or others on your behalf

1 pertaining to every primate study, including but not limited to, necropsy findings, and  
2 cage side observations of monkeys during the 91-day toxicity evaluation performed by  
3 employees of Oread, Inc.

4 146. All DOCUMENTS, raw data, summaries of data, commentary,  
5 correspondence, notes, memoranda, emails, and internal DOCUMENTS relating to the  
6 evaluation of amylase and lipase data from exenatide pre-clinical through post-marketing  
7 sources, including but not limited to studies undertaken in connection with NDA 21-919,  
8 Study BCB 108, Duration-2 and in any other context.

9  
10 DATED: January 30, 2014

  
**PLAINTIFFS' COUNSEL**

---

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Tor A. Hoerman  
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# **EXHIBIT 6**

1 GAYLE M. BLATT  
2 CASEY GERRY SCHENK FRANCAVILLA  
3 BLATT & PENFIELD, LLP  
4 110 Laurel St.  
5 San Diego, CA 92101  
6 Phone: (619) 238-1811  
7 Facsimile: (619) 544-9232  
8 gmb@cglaw.com

9 *Plaintiff Co-Liaison Counsel*

10 UNITED STATES DISTRICT COURT  
11 SOUTHERN DISTRICT OF CALIFORNIA

12 IN RE INCRETIN-BASED  
13 THERAPIES PRODUCTS  
14 LIABILITY LITIGATION

15 *As to All Related and Member Cases*

CASE NO. 13md2452-AJB (MDD)

MDL 2452

Magistrate: Hon. Mitchell D. Dembin  
Judge: Hon. Anthony J. Battaglia

17  
18 **PLAINTIFFS' FIRST SET OF INTERROGATORIES**  
19 **TO DEFENDANT AMYLIN PHARMACEUTICALS, LLC**

20 To: Amylin Pharmaceuticals, LLC c/o O'Melveny & Myers LLP,  
21 610 Newport Center Drive, 17<sup>th</sup> Floor, Newport Beach, CA 92660

22 Pursuant to Rule 33 Federal Rules of Civil Procedure, the Plaintiffs in the above  
23 referenced case, hereby propound the following First Set of Interrogatories to Amylin  
24 Pharmaceuticals, LLC ("Defendant"). Plaintiffs request Defendant to permit the Plaintiffs  
25 to review and copy the answers listed below.  
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1 Each interrogatory, as provided by law, shall be answered separately and fully in  
2 writing under oath, unless it is objected to, in which event the reasons for the objection  
3 shall be stated. The answers are to be signed by the person making them, and the  
4 objections signed by the attorney making them. Answers to these interrogatories, or  
5 objections in lieu thereof, shall be served within 30 days from the service of this  
6 document.  
7

8 Under Rule 33 Federal Rules of Civil Procedure, these Interrogatories are  
9 continuing in nature. Defendant, therefore, is required to supplement their responses as  
10 new or different information becomes known.  
11

### 12 DEFINITIONS

13  
14 1. "DOCUMENTS," "DOCUMENT," and "DOCUMENTATION" as used in  
15 this Request is coextensive with the meaning of the terms "DOCUMENTS" and "tangible  
16 things" in Rule 34 of the Federal Rules of Civil Procedure, and shall have the broadest  
17 possible meaning and interpretation ascribed to the terms "DOCUMENTS" and "tangible  
18 things" under Rule 34, and the applicable Local Rules. Consistent with the above  
19 definition, the term "DOCUMENT" shall include, without limitation, any database,  
20 written, printed, typed, photostatic, photographed, recorded, computer-generated,  
21 computer-stored, or otherwise maintained or reproduced communication or  
22 representation, any data compilation in any form, whether comprised of letters, words,  
23 numbers, pictures, sounds, bytes, e-mails, electronic signals or impulses, electronic data,  
24 active files, deleted files, file fragments, or any combination thereof including, without  
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1 limitation, all memoranda, notes, records, letters, envelopes, telegrams, messages, studies,  
2 analyses, contracts, agreements, projections, estimates, working papers, accounts,  
3 analytical records, reports and/or summaries of investigations, opinions or reports of  
4 consultants, opinions or reports of experts, opinions or reports of accountants, other  
5 reports, trade letters, press releases, comparisons, books, diaries, articles, magazines,  
6 newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, forecasts,  
7 drawings, diagrams, instructions, minutes of meetings, correspondence and  
8 communications (as defined below) of any type (including but not limited to video files,  
9 audio files, inter- and intra-office communications), questionnaires, surveys, charts,  
10 graphs, photographs, phonographs, films, tapes, discs, data cells, drums, printouts, all  
11 other compiled data which can be obtained (translated, if necessary, through intermediary  
12 or other devices into usable forms), DOCUMENTS maintained on, stored in or generated  
13 on any electronic transfer or storage system, any preliminary versions, drafts or revisions  
14 of any of the foregoing, and other writings or DOCUMENTS of whatever description or  
15 kind, whether produced or authorized by or on behalf of YOU or anyone else, and shall  
16 include all non-identical copies and drafts of any of the foregoing now in the possession,  
17 custody or control of YOU, or the former or present directors, officers, counsel, agents,  
18 employees, partners, consultants, principals, and/or persons acting on YOUR behalf.  
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23           2.     "Communication", "communications" and/or "correspondence" shall mean  
24 and refer to any oral, written, spoken or electronic transmission of information, including  
25 but not limited to, meetings, discussions, conversations, telephone calls, memoranda,  
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1 letters, emails, text messages, postings, instructions, conferences, or seminars or any other  
2 exchange of information between yourselves or between you and any other person or  
3 entity.

4 3. "Electronic data" or "data" means the original (native electronic format),  
5 and any non-identical copies (whether non-identical because of notes made on copies or  
6 attached comments, annotations, marks, transmission notations, or highlighting of any  
7 kind) of writings of every kind and description whether inscribed by mechanical,  
8 facsimile, electronic, magnetic, digital, or other means. Electronic data includes, by way  
9 of example only, computer programs (whether private, commercial, or works-in-  
10 progress), programming notes or instructions, activity listings of electronic mail receipts  
11 and/or transmittals, output resulting from the use of any software program, including  
12 word processing documents, spreadsheets, database files, charts, graphs and outlines,  
13 electronic mail, operating systems, source code of all types, peripheral drivers, PIF files,  
14 batch files, ASCII files, and any and all miscellaneous files and/or file fragments,  
15 regardless of the media on which they reside and regardless of whether said electronic  
16 data consists of an active file, deleted file or file fragment. Electronic data includes any  
17 and all items stored on computer memories, hard disks, floppy disks, CD-ROMs,  
18 removable media such as zip drives, usb drives, storage cartridges, Bernoulli Boxes and  
19 their equivalent, magnetic tapes of all types, microfiche, punched cards, punched tape,  
20 computer chips, including, but not limited to EPROM, PROM, RAM and ROM, on or in  
21 any other vehicle for digital data storage and/or transmittal. The term electronic data also  
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1 includes the file, folder tabs and/or containers and labels appended to, or associated with,  
2 any physical storage device associated with each original and/or copy.

3 4. "Possession, custody or control" shall mean and refer to any documents in  
4 your possession, custody or control. A document is deemed to be in your "possession,  
5 custody or control" if it is in your physical custody, or if it is in the physical custody of  
6 another person or entity and you: (a) own such document in whole or in part; (b) have a  
7 right by contract, statute or otherwise to use, inspect, examine or copy such document on  
8 any terms; (c) have an understanding, express or implied, that you may use, inspect,  
9 examine or copy such document on any terms; or (d) have, as a practical matter, been able  
10 to use, inspect, examine or copy such document when you have sought to do so. Such  
11 documents shall include, without limitation, documents that are in the custody of your  
12 attorney(s), employees, staff, representatives and agents.

13 5. "Relating to," "relate to," "referring to," "refer to," "reflecting," "reflect,"  
14 "concerning," or "concern" shall mean evidencing, regarding, concerning, discussing,  
15 embodying, describing, summarizing, containing, constituting, showing, mentioning,  
16 reflecting, pertaining to, dealing with, relating to, referring to in any way or manner, or in  
17 any way logically or factually, connecting with the matter described in that paragraph of  
18 these demands, including DOCUMENTS attached to or used in the preparation of or  
19 concerning the preparation of the DOCUMENTS.

20 6. Unless otherwise indicated, the "relevant period" for the information sought  
21 is 1995 to the present.



1 c. Date of correspondence; and

2 d. Location of correspondence.

3 **Interrogatory No. 2:**

4 Has any employee, officer, director, agent, contractor, director, key opinion leader,  
5 member of speaker bureau, advisory board member, or scientific advisor of YOURS  
6 submitted a manuscript, case report, article described as an "advertisement," opinion  
7 piece or topic to any scientific journal on any of the following topics: incretin mimetic  
8 therapies, glucagon-like peptide 1 therapies, dipeptidyl peptidase-4 inhibitor therapies,  
9 exenatide, liraglutide, sitagliptin, saxagliptin, alogliptin, and linagliptin? If so, for each,  
10 please state:  
11  
12

13 a. Individual's name, title, address, phone number who submitted the  
14 manuscript, case report, article, opinion piece or topic;

15  
16 b. Journal name(s) to which the manuscript, case report, article, opinion  
17 piece or topic was submitted;

18 c. Working title of manuscript, case report, article, opinion piece or  
19 topic;

20  
21 d. Date of submission;

22 e. Location of the manuscript, case report, article, opinion piece or topic;

23 f. The amount paid for every manuscript, case report, article, opinion  
24 piece or topic for which payment was made by or on behalf of YOU  
25 for the publication of such document.  
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1 **Interrogatory No. 3:**

2 Has any employee, officer, director, agent, contractor, director, key opinion leader,  
3 member of speaker bureau, advisory board member, or scientific advisor of YOURS  
4 participated in or supplied information to any expert meeting, panel or committee  
5 anywhere in the world, investigating or reviewing glucagon-like peptide 1 based or  
6 dipeptidyl peptidase-4 inhibitor therapies? If so, for each, please state:  
7

- 8 a. Individual's name, title, address, phone number who participated in or  
9 supplied such information;  
10  
11 b. Name and place of meeting, panel or committee the individual  
12 participated or supplied information;  
13  
14 c. Date(s) of meeting, panel or committee proceedings; and  
15  
16 d. Location of all writings, data, correspondence and attachments  
17 supplied, received or created through such meeting, panel or  
committee.

18 **Interrogatory No. 4:**

19 Has any employee, officer, director, agent, contractor, director, key opinion leader,  
20 member of speaker bureau, advisory board member, or scientific advisor of YOURS  
21 corresponded with or supplied information or data to the European Medicines Agency  
22 ("EMA") about or in connection with its 2013 "Assessment report for GLP-1 based  
23 therapies." If so, for each, please state:  
24  
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- 26 a. Correspondent's name, title, address, phone number;  
27  
28

- b. Journal name(s);
- c. Date of correspondence; and
- d. Location of correspondence.

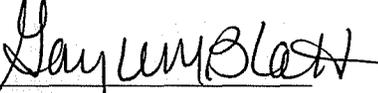
**Interrogatory No. 5:**

Has any employee, officer, director, agent, contractor, director, key opinion leader, member of speaker bureau, advisory board member, or scientific advisor of YOURS corresponded with or supplied information or data to any scientific journal about any of the following individuals: Dr. Peter C. Butler, Dr. Michael Elashoff, Dr. Robert Elashoff, Dr. Alexandra E. Butler, Dr. Belinda Gier, Dr. Aleksey V. Matveyenko, Dr. Edwin Gale, Dr. Sonal Singh? If so, for each, please state:

- a. Correspondent's name, title, address, phone number;
- b. Journal name(s);
- c. Date of correspondence; and
- d. Whereabouts of correspondence .

Dated: November 21, 2013

RESPECTFULLY SUBMITTED,

By: 

**GAYLE M. BLATT**  
CASEY GERRY SCHENK FRANCAVILLA  
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110 Laurel St.  
San Diego, CA 92101  
Phone: (619) 238-1811  
Facsimile: (619) 544-9232  
gmb@cglaw.com

*Plaintiff Co-Liaison Counsel*



Hasler

11/22/2013

US POSTAGE

PRIORITY MAIL  
ComBasPrice

\$05.05<sup>00</sup>



ZIP 92101  
011D11627221

**CASEY, GERRY, SCHENK, FRANCAVILLA,  
BLATT & PENFIELD LLP**

110 LAUREL STREET  
SAN DIEGO, CA 92101-1419

*To:*



Richard B. Goetz, Esq.  
O'Melveny & Myers, LLP  
400 South Hope Street  
Los Angeles, CA 90071

WILLIAMS LEA | SYMPHONY  
400 S. HOPE ST. ROOM 1616

### CALENDAR REQUEST

Job Number   
0 0 0 0 1 3 6 4 9 9 - 0 0 0

Requested Date 11/25/2013 05:03 PM

Requested By CALENDAR,LITIGATION

Due Date 11/25/2013 08:03 PM

User ID 100000000

Case Number 3:13-md-02452-AJB-MDD

Phone

Client Number 0021355

Office Floor

Matter Number 00077(41)

Room Number

Number of Documents 9.000

Client Name AMYLIN PHARMACEUTICALS, LLC

Matter Name IN RE: INCRETIN MIMETICS PRODUCTS LIABILITY LITG

Email Legal Team 1

Email Legal Team 2

Number of Pages including coversheet 65  Document sent to Calendar

Document Type NTC

Method of Service
<input checked="" type="checkbox"/> USPS Mail
<input type="checkbox"/> Overnight Courier
<input type="checkbox"/> Personally Served
Other
<input type="text"/>

Exception
<input type="checkbox"/> Digital media copy enclosure
<input type="checkbox"/> Medical records
<input type="checkbox"/> Originally signed documents

Partial Scan
<input type="checkbox"/> Document larger than 100 pages
<input type="checkbox"/> Bound document
<input type="checkbox"/> Certified document
<input type="checkbox"/> Exhibits

Postmark date-Date sent 11/22/2013 Deliver Original To SERMONS,SYLVIA

Time Received to Mailroom 11/25/2013 04:00 PM

Special Instructions

# **EXHIBIT 7**

1 Michael K. Johnson  
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**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF CALIFORNIA**

**IN RE INCRETIN-BASED  
THERAPIES PRODUCTS  
LIABILITY LITIGATION**

**Relates to: ALL CASES**

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

**MDL – 2452**

**Judge: Hon. Anthony J. Battaglia**

**PLAINTIFFS' AMENDED SECOND SET OF INTERROGATORIES**  
**TO DEFENDANT AMYLIN PHARMACEUTICALS, LLC**

To: Amylin Pharmaceuticals, LLC c/o O'Melveny & Myers, LLP  
610 Newport Center Drive, 17<sup>th</sup> Floor, Newport Beach, CA 92660

Pursuant to Fed. R. Civ. P. 33, Plaintiffs propound the following Amended Second Set of Interrogatories to Amylin Pharmaceuticals, LLC ("Defendant"). Each interrogatory shall be answered separately and fully in writing under oath unless it is objected to, in which event the reasons for the objection shall be stated. The answers are to be signed by the person making them, and the objections signed by the attorney making

1 them. By agreement of the parties, service of this amended Second Set of Interrogatories  
2 has not restarted the 30-day limit for responding, inasmuch as it is identical to the  
3 interrogatories served on January 7, 2014, but for deletion of interrogatories 7, 12, 15, 20,  
4 26 and 38 of the prior set. Nonetheless, Defendant has requested a modest extension of  
5 time to respond, and the parties are currently negotiating the exact date on which  
6 Defendant's responses will be due.

7 These interrogatories are continuing in nature pursuant to Fed. R. Civ. P. 33.  
8 Defendant is therefore required to supplement its responses as new or different  
9 information becomes known.

### 10 **DEFINITIONS AND INSTRUCTIONS**

11 The following terms shall have the following meanings, unless the context requires  
12 otherwise:

13 1. "YOU," "YOUR," or "DEFENDANT" – means Amylin Pharmaceuticals,  
14 LLC, as well as its divisions, parents, subsidiaries, and each of their present and former  
15 officers, directors, employees, agents, and representatives.

16 2. "ELECTRONIC STORAGE DEVICE" – means any device capable of storing  
17 ESI for any period of time, including without limitation, disks, including hard disks and  
18 floppy disks, CD-ROMs, DVDs, network servers, shared servers, computers, magnetic  
19 tape, back-up tape, voice-mail, temporary files, telephones, and PDAs, whether currently  
20 on Defendant's premises or otherwise (e.g. at an employee's home or remote office).

21 3. "ELECTRONICALLY STORED INFORMATION" or "ESI" – means any  
22 information stored in an electronic medium, and shall include, without limitation, any  
23 information, including files, documents, images, video, metadata or any combination  
24 thereof stored, created, or used on any ELECTRONIC STORAGE DEVICE, disk, tape  
25 (including backup tapes and other backup media), or other computer or digital storage  
26 medium, microfilm, microfiche, floppy, or any other storage or recording medium. ESI  
27 includes without limitation electronic mail messages, information stored on web pages or  
28 web servers, and database records.

1           4. "RELATE" – or any variant thereof, including, but not limited to, the term  
2 "RELATING TO," shall be understood to apply if the data or information evidences,  
3 mentions, constitutes, contains, summarizes, describes, concerns, refers to, supports,  
4 contradicts or addresses the subject matter described in this set of demands in which the  
5 term "relate," or any variant thereof, appears.

6           5. "DOCUMENT" or "DOCUMENTS" – means any handwriting, typewriting,  
7 printing, photostating, photographing, photocopying, transmitting by electronic mail or  
8 facsimile, and every other means of recording upon any tangible thing, any form of  
9 communication or representation, including letters, words, pictures, sounds, or symbols,  
10 or combinations thereof, and any record thereby created, regardless of the manner in  
11 which the record has been stored; and shall include, without limitation, the original (and  
12 absent the original then a copy thereof), and all file copies and copies not identical to the  
13 original of any writing or record of every type, form, and description that is in the  
14 possession, custody, or control of the responding party, or which is no longer in the  
15 responding party's possession but of which the responding party still has knowledge,  
16 whether or not said writings or records are claimed to be privileged or otherwise immune  
17 from discovery, including by way of illustration and not limitation, the following items:  
18 notes, correspondence, communications of any nature (including intra-company  
19 communications and correspondence), electronic mail messages, telegrams, cables,  
20 memoranda (including internal memoranda), notebooks of any nature, including  
21 laboratory and engineering reports; summaries, minutes, and records of telephone  
22 conversations, personal conversations or interviews; diaries, routing slips or memoranda,  
23 reports (including tests and analysis reports), books, manuals, publications, invoices,  
24 specifications, shipping papers, purchase orders, flow charts, schematics, diagrams,  
25 photographs of any nature, minutes or recordings of any meetings or conferences,  
26 including lists of persons attending meetings or conferences; transcripts of oral testimony  
27 or statements; labels, tags, fliers, brochures, pamphlets, advertisements, advertising  
28 layouts, circulars, trade letters, press releases, and translations; presentations, including  
boards, transparencies, storybooks and/or scripts; drafts of original or preliminary notes

1 on, and marginal comments appearing on, any DOCUMENTS; whether those writings or  
2 records are on paper, magnetic disk, tape or other computer or digital storage medium,  
3 microfilm, floppy, or any other storage media or recording media.

4 6. "ADVERSE EVENT" – refers to any harmful or undesired experience related  
5 or potentially related to the use of BYETTA, including, without limitation, disability  
6 caused by use of the drug, life-threatening adverse drug experience that caused or placed  
7 the patient at risk of death, or unexpected adverse drug experiences not previously  
8 observed or anticipated.

9 7. Use of the term "BYETTA" includes reference to the medication bearing that  
10 trade name as well as the chemical compound exenatide.

11 8. Unless otherwise indicated, the "relevant period" for the information sought is  
12 1995 to the present.

### 13 INTERROGATORIES

#### 14 **INTERROGATORY NO. 1:**

15 Please identify the name(s) of the company(ies) or other entities that manufactured,  
16 marketed, tested, created, distributed, packaged, promoted, and/or sold BYETTA during  
17 each year that BYETTA was manufactured, marketed, tested, created, distributed,  
18 packaged, promoted, and/or sold. If separate companies or other entities were responsible  
19 for different aspects of the manufacturing, marketing, testing, creating, distributing,  
20 packaging, promoting, and/or selling of BYETTA, then indicate which company or other  
21 entity was responsible for each of the above aspects for each year BYETTA was  
22 manufactured, marketed, tested, created, distributed, packaged, promoted, and/or sold, up  
23 through and including the present.

#### 24 **INTERROGATORY NO. 2:**

25 Describe in detail the relationship between and among Defendant and any other  
26 companies or other entities that manufactured, marketed, tested, created, distributed,  
27 packaged, promoted, and/or sold BYETTA. Provide with your answer any  
28 DOCUMENTS memorializing the agreements between and among Defendant and any  
such companies or other entities.

1 **INTERROGATORY NO. 3:**

2 Identify all license agreements and/or development agreements with any person  
3 and/or entity concerning BYETTA, and produce a copy of any written agreement.

4 **INTERROGATORY NO. 4:**

5 Identify the names and state the present and/or last known address(es) of the  
6 individual(s)/employee(s) with the most knowledge pertaining to BYETTA, including but  
7 not limited to:

- 8 (a) The Product managers at all times Defendant manufactured, produced,  
9 promoted, formulated, created, designed, sold and/or tested BYETTA,  
10 identifying the individuals by time period;
- 11 (b) The sales representatives (whether nationally, regionally, etc.) at all times  
12 Defendant manufactured, produced, promoted, formulated, created,  
13 designed, sold and/or tested BYETTA, identifying the individuals by time  
14 period;
- 15 i. If the sales representative was a regional position, please identify all  
16 regions that Defendant utilized and the person(s) most  
17 knowledgeable for each specific region, identifying the individuals  
18 by time period; and
- 19 ii. Describe the sales and marketing organizational structure utilized  
20 by YOU regarding BYETTA;
- 21 (c) The safety and compliance individuals in charge of reporting ADVERSE  
22 EVENTS and complaints of side effects to the FDA or any other agency,  
23 and investigating all ADVERSE EVENTS and complaints of side effects  
24 at all times Defendant manufactured, produced, promoted, formulated,  
25 created, designed, sold and/or tested BYETTA, identifying the  
26 individuals by time period;
- 27 (d) The person or persons at all times responsible for Quality Assurance with  
28 regard to BYETTA;
- (e) Defendant's liaison(s) to the FDA, whether or not part of the regulatory  
affairs department, with regard to BYETTA at all times Defendant  
manufactured, produced, promoted, formulated, created, designed, sold  
and/or tested BYETTA, identifying the individuals by time period;
- (f) Defendant's researcher(s) and developer(s) responsible for BYETTA at  
all times Defendant manufactured, produced, promoted, formulated,  
created, designed, sold and/or tested BYETTA, identifying the  
individuals by time period;

- 1 (g) Defendant's scientific researcher(s) of BYETTA at all times Defendant  
2 manufactured, produced, promoted, formulated, created, designed, sold  
and/or tested BYETTA, identifying the individuals by time period;
- 3 (h) The person or persons responsible for Defendant's marketing and/or  
4 detailing of BYETTA at all times Defendant manufactured, produced,  
5 promoted, formulated, created, designed, sold and/or tested BYETTA,  
identifying the individuals by time period;
- 6 (i) Defendant's Chief Medical Officer at all times Defendant manufactured,  
7 produced, promoted, formulated, created, designed, sold and/or tested  
BYETTA, identifying the individuals by time period;
- 8 (j) Defendant's Chief Executive Officer ("CEO") at all times Defendant  
9 manufactured, produced, promoted, formulated, created, designed, sold  
and/or tested BYETTA, identifying the individuals by time period;
- 10 (k) Defendant's President at all times Defendant manufactured, produced,  
11 promoted, formulated, created, designed, sold and/or tested BYETTA,  
identifying the individuals by time period;
- 12 (l) Defendant's Chief Financial Officer ("CFO") at all times Defendant  
13 manufactured, produced, promoted, formulated, created, designed, sold  
and/or tested BYETTA, identifying the individuals by time period;
- 14 (m) Defendant's Chief Information Officer ("CIO") at all times Defendant  
15 manufactured, produced, promoted, formulated, created, designed, sold  
16 and/or tested BYETTA, identifying the individuals by time period;
- 17 (n) The person responsible for regulatory affairs at all times Defendant  
18 manufactured, produced, promoted, formulated, created, designed, sold  
and/or tested BYETTA, identifying the individuals by time period;
- 19 (o) Defendant's liaison(s) with any subsidiary or affiliate located outside the  
20 United States that manufactured, produced, promoted, formulated,  
21 created, designed, sold and/or tested BYETTA, identifying the  
individuals by time period;
- 22 (p) Defendant's General Counsel and/or the names of all associate general  
23 counsel at all times Defendant manufactured, produced, promoted,  
24 formulated, created, designed, sold and/or tested BYETTA, identifying  
the individuals by time period;
- 25 (q) Defendant's Chief Operating Officer ("COO") at all times Defendant  
26 manufactured, produced, promoted, formulated, created, designed, sold  
and/or tested BYETTA, identifying the individuals by time period; and
- 27 (r) Members of any International Product Team maintained or utilized by  
28 YOU at all times Defendant manufactured, produced, promoted,

1 formulated, created, designed, sold and/or tested BYETTA, identifying  
2 the individuals by time period.

3 **INTERROGATORY NO. 5:**

4 Identify all persons and/or entities paid by YOU for consulting services of any kind  
5 concerning BYETTA, and for each such person or entity state the nature of the consulting  
6 services rendered and the time frame(s) during which they were rendered.

7 **INTERROGATORY NO. 6:**

8 Did YOU or others acting on YOUR behalf ever consult with researchers,  
9 physicians, nurse scientists, public health advocates, governmental bodies, or others not  
10 on your own staff about whether BYETTA, JANUVIA, JANUMET and/or VICTOZA  
11 were effective and/or as effective as other therapeutic agents for the treatment of type 2  
12 diabetes? If so, state: (a) how efficacy was defined; (b) the method(s) by which efficacy  
13 was determined; (c) the name of each consultant; (d) the date or time periods of each  
14 consultation; (e) the amounts paid to each consultant; (f) the opinions and/or findings  
15 given to YOU by each consultant; (g) if those opinions and/or findings were ever  
16 published, identify the name(s) and location(s) of the publication(s); and (h) if those  
17 opinions and/or findings were not published, (1) explain why not, (2) state whether they  
18 were written anywhere, and (3) state the location of each such writing.

19 **INTERROGATORY NO. 7:**

20 Identify every country in which BYETTA is or has been marketed or sold by YOU  
21 and/or marketed or sold by other corporate entities pursuant to an agreement with YOU,  
22 whether it was marketed or sold under the brand name BYETTA or any other name.  
23 Include in your answer: (a) the date YOU or your agents first sought regulatory approval  
24 to market or sell BYETTA in each country; (b) the date on which approval to market or  
25 sell BYETTA was granted in each country; and (c) the date on which BYETTA first  
26 became commercially available in each country.

27 **INTERROGATORY NO. 8:**

28 Did Defendant ever sell, manufacture, market, promote, test, or issue warnings  
about side effects concerning BYETTA outside the United States, even if the product had

1 a different name or formulation? If so, please state the countries and the dates that  
2 BYETTA or the differently named and/or formulated product was and/or is sold,  
3 manufactured, marketed, promoted, or tested, and specify each country where the  
4 warnings were different than those issued in the United States.

5 **INTERROGATORY NO. 9:**

6 Identify the design used by YOU with respect to BYETTA, and any changes in the  
7 design of BYETTA from the time it was first developed until the present. Include in your  
8 answer the specific changes made to the design, the date of the changes, and why the  
9 changes were made.

10 **INTERROGATORY NO. 10:**

11 Identify each and every database that YOU or others acting on YOUR behalf  
12 maintain or have maintained that is likely to contain any data or information about  
13 BYETTA, JANUVIA, JANUMET, VICTOZA and/or any other GLP-1 agonist or DPP-4  
14 inhibitor. Include in your answer:

- 15 (a) The name of each database;
- 16 (b) The identity of the database administrators;
- 17 (c) The dates of use for each database;
- 18 (d) The hardware and software platforms each database utilized;
- 19 (e) The type of information about BYETTA, JANUVIA, JANUMET,  
20 VICTOZA, and/or any other GLP-1 agonist or DPP-4 inhibitor contained  
21 in each database;
- 22 (f) Whether each database was a transactional database;
- 23 (g) Whether each database was a warehouse database;
- 24 (h) The identity of all other databases that fed information into each database  
25 identified;
- 26 (i) The search capabilities of each database;
- 27 (j) The back-up schedule for each database;
- 28 (k) Whether each database has an audit trail feature that has been enabled;
- (l) The archival, retention and destruction policies with respect to each  
database; and,

1 (m) Whether any database has been discontinued and what was done with the  
2 data contained in any retired database.

3 **INTERROGATORY NO. 11:**

4 Have YOU ever had a document retention policy, document destruction policy, or  
5 document archiving policy? If so, describe each such policy, indicating the applicable  
6 time frames for each policy.

7 **INTERROGATORY NO. 12:**

8 Identify any and all insurance agreements under which any insurer may be liable to  
9 satisfy part or all of a judgment which may be entered against YOU in this litigation  
10 and/or any individual case, or to indemnify or reimburse YOU for payments made to  
11 satisfy a judgment, and with respect to each, please state:

- 12 (a) The name and address of each insurance company and the maximum  
13 amount of all liability coverage of each insurance company, indicating  
14 the amount per person, the amount for all persons, and the amount for  
15 each accident or occurrence;
- 16 (b) If there is excess or umbrella liability insurance coverage, state the name  
17 and address of each insurance carrier for such coverage and the amounts  
18 of coverage available from each, indicating the amount of such coverage,  
19 the aggregate limits and the amount of the underlying limits that must be  
20 exhausted prior to such policy being impacted;
- 21 (c) Set forth how the available insurance coverage identified in paragraphs  
22 (a) and (b) above have been impacted or diminished by any settlements,  
23 awards or judgments that have been paid by any insurance company  
24 identified in paragraph (a) or (b) above;
- 25 (d) If YOU are self-insured, identify the available amounts of such self-  
26 insurance per person for all persons, and the amount for each accident or  
27 occurrence; and
- 28 (e) Identify any entity that has made a reservation of rights.

29 **INTERROGATORY NO. 13:**

30 Have YOU performed or had performed on YOUR behalf any animal studies in  
31 which the safety, side effects, and/or efficacy of BYETTA was tested or otherwise  
32 documented? If so, please state the following:

- 33 (a) When was the first time such a study was made by or for YOU;

- 1 (b) How many studies were done by or for YOU, and state the inclusive dates  
2 of each study;
- 3 (c) Why each study was done;
- 4 (d) Identify the type(s) of animal(s) tested, and state the number of animals  
involved in each study;
- 5 (e) Why the particular test animal was selected for each study;
- 6 (f) What dosage of BYETTA was selected for each study;
- 7 (g) Why the particular dosage of BYETTA was selected for each study;
- 8 (h) What comparator drug or drugs, if any, were used for each study;
- 9 (i) Why the particular comparator drug or drugs, if any, were used for each  
study;
- 10 (j) Whether the studies were completed and whether the data was ever  
11 published; if the data was published, identify the date, publication, and  
authors; and if the data was not published, state why not; and
- 12 (k) Whether the study results were submitted to the FDA and, if so, state the  
13 date on which it was submitted and identify the Bates number of any  
cover letter accompanying the submission.

14 **INTERROGATORY NO. 14:**

15 Identify all pre-approval or post-approval clinical trials or other studies that were  
16 conducted by YOU or on YOUR behalf (whether completed or not) concerning  
17 BYETTA, pursuant to an Investigational New Drug (“IND”) Application, New Drug  
18 Application (“NDA”), Supplemental New Drug Application (“SNDA”), or Abbreviated  
19 New Drug Application (“ANDA”) or conducted for any other reason and, with respect to  
20 each such trial or study, state:

- 21 (a) The protocol number and study name;
- 22 (b) The names and addresses of all clinical investigation sites;
- 23 (c) The names and addresses of all clinical investigators, including any  
medical institution they are affiliated with;
- 24 (d) The names and addresses of all sponsor-investigators;
- 25 (e) The names and addresses of all contract research organizations;
- 26 (f) Whether the studies have been concluded;
- 27 (g) The duration of each study;
- 28

- 1 (h) The Bates number for each final study report and each study protocol;
- 2 (i) A description of what each study concerned, and the results of each
- 3 study;
- 4 (j) The identity of each person responsible for maintaining the records
- 5 regarding these studies;
- 6 (k) Whether any study was terminated before it was fully completed, and if
- 7 so state why;
- 8 (l) Whether any studies have been terminated at the request and/or the
- 9 demand of the FDA;
- 10 (m) Whether the study was submitted for publication and, if so, whether it
- 11 was accepted for publication;
- 12 (n) The citation to any published study;
- 13 (o) The date that the data from each study was "locked" and the date that the
- 14 data was unblended;
- 15 (p) The number of patients enrolled in each study and the number of patients
- 16 who completed each study;
- 17 (q) Identify those studies that were designed to test the safety of BYETTA;
- 18 (r) Identify those studies that were designed to test the efficacy of BYETTA;
- 19 (s) Whether the FDA has ever lodged any complaints, warnings, or
- 20 reprimands with respect to the conduct of any of the studies;
- 21 (t) All amendments to any study protocol and the reason why the protocol
- 22 was amended;
- 23 (u) Whether any human tissue was obtained as part of any study and, if so,
- 24 identify the study and state the location of the tissue;
- 25 (v) If an animal study, state the type of animal used in the study;
- 26 (w) Whether any animal tissue was obtained as part of any study and, if
- 27 so, identify the study and state the location of the tissue;
- 28 (x) Whether any animal pancreatic tissue was obtained as part of any study
- and, if so, identify the study and state the location of the tissue;
- (y) Whether any pancreatic islet cell hyperplasia was diagnosed in any
- animal study and, if so, identify the study and state the location of the
- tissue;
- (z) Whether any pancreatic duct inflammation was diagnosed in any animal
- study and, if so, identify the study and state the location of the tissue;
- (aa) Whether any PanIN lesions were diagnosed in any animal study and,

- 1 if so, identify the study and state the location of the tissue;
- 2 (bb) Whether any nesidioblastosis was diagnosed in any animal study and,  
3 if so, identify the study and state the location of the tissue;
- 4 (cc) Whether any animal thyroid tissue was obtained as part of any study  
5 and, if so, identify the study and state the location of the tissue;
- 6 (dd) The Bates number for all informed consent forms;
- 7 (ee) Identify who has custody of the protocols followed in each study;
- 8 (ff) Identify all records and data from, reflecting and/or relating to each  
9 such study; and,
- 10 (gg) Whether the study results were submitted to the FDA and, if so, the  
11 date on which they were submitted and the Bates number of any cover  
12 letter accompanying the submissions.

13 **INTERROGATORY NO. 15:**

14 Identify all clinical trials or other studies that were conducted by YOU or on  
15 YOUR behalf (whether completed or not) concerning any product (whether or not it was  
16 ever approved for marketing or submitted to any Regulatory Authority for such approval)  
17 containing exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or DPP-4  
18 inhibitor as one of its components and, with respect to each such trial or study, state:

- 19 (a) The names and addresses of all clinical investigation sites;
- 20 (b) The names and addresses of all clinical investigators;
- 21 (c) The names and addresses of all sponsor-investigators;
- 22 (d) The names and addresses of all contract research organizations;
- 23 (e) Whether such studies have been concluded;
- 24 (f) A description of what each study concerned, and the results of each such  
25 study;
- 26 (g) The identity of each person responsible for maintaining the records  
27 regarding these studies;
- 28 (h) Whether any study was terminated before it was fully completed and, if  
so, state why;
- (i) Whether any studies have been terminated at the request and/or the  
demand of the FDA;
- (j) Whether the FDA has ever lodged any complaints, warnings, or  
reprimands with respect to the conduct of any of the studies;

- 1 (k) Identify who has custody of the protocols followed in each study;
- 2 (l) Identify all records and data from, reflecting and/or relating to each such
- 3 study; and,
- 4 (m) Whether the study results were submitted to the FDA and, if so, the date
- 5 on which they were submitted and the Bates number of any cover letter
- 6 accompanying the submissions.

7 **INTERROGATORY NO. 16:**

8 Please identify and describe all tests, investigations, studies, evaluations and/or

9 assessments conducted by YOU or on YOUR behalf, and/or relied upon by YOU either in

10 whole or in part, relating in any way to BYETTA, JANUVIA, JANUMET and/or

11 VICTOZA and pancreatitis and/or pancreatic cancer, including:

- 12 (a) If published, the exact title, author, publisher, place of publication, and
- 13 year of publication of any such test, investigation, study, evaluation
- 14 and/or assessment;
- 15 (b) The dates that each such test, investigation, study, evaluation and/or
- 16 assessment was conducted;
- 17 (c) The name and job title of each of YOUR employees, agents and/or
- 18 servants, if any, who were responsible for the performance and/or
- 19 evaluation of, and/or were in any way involved with the performance
- 20 and/or evaluation of, each such test, investigation, study, evaluation
- 21 and/or assessment;
- 22 (d) Whether the individuals identified in sub-paragraph (c) above are still
- 23 employed by YOU and, if not, their last known address;
- 24 (e) A step-by-step description of the methodology of each such test,
- 25 investigation, study, evaluation and/or assessment;
- 26 (f) The purpose of each such test, investigation, study, evaluation and/or
- 27 assessment;
- 28 (g) The full and complete verbatim results of each such test, investigation,
- study, evaluation and/or assessment;
- (h) All raw data for each such test, investigation, study, evaluation and/or
- assessment;
- (i) The date, manner, and means by which YOU first became aware of each
- such test, investigation, study, evaluation and/or assessment; and,
- (j) Whether such data from each such test, investigation, study, evaluation
- and/or assessment was submitted to the FDA, and if so, on what date.

1 **INTERROGATORY NO. 17:**

2 From the date YOU first developed, designed, manufactured, distributed, sold,  
3 and/or made BYETTA available to consumers up through the present, identify all studies  
4 YOU relied on, if any, as proof of the safety and/or efficacy of BYETTA, and/or the  
5 relative safety and/or efficacy of BYETTA compared to other diabetes medications. As  
6 to each such published study, identify the study by title, author, publication, and year of  
7 publication. If any unpublished study was involved, state the title of such unpublished  
8 study and the date YOU received its results. For each study, also provide:

- 9 (a) If the study was not published, explain why not;
- 10 (b) For studies undertaken by YOU, the date YOU first undertook each such  
11 study;
- 12 (c) The name and title of each of YOUR employee(s) and/or agent(s) who  
13 were responsible and/or involved with each such study, and state whether  
14 they are still employed by YOU, and if not, provide their last known  
addresses and phone numbers; and
- (d) Produce all raw data for each study in native electronic format.

15 **INTERROGATORY NO. 18:**

16 From the date YOU first developed, designed, manufactured, distributed, sold,  
17 and/or made BYETTA available to consumers up through the present, identify all studies  
18 YOU relied on, if any, as proof that the use of the exenatide, sitagliptin, liraglutide and/or  
19 any other GLP-1 agonist or DPP-4 inhibitor in BYETTA is as safe as other diabetes  
20 medications, specifically indicating which studies, if any, show the following:

- 21 (a) That exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or  
DPP-4 inhibitor is safe;
- 22 (b) That exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or  
23 DPP-4 inhibitor does not cause cancer at a higher rate than any other  
therapeutic agents for the treatment of type 2 diabetes;
- 24 (c) That exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or  
25 DPP-4 inhibitor does not cause pancreatitis at a higher rate than any other  
therapeutic agents for the treatment of type 2 diabetes;
- 26 (d) That exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or  
27 DPP-4 inhibitor does not cause pancreatic cancer at a higher rate than any  
28 other therapeutic agents for the treatment of type 2 diabetes;

- 1 (e) That exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or  
2 DPP-4 inhibitor does not cause death at a higher rate than any other  
3 therapeutic agents for the treatment of type 2 diabetes; and  
4 (f) That exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or  
5 DPP-4 inhibitor does not cause any other severe personal injuries at a  
6 higher rate than any other therapeutic agents for the treatment of type 2  
7 diabetes.

8 As to each such study YOU identify in response to this interrogatory, if the study was  
9 published, state the study's exact title, author, publisher, place of publication, and year of  
10 publication; if the study was not published, explain why not and state the title of such  
11 unpublished study and the date you received its results; state the date YOU first  
12 undertook each such study; state the name and title of each of YOUR employee(s) and/or  
13 agent(s) who were responsible for and/or involved with each study, and if such employees  
14 are not still employed by YOU, provide their last known addresses and phone numbers;  
15 and provide all raw data for each study in native electronic format.

16 **INTERROGATORY NO. 19:**

17 Identify all testing that was done by YOU or on YOUR behalf, and/or relied upon  
18 by YOU either in whole or in part, which indicated the following:

- 19 (a) That BYETTA, JANUVIA, JANUMET, and/or VICTOZA is safe;  
20 (b) That BYETTA, JANUVIA, JANUMET and/or VICTOZA does not  
21 cause cancer at a higher rate than any other therapeutic agents for the  
22 treatment of type 2 diabetes;  
23 (c) That BYETTA, JANUVIA, JANUMET and/or VICTOZA does not cause  
24 pancreatitis at a higher rate than any other therapeutic agents for the  
25 treatment of type 2 diabetes;  
26 (d) That BYETTA, JANUVIA, JANUMET and/or VICTOZA does not  
27 cause pancreatic cancer at a higher rate than any other therapeutic agents  
28 for the treatment of type 2 diabetes;  
(e) That BYETTA, JANUVIA, JANUMET and/or VICTOZA does not cause  
death at a higher rate than any other therapeutic agents for the treatment  
of type 2 diabetes; and  
(f) That BYETTA, JANUVIA, JANUMET and/or VICTOZA does not cause  
any other severe personal injuries at a higher rate than any other  
therapeutic agents for the treatment of type 2 diabetes.

1 As to each such test, attach copies of all test results and indicate whether they were ever  
2 published and/or submitted to the FDA.

3 **INTERROGATORY NO. 20:**

4 Please identify and describe all tests, investigations, studies, evaluations and/or  
5 assessments conducted by YOU or on YOUR behalf, and/or relied upon by YOU either in  
6 whole or in part, relating in any way to BYETTA, JANUVIA, JANUMET and/or  
7 VICTOZA, including the following information:

- 8 (a) If published, the exact title, author, publisher, place of publication, and  
9 year of publication of any such test, investigation, study, evaluation  
and/or assessment;
- 10 (b) The dates that each such test, investigation, study, evaluation and/or  
11 assessment was conducted;
- 12 (c) The name and job title of each of YOUR employees, agents and/or  
13 servants who were responsible for the performance and/or evaluation of,  
and/or were in any way involved with the performance and/or evaluation  
of, each such test, investigation, study, evaluation and/or assessment;
- 14 (d) Whether the individuals identified in sub-paragraph (c) above are still  
15 employed by YOU, and if not, their last known addresses and phone  
numbers;
- 16 (e) A step-by-step description of the methodology of each such test,  
17 investigation, study, evaluation and/or assessment;
- 18 (f) The purpose of each such test, investigation, study, evaluation and/or  
19 assessment;
- 20 (g) The full and complete verbatim results of each such test, investigation,  
study, evaluation and/or assessment;
- 21 (h) All raw data for each such test, investigation, study, evaluation and/or  
22 assessment;
- 23 (i) The date, manner, and means by which YOU first became aware of each  
such test, investigation, study, evaluation and/or assessment; and
- 24 (j) Whether such data was submitted to the FDA, and if so, on what date.

25 **INTERROGATORY NO. 21:**

26 Identify any third parties utilized by YOU in the regulatory process either pre-  
27 launch or post-launch, whether in the United States regulatory process or the regulatory  
28

1 process in any other country (identifying each such country). Provide copies of any  
2 contracts, agreement, or communications between YOU and any such third party.

3 **INTERROGATORY NO. 22:**

4 Did YOU or YOUR BYETTA advisory board ever send or receive any oral or  
5 written correspondence with the FDA and/or have any communication with the FDA,  
6 whether in person, telephonic, or otherwise, concerning BYETTA? If yes, then identify  
7 and describe fully (a) all of the correspondence and/or communications; and (b) the date  
8 all correspondence was sent and/or received by YOU and/or the date when the  
9 communications occurred. Attach copies of all such correspondence and any recordings  
10 (written or otherwise) of such communications. If the correspondence exists in electronic  
11 format, produce it in its native electronic format.

12 **INTERROGATORY NO. 23:**

13 Did the FDA or any advisory committee or sub-committee of the FDA or any other  
14 governmental body ever hold any hearings as to the safety and/or efficacy of BYETTA,  
15 JANUVIA, JANUMET and/or VICTOZA? If yes, identify the date(s), time(s), place(s),  
16 and participants in the hearings; state whether YOU or anyone acting on YOUR behalf  
17 provided testimony at any such hearings (including but not limited to hearings by the  
18 FDA, CDC, NIH, USDA, U.S. Congress, and/or U.S. Senate); state the outcome of the  
19 hearings; attach all transcripts of such hearings in native electronic form; and state  
20 whether the FDA and/or any other governmental body ever suggested, requested, or  
21 required YOU to provide further information and/or perform further tests as to the safety  
22 of BYETTA, JANUVIA, JANUMET and/or VICTOZA.

23 **INTERROGATORY NO 24:**

24 Identify all governmental agencies in all countries worldwide that declined to  
25 approve, challenged, asked for additional study, or sought additional warnings before  
26 approving YOUR application to market BYETTA for any indication. Include in your  
27 answer:

28 (a) The country and agency;

(b) The date approval was sought;

- 1 (c) The date approval was denied, challenged, declined, or additional study  
2 or warnings were sought;
- 3 (d) The indication involved;
- 4 (e) The reason for denial, challenge, decline, or seeking additional study or  
5 warnings regarding the application;
- 6 (f) The specifics of any additional study requested; and
- 7 (g) The specifics of any additional warnings requested.

8 **INTERROGATORY NO. 25:**

9 State whether BYETTA was marketed, promoted, and/or advertised in the  
10 following manners, indicating yes or no for each:

- 11 (a) To doctors and/or other healthcare professionals via trade journals;
- 12 (b) To doctors and/or other healthcare professionals via a direct sales force;
- 13 (c) To doctors and/or other healthcare professionals by mailings;
- 14 (d) To doctors and/or other healthcare professionals by email;
- 15 (e) To doctors and/or other healthcare professionals by newsletter;
- 16 (f) To doctors and/or other healthcare professionals via CMS database;
- 17 (g) To consumers via outdoors marketing, promotion, and/or advertising;
- 18 (h) To consumers via magazine;
- 19 (i) To consumers via television;
- 20 (j) To consumers via newspaper;
- 21 (k) To consumers via radio;
- 22 (l) To consumers via newsletter;
- 23 (m) To consumers via e-mail; and/or
- 24 (n) To consumers via internet advertising/marketing.

25 **INTERROGATORY NO. 26:**

26 Identify all direct-to-consumer advertising, promotional, marketing, sales and/or  
27 public relations efforts or campaigns planned and/or implemented by YOU or on YOUR  
28 behalf concerning BYETTA, whether in writing or communicated by any other media  
and/or medium. For all such direct-to-consumer advertising, promotional, marketing,  
sales and/or public relations efforts or campaigns, please identify:

- 1 (a) The names and addresses of all persons and/or entities responsible for all  
2 such direct-to-consumer advertising, promotional, marketing, sales and/or  
3 public relations efforts or campaigns;
- 4 (b) The dates that YOU conducted such direct-to-consumer advertising,  
5 promotional, marketing, sales and/or public relations efforts or  
6 campaigns;
- 7 (c) The specific media vehicles by which the direct-to-consumer advertising,  
8 promotional, marketing, sales and/or public relations efforts or campaigns  
9 were conducted (i.e., print, television, radio, outdoor, etc.);
- 10 (d) All documents pertaining to the development of marketing strategies or  
11 programs for the sale and/or distribution of BYETTA;
- 12 (e) All documents pertaining to the implementation of marketing strategies  
13 or marketing programs concerning BYETTA;
- 14 (f) All documents describing all marketing strategies or programs concerning  
15 BYETTA;
- 16 (g) All documents pertaining to the intended "market" for BYETTA,  
17 including documents pertaining to sales targets, distribution and/or survey  
18 data;
- 19 (h) All drafts of any advertising and/or promotional literature concerning  
20 BYETTA;
- 21 (i) All documents reflecting pricing for BYETTA;
- 22 (j) All documents pertaining to sums of money that YOU budgeted in order  
23 to advertise, promote and/or market BYETTA;
- 24 (k) All press releases prepared in connection with BYETTA; and
- 25 (l) All press kits prepared in connection with BYETTA.

26 **INTERROGATORY NO. 27:**

27 State whether YOU hired, employed, consulted, and/or retained any advertising  
28 agency, public relations firm, and/or any other entity paid to assist in the marketing and/or  
promotion of BYETTA. If so, provide the names and addresses of all advertising  
agencies utilized by YOU in selling, marketing, and/or promoting BYETTA during the  
entire period of time YOU manufactured, marketed, promoted, distributed, and/or sold  
BYETTA, up through and including the present.

1 **INTERROGATORY NO. 28:**

2 State whether YOU and/or any advertising agency hired, employed, consulted,  
3 and/or retained by YOU to market, advertise, and/or promote BYETTA conducted direct-  
4 to consumer advertising. If so, provide the following information:

- 5 (a) The dates that YOU conducted the direct-to-consumer advertising;
- 6 (b) The specific media vehicles by which the direct to consumer advertising  
7 was conducted (i.e., print, television, outdoor, etc.) and the names of all  
8 vehicles that carried the direct-to-consumer ads;
- 9 (c) The specific media vehicles by which the direct to consumer advertising  
10 was conducted (i.e., print, television, outdoor, etc.) and the names of all  
11 vehicles that carried the direct-to-consumer ads;
- 12 (d) The names and addresses of all outside entities hired by YOU that  
13 worked on any Direct-To-Consumer marketing and/or advertising  
14 campaigns relating to BYETTA, and state the location(s) at which each  
15 respective entity did work for YOU on Direct-To-Consumer marketing  
16 and/or advertising campaigns relating to BYETTA;
- 17 (e) The identities of all individuals employed by YOU who worked on any  
18 Direct-To-Consumer marketing and/or advertising campaigns relating to  
19 BYETTA, and with respect to each, state the job title and location at  
20 which each respective individual worked on any Direct-To-Consumer  
21 marketing and/or advertising campaigns relating to BYETTA;
- 22 (f) Whether YOU or any advertising agency hired, employed, consulted,  
23 and/or retained by YOU targeted in its advertising and/or marketing  
24 and/or promotion of BYETTA any specific sub-demographic(s) within  
25 the demographic of potential BYETTA users; and
- 26 (g) If any specific condition was targeted in YOUR Direct-to-Consumer  
27 advertising:
- 28 (1) Identify each condition targeted;
- (2) Explain why each condition was targeted;
- (3) Identify how each condition was determined to be targeted by  
YOU; and
- (4) Provide the names and addresses of all advertising agencies  
utilized by YOU that were or are involved in targeting each  
specific condition listed.

1 **INTERROGATORY NO. 29:**

2 Identify all advertising, promotional, marketing, sales and/or public relations  
3 efforts or campaigns directed to health care providers planned and/or implemented by  
4 YOU or others on YOUR behalf concerning BYETTA, whether in writing or  
5 communicated by any other media and/or medium. For all such advertising, promotional,  
6 marketing, sales and/or public relations efforts or campaigns directed to health care  
7 providers, please identify:

- 8 (a) The names and addresses of all persons and/or entities responsible for all  
9 such advertising, promotional, marketing, sales and/or public relations  
10 efforts or campaigns;  
11 (b) The dates that such advertising, promotional, marketing, sales and/or  
12 public relations efforts or campaigns were conducted;  
13 (c) The specific media vehicles by which the advertising, promotional,  
14 marketing, sales and/or public relations efforts or campaigns were  
15 conducted (i.e., print, television, radio, outdoor, etc.);  
16 (d) All documents pertaining to the development of marketing strategies or  
17 programs for the sale and/or distribution of BYETTA;  
18 (e) All documents pertaining to the implementation of marketing strategies or  
19 marketing programs in connection with BYETTA;  
20 (f) All documents describing all marketing strategies and/or programs  
21 concerning BYETTA;  
22 (g) All documents pertaining to the intended "market" for BYETTA, including  
23 documents pertaining to sales targets, distribution and/or survey data;  
24 (h) All drafts of any advertising and/or promotional literature concerning  
25 BYETTA;  
26 (i) All documents reflecting pricing for BYETTA;  
27 (j) All documents pertaining to sums of money that YOU budgeted in order to  
28 advertise, promote and/or market BYETTA;  
(k) All press releases prepared in connection with BYETTA; and  
(l) All press kits prepared in connection with BYETTA.

25 **INTERROGATORY NO. 30:**

26 Identify all forms of Internet marketing employed by YOU or others on YOUR  
27 behalf with regard to BYETTA, and identify the person with the most knowledge about  
28 such Internet marketing.

1 **INTERROGATORY NO. 31:**

2 Identify all conferences and/or events sponsored by YOU where BYETTA was  
3 referred to, including in your response the title, date and location of the conferences  
4 and/or events; a description of the materials provided at each conference and/or event,  
5 including but not limited to any brochures for the conferences and/or events; and describe  
6 any agenda for each such conference and/or event.

7 **INTERROGATORY NO. 32:**

8 Did the FDA or any advisory committee or sub-committee of the FDA or any other  
9 governmental body ever request that YOU cease dissemination of promotional materials  
10 for BYETTA for any of the following reasons:

- 11 (a) Broadening of the BYETTA indication;
- 12 (b) Overstating the efficacy of BYETTA;
- 13 (c) Minimizing serious risks associated with the use of BYETTA; or
- 14 (d) Any other reasons not included in a-c.

15 If so, identify any and all ways in which the promotional materials were deemed to be  
16 misleading; and identify any and all submissions, corrections and/or plans of action to  
17 correct the misleading promotional materials.

18 **INTERROGATORY NO. 33:**

19 Identify all reports of adverse reactions, injuries, and/or ADVERSE EVENTS in  
20 humans that YOU ever became aware from any source, including but not limited to the  
21 medical community, the press, and/or peer reviewed medical and/or scientific articles,  
22 domestic or international, with respect to exenatide, sitagliptin, liraglutide and/or any  
23 other GLP-1 agonist or DPP-4 inhibitor. As to each report, if published, identify the  
24 author(s), date of publication, place(s) of publications, and title; and identify YOUR  
25 action(s), if any, with respect to the continued sales, distribution, and/or marketing of an  
26 exenatide, sitagliptin, liraglutide, and/or any other GLP-1 agonist or DPP-4 inhibitor-  
27 containing diabetes medication upon learning of each report. Provide copies of all such  
28 reports, and if these reports exist in electronic format, please produce them in their native  
electronic format.

1 **INTERROGATORY NO. 34:**

2 Beginning with the time when YOU first began to design, develop, manufacture,  
3 market, distribute, and/or sell BYETTA, up through and including the present, was  
4 BYETTA ever listed in the Physicians' Desk Reference ("PDR")? If so, please state  
5 whether YOU or others on YOUR behalf indicated a use for BYETTA in the PDR or in  
6 any other source and, if so, describe with particularity the information provided by YOU  
7 or others on YOUR behalf to the PDR, including but not limited to all correspondence,  
8 cover letters, attachments and other documents, as well as all information actually  
9 published in the PDR.

10 **INTERROGATORY NO. 35:**

11 During the period when YOU first began to develop, design, manufacture, market,  
12 distribute and/or sell BYETTA, up through the present, please state the following as to  
13 the BYETTA package insert:

- 14 (a) The indications for use during each year;
- 15 (b) The contraindications each year;
- 16 (c) The warnings each year;
- 17 (d) The adverse reactions each year; and,
- 18 (e) The dosage amounts each year.

19 Identify any and all changes made during this time period in each of the above categories,  
20 stating the date when each change was made, why each change was made, and who  
21 ordered each change. Please also state, if and when any changes were made, whether  
22 there were any drafts and/or other proposals prior to the final and/or ultimate change. If  
23 YOUR answer is in the affirmative, please identify each draft and/or proposal and provide  
24 copies of same. If each draft and/or proposal exists in electronic format, please produce  
25 them in their native electronic format.

26 **INTERROGATORY NO. 36:**

27 Identify all medical literature, including articles, studies, editorials, and/or any peer  
28 reviewed material in YOUR possession that mentions, identifies or sets forth any elevated  
hazards, risks, side effects, adverse reactions and/or dangers from the use of BYETTA,

1 JANUVIA, JANUMET and/or VICTOZA, and with respect to each, please identify the  
2 date, manner, and means by which YOU first became aware of same.

3 **INTERROGATORY NO. 37:**

4 State whether BYETTA subjected users to any adverse effects and/or side effects  
5 that a user of BYETTA may experience at a higher rate than they would as a user of any  
6 other therapeutic agents for the treatment of type 2 diabetes. If YOUR answer is in the  
7 affirmative, please describe any and all adverse effects and/or side effects that a user of  
8 BYETTA may experience from the use of BYETTA at a higher rate than as a user of any  
9 other therapeutic agents for the treatment of type 2 diabetes. Please also identify the  
10 means by which these adverse effects and/or side effects and the rate at which they are  
11 likely to occur are made known to the patient and/or user of BYETTA, whether by any  
12 writing, instructional video, package insert, poster, letter, and/or any other means. Please  
13 also provide copies of all the writing(s), instructional video(s), package insert(s),  
14 poster(s), letter(s), and/or any other means referred to above, including copies of any and  
15 all change(s), drafts, revision(s), and/or modification(s) made to same.

15 **INTERROGATORY NO. 38:**

16 State whether YOU have ever received any complaint(s), domestic or international,  
17 of any of the following ADVERSE EVENTS: (a) cancer; (b) pancreatic cancer; (c)  
18 pancreatitis; and (d) death, from any consumer, BYETTA user, doctors, physicians and/or  
19 healthcare professionals concerning BYETTA, beginning in the year YOU first started  
20 developing, designing, manufacturing, marketing, distributing, promoting, and/or selling  
21 BYETTA, up through and including the present. If YOUR answer is in the affirmative,  
22 then identify and explain the process by which YOU receive complaints regarding  
23 BYETTA from consumers, as well as doctors, physicians and/or healthcare professionals.  
24 Please also state the total number of complaints YOU have received for each type of  
25 complaint, (a) through (d), from consumers, doctors, physicians and/or healthcare  
26 professionals concerning BYETTA, and state the number of each type of complaint, (a)  
27 through (d), by year. Please provide copies of all such complaints or reports of  
28

1 complaints. If the complaints or reports of complaints exist in electronic format, produce  
2 them in their native electronic format.

3 **INTERROGATORY NO. 39:**

4 Identify each person acting on YOUR behalf who has been responsible for: (a)  
5 receiving any complaints, inquiries, letters and other documents pertaining to BYETTA;  
6 (b) evaluating any complaints, inquiries, letters, and other documents pertaining to  
7 BYETTA; (c) investigating any complaints, inquiries, letters or other documents  
8 pertaining to BYETTA; and (d) responding to any complaints, inquiries, letters and other  
9 documents pertaining to BYETTA.

10 **INTERROGATORY NO. 40:**

11 Identify each of YOUR employees, independent contractors or other agents,  
12 whether in the United States or abroad, who at any time expressed any concerns regarding  
13 the safety of BYETTA, JANUVIA, JANUMET and/or VICTOZA, including, without  
14 limitation, concerns about the risks of cancers, including but not limited to pancreatic  
15 cancer, pancreatitis, and/or death from the use of BYETTA, JANUVIA, JANUMET  
16 and/or VICTOZA. Include in your response any concerns expressed about matters before  
17 the FDA, or matters that arose during clinical studies, testing, or post-market surveillance.  
18 With respect to each matter for which concerns were expressed regarding the safety of  
19 BYETTA, JANUVIA, JANUMET and/or VICTOZA as described above, state the  
20 substance of the concerns expressed by each person identified; identify all documents that  
21 state or discuss such concerns; and describe in detail what action, if any, YOU took in  
22 response to those concerns.

23 **INTERROGATORY NO. 41:**

24 State whether exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or  
25 DPP-4 inhibitor subjects users to any potential adverse effects and/or side effects. If  
26 YOUR answer is in the affirmative, please describe any and all adverse effects and/or  
27 side effects that a user of exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist  
28 or DPP-4 inhibitor could experience. Please also identify the means by which those  
adverse effects and/or side effects are made known by YOU to the users of exenatide,

1 sitagliptin, liraglutide and/or any other GLP-1 agonist or DPP-4 inhibitor, whether by any  
2 writing, instructional video, package insert, poster, letter, and/or any other means. Please  
3 also provide copies of all writing(s), instructional video(s), package insert(s), poster(s),  
4 letter(s), and/or any other means employed by YOU, including copies of any and all  
5 change(s), drafts, revision(s), and/or modification(s) made to same.

6 **INTERROGATORY NO. 42:**

7 State whether exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or  
8 DPP-4 inhibitor subjects users to any potential adverse effects and/or side effects at a  
9 higher rate than they would experience as a user of a therapeutic agent for the treatment  
10 of type 2 diabetes containing an active ingredient other than exenatide, sitagliptin,  
11 liraglutide and/or any other GLP-1 agonist or DPP-4 inhibitor. If YOUR answer is in the  
12 affirmative, please describe any and all adverse effects and/or side effects that a user of  
13 exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or DPP-4 inhibitor  
14 would experience at a higher rate than they would experience as a user of a therapeutic  
15 agent for the treatment of type 2 diabetes containing an active ingredient other than  
16 exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or DPP-4 inhibitor.  
17 Please also identify the means by which the higher rates of those adverse effects and/or  
18 side effects are made known by YOU to the users of exenatide, sitagliptin, liraglutide  
19 and/or any other GLP-1 agonist or DPP-4 inhibitor, whether by any writing, instructional  
20 video, package insert, poster, letter, and/or any other means. Please also provide copies  
21 of all writing(s), instructional video(s), package insert(s), poster(s), letter(s), and/or any  
22 other means employed by YOU, including copies of any and all change(s), drafts,  
23 revision(s), and/or modification(s) made to same.

24 **INTERROGATORY NO. 43:**

25 Identify all instructions and/or warnings that accompanied BYETTA and all drafts  
26 of instructions and/or warnings regarding BYETTA at any time that BYETTA was  
27 marketed or sold in any country. Please also:

- 28 (a) Provide the content of any such instruction and/or warning and/or draft of  
such instruction and/or warning;

- 1 (b) State the manner each instruction and/or warning was attached to and/or  
2 accompanied BYETTA;
- 3 (c) Identify the name(s) of the person(s) responsible for creating each such  
4 instruction and/or warning and/or draft of such instruction and/or  
5 warning, and state whether they are still employed by YOU, and if not,  
6 then provide their last known addresses and phone numbers;
- 7 (d) Identify the name(s) of the person(s) who approved each such instruction  
8 and/or warning, and state whether they are still employed by YOU, and if  
9 not, then provide their last known addresses and phone numbers; and
- 10 (e) State the purpose of each such warning and instruction.

11 **INTERROGATORY NO. 44:**

12 State whether any changes, revisions and/or modifications were made to any  
13 warning and/or instruction that accompanied BYETTA at any time that BYETTA was  
14 marketed or sold in any country. If YOUR answer is in the affirmative, please:

- 15 (a) Identify the change(s), revision(s) and/or modification(s);
- 16 (b) State the date(s) of any change(s), revision(s), and/or modification(s);
- 17 (c) State the reason for the change(s), revision(s), and/or modification(s); and
- 18 (d) Identify the name(s) of the person(s) who approved the change(s),  
19 revision(s) and/or modification(s), and state whether they are still  
20 employed by YOU, and if not, then provide their last known addresses  
21 and phone numbers.

22 Please also attach copies of all documents pertaining to the changes, revisions and/or  
23 modifications made to the instructions and/or warnings, as well as copies of all  
24 communications (written or otherwise), both internal and/or with the FDA, concerning  
25 any changes, revisions and/or modification concerning BYETTA.

26 **INTERROGATORY NO. 45:**

27 Have YOU ever issued a warning letter and/or “Dear Doctor” and/or “Dear  
28 healthcare provider” letter to the medical community either in the United States or in any  
other country regarding BYETTA? If YOUR answer is in the affirmative, please state:

- (a) Who first suggested sending such letter;
- (b) Who composed each letter;
- (c) The date of each letter;

- 1 (d) To whom the letter was sent;
- 2 (e) How the identities and addresses of the recipients of each letter were
- 3 determined; and
- 4 (f) Whether subsequent letter(s) were sent and, if so, please identify:
- 5 1. Who suggested sending the subsequent letter(s);
- 6 2. Who composed the letter(s);
- 7 3. The dates of the letter(s); and
- 8 4. To whom the letter(s) were sent.

9 Please also attach copies of all letters sent to medical professionals and/or “Dear Doctor”

10 and/or “Dear healthcare provider” letters.

11 **INTERROGATORY NO. 46:**

12 Did YOU or anyone on YOUR behalf communicate with any physician concerning

13 BYETTA and its potential for ADVERSE EVENTS, including but not limited to cancers,

14 pancreatitis, other severe personal injuries and/or death ? If so, provide:

- 15 (a) The date of the communication(s);
- 16 (b) The manner by which the communication(s) took place;
- 17 (c) The substance of the communication(s);
- 18 (d) Why the communication(s) were made; and
- 19 (e) The identity of the person(s) acting on YOUR behalf who made and/or
- 20 issued the communication(s).

21 Please provide copies of all such communications. If the communications exist in

22 electronic format, produce them in their native electronic format.

23 **INTERROGATORY NO. 47:**

24 Please state whether there have been any changes or discussions of changes to the

25 warnings associated with BYETTA within the last year. If YOUR answer is in the

26 affirmative, please specify:

- 27 (a) The areas in which any changes were implemented;
- 28 (b) The reason behind any changes;
- (c) The dates of any changes;
- (d) The studies, if any, that supported and/or prompted the changes;

1 (e) Any and all other information that supported and/or prompted the  
2 changes; and

3 (f) As to discussions of changes to warnings, describe in detail the nature of  
4 the changes considered, and specifically state whether there have been  
any references to potentially placing a black box warning on BYETTA.

5 **INTERROGATORY NO. 48:**

6 At any time since BYETTA became publicly available in the United States, have  
7 YOU discussed or considered withdrawing it from the market due to reports of  
8 ADVERSE EVENTS or for any other reason? If YOUR answer is in the affirmative,  
9 please state:

10 (a) When withdrawal was discussed or considered;

11 (b) Who was involved in any discussions regarding withdrawal;

12 (c) What prompted any discussions regarding withdrawal;

13 (d) Whether any studies were undertaken or reviewed in discussing or  
14 considering withdrawal and, if so, identify which ones; and

15 (e) Why it was determined not to withdraw BYETTA from the United States  
market.

16 **INTERROGATORY NO. 49:**

17 Has there ever been a discontinuance, either temporary or otherwise, of any  
18 exenatide, sitagliptin, liraglutide and/or any other GLP-1 agonist or DPP-4 inhibitor -  
19 containing medication in the United States or any other country? If YOUR answer is in  
the affirmative, indicate the following:

20 (a) Which drug(s) were removed from the market;

21 (b) When the removal(s) occurred;

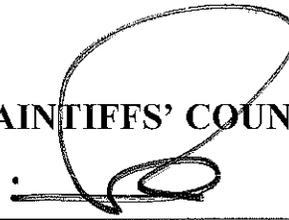
22 (c) Whether the discontinuance(s) were permanent or temporary;

23 (d) The primary motivations behind the discontinuance(s); and,

24 (e) The rate of discontinuance in comparison to the overall prevalence of the  
25 drug(s) on the market.  
26  
27  
28

1 DATED: January 30, 2014

PLAINTIFFS' COUNSEL



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# **EXHIBIT 8**

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9 *Plaintiff Co-Liaison Counsel*

10 UNITED STATES DISTRICT COURT  
11 SOUTHERN DISTRICT OF CALIFORNIA

12 IN RE INCRETIN-BASED  
13 THERAPIES PRODUCTS  
14 LIABILITY LITIGATION

15 *As to All Related and Member Cases*

CASE NO. 13md2452-AJB (MDD)

MDL 2452

Magistrate: Hon. Mitchell D. Dembin  
Judge: Hon. Anthony J. Battaglia

17  
18 **PLAINTIFFS' FIRST SET OF REQUESTS TO PRODUCE**

19 **TO DEFENDANT AMYLIN PHARMACEUTICALS, LLC**

20 To: Amylin Pharmaceuticals, LLC c/o O'Melveny & Myers LLP,  
21 610 Newport Center Drive, 17<sup>th</sup> Floor, Newport Beach, CA 92660

22  
23 Pursuant to Rule 34 of the Federal Rules of Civil Procedure, Plaintiff in the above-  
24 referenced case requests Defendant Amylin Pharmaceuticals, LLC to produce and permit  
25 the Plaintiff to inspect and copy the documents listed below.  
26

## DEFINITIONS

1  
2 1. "DOCUMENTS," "DOCUMENT," and "DOCUMENTATION" as used in  
3 this Request is coextensive with the meaning of the terms "DOCUMENTS" and "tangible  
4 things" in Rule 34 of the Federal Rules of Civil Procedure, and shall have the broadest  
5 possible meaning and interpretation ascribed to the terms "DOCUMENTS" and "tangible  
6 things" under Rule 34, and the applicable Local Rules. Consistent with the above  
7 definition, the term "DOCUMENT" shall include, without limitation, any database,  
8 written, printed, typed, photostatic, photographed, recorded, computer-generated,  
9 computer-stored, or otherwise maintained or reproduced communication or  
10 representation, any data compilation in any form, whether comprised of letters, words,  
11 numbers, pictures, sounds, bytes, e-mails, electronic signals or impulses, electronic data,  
12 active files, deleted files, file fragments, or any combination thereof including, without  
13 limitation, all memoranda, notes, records, letters, envelopes, telegrams, messages, studies,  
14 analyses, contracts, agreements, projections, estimates, working papers, accounts,  
15 analytical records, reports and/or summaries of investigations, opinions or reports of  
16 consultants, opinions or reports of experts, opinions or reports of accountants, other  
17 reports, trade letters, press releases, comparisons, books, diaries, articles, magazines,  
18 newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, forecasts,  
19 drawings, diagrams, instructions, minutes of meetings, correspondence and  
20 communications (as defined below) of any type (including but not limited to video files,  
21 audio files, inter- and intra-office communications), questionnaires, surveys, charts,  
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1 graphs, photographs, phonographs, films, tapes, discs, data cells, drums, printouts, all  
2 other compiled data which can be obtained (translated, if necessary, through intermediary  
3 or other devices into usable forms), DOCUMENTS maintained on, stored in or generated  
4 on any electronic transfer or storage system, any preliminary versions, drafts or revisions  
5 of any of the foregoing, and other writings or DOCUMENTS of whatever description or  
6 kind, whether produced or authorized by or on behalf of YOU or anyone else, and shall  
7 include all non-identical copies and drafts of any of the foregoing now in the possession,  
8 custody or control of YOU, or the former or present directors, officers, counsel, agents,  
9 employees, partners, consultants, principals, and/or persons acting on YOUR behalf.  
10

11  
12 2. "Communication", "communications" and/or "correspondence" shall mean  
13 and refer to any oral, written, spoken or electronic transmission of information, including  
14 but not limited to, meetings, discussions, conversations, telephone calls, memoranda,  
15 letters, emails, text messages, postings, instructions, conferences, or seminars or any other  
16 exchange of information between yourselves or between you and any other person or  
17 entity.  
18

19  
20 3. "Electronic data" or "data" means the original (native electronic format),  
21 and any non-identical copies (whether non-identical because of notes made on copies or  
22 attached comments, annotations, marks, transmission notations, or highlighting of any  
23 kind) of writings of every kind and description whether inscribed by mechanical,  
24 facsimile, electronic, magnetic, digital, or other means. Electronic data includes, by way  
25 of example only, computer programs (whether private, commercial, or works-in-  
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1 progress), programming notes or instructions, activity listings of electronic mail receipts  
2 and/or transmittals, output resulting from the use of any software program, including  
3 word processing documents, spreadsheets, database files, charts, graphs and outlines,  
4 electronic mail, operating systems, source code of all types, peripheral drivers, PIF files,  
5 batch files, ASCII files, and any and all miscellaneous files and/or file fragments,  
6 regardless of the media on which they reside and regardless of whether said electronic  
7 data consists of an active file, deleted file or file fragment. Electronic data includes any  
8 and all items stored on computer memories, hard disks, floppy disks, CD-ROMs,  
9 removable media such as zip drives, usb drives, storage cartridges, Bernoulli Boxes and  
10 their equivalent, magnetic tapes of all types, microfiche, punched cards, punched tape,  
11 computer chips, including, but not limited to EPROM, PROM, RAM and ROM, on or in  
12 any other vehicle for digital data storage and/or transmittal. The term electronic data also  
13 includes the file, folder tabs and/or containers and labels appended to, or associated with,  
14 any physical storage device associated with each original and/or copy.  
15  
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18 4. "Possession, custody or control" shall mean and refer to any documents in  
19 your possession, custody or control. A document is deemed to be in your "possession,  
20 custody or control" if it is in your physical custody, or if it is in the physical custody of  
21 another person or entity and you: (a) own such document in whole or in part; (b) have a  
22 right by contract, statute or otherwise to use, inspect, examine or copy such document on  
23 any terms; (c) have an understanding, express or implied, that you may use, inspect,  
24 examine or copy such document on any terms; or (d) have, as a practical matter, been able  
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1 to use, inspect, examine or copy such document when you have sought to do so. Such  
2 documents shall include, without limitation, documents that are in the custody of your  
3 attorney(s), employees, staff, representatives and agents.

4           5.     “Relating to,” “relate to,” “referring to,” “refer to,” “reflecting,” “reflect,”  
5 “concerning,” or “concern” shall mean evidencing, regarding, concerning, discussing,  
6 embodying, describing, summarizing, containing, constituting, showing, mentioning,  
7 reflecting, pertaining to, dealing with, relating to, referring to in any way or manner, or in  
8 any way logically or factually, connecting with the matter described in that paragraph of  
9 these demands, including DOCUMENTS attached to or used in the preparation of or  
10 concerning the preparation of the DOCUMENTS.  
11

12           6.     Unless otherwise indicated, the “relevant period” for the information sought  
13 is 1995 to the present.  
14

15           7.     “YOU,” “YOUR,” “YOURS,” or “Defendants” refer to Defendants (both  
16 collectively and individually) as well as all of their partners, directors, officers,  
17 employees, servants, agents, attorneys, joint venturers, third-party contractors or other  
18 representatives, including all corporations and entities affiliated with Defendants. The  
19 terms “YOU” or “YOUR” or “YOURS” shall also include all predecessor business  
20 entities, as well as any predecessor’s partners, directors, officers, employees, servants,  
21 agents, attorneys, joint venturers, third-party contractors or other representatives. The  
22 terms “YOU” or “YOUR” or “YOURS” shall also include all foreign subsidiaries or  
23 foreign parent companies, as well as any foreign subsidiaries’ or parent companies’  
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1 partners, directors, officers, employees, servants, agents, attorneys, joint ventures or other  
2 representatives.

### 3 4 REQUESTS FOR PRODUCTION

#### 5 Request to Produce No. 1:

6 Produce any and all correspondence and DOCUMENTS, including but not limited  
7 to attachments, data and articles, submitted by YOU or anyone on YOUR behalf to the  
8 FDA in connection with the FDA's evaluation of "findings by a group of researchers that  
9 suggest an increased risk of pancreatitis and pre-cancerous cellular changes called  
10 pancreatic duct metaplasia," as noted in the FDA's Drug Safety Communication posted  
11 March 14, 2013. This request extends to correspondence and attachments before and  
12 after the FDA's evaluation.  
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14

#### 15 Request to Produce No. 2:

16 Produce any and all correspondence and DOCUMENTS, including but not limited  
17 to attachments, data and articles, submitted by YOU or anyone on YOUR behalf to any  
18 scientific journal on any of the following topics: incretin mimetic therapies, glucagon-  
19 like peptide 1 therapies, dipeptidyl peptidase-4 inhibitor therapies, exenatide, liraglutide,  
20 sitagliptin, saxagliptin, alogliptin, and linagliptin?  
21  
22

#### 23 Request to Produce No. 3:

24 Produce any and all correspondence and DOCUMENTS submitted by YOU or  
25 anyone on YOUR behalf to any scientific journal on any of the following topics:

- 26 a. Pancreatic cancer in patients with Type 2 Diabetes Mellitus;  
27  
28

- 1 b. Pancreatic cancer in animals following administration of any GLP-1 or DPP-  
2 4 inhibitor based therapy; and  
3 c. Pancreatic cancer in humans following treatment with any GLP-1 or DPP-4  
4 inhibitor based therapy.  
5

6 **Request to Produce No. 4:**

7 Produce any and all correspondence and DOCUMENTS, including but not limited  
8 to attachments, data and articles, submitted by YOU or anyone on YOUR behalf to the  
9 European Medicines Agency (“EMA”) in connection with its 2013 “Assessment report  
10 for GLP-1 based therapies.”  
11

12 **Request to Produce No. 5:**

13 Produce any and all notes, minutes, recordings, made at or in connection with, and  
14 any DOCUMENTS received at, the “ad hoc expert meeting” referred to by the EMA in its  
15 2013 Assessment report for GLP-1 based therapies.  
16

17 **Request to Produce No. 6:**

18 Produce any and all notes, minutes, recordings, made at or in connection with, and  
19 any DOCUMENTS received at, the “Committee for Medicinal Products for Human Use”  
20 referred to by the EMA in its 2013 Assessment report for GLP-1 based therapies.  
21

22 **Request to Produce No. 7:**

23 Produce any and all notes, minutes, recordings, made at or in connection with, and  
24 any DOCUMENTS received at, the “Pharmacovigilance Risk Assessment Committee”  
25 referred to by the EMA in its 2013 Assessment report for GLP-1 based therapies.  
26  
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1 **Request to Produce No. 8:**

2 Produce any and all correspondence, communications or other DOCUMENTS that  
3 refer in any way to the Global Technology Communities Diabetes Summit held in  
4 Boston, Massachusetts April 29-30, 2013.  
5

6 **Request to Produce No. 9:**

7 Produce all correspondence and DOCUMENTS, including but not limited to  
8 attachments, data and articles, submitted by YOU or anyone on YOUR behalf related to  
9 presentations made at the Global Technology Communities Diabetes Summit held in  
10 Boston, Massachusetts April 29-30, 2013.  
11

12 **Request to Produce No. 10:**

13 Produce any and all correspondence, communications or other DOCUMENTS that  
14 refer in any way to the NIDKK-NCI Workshop on Pancreatitis-Diabetes-Pancreatic  
15 Cancer held on June 12-13, 2013 in Bethesda, Maryland.  
16

17 **Request to Produce No. 11:**

18 Produce any and all correspondence and DOCUMENTS, including but not limited  
19 to attachments, data and articles, submitted by YOU or anyone on YOUR behalf related  
20 to presentations made at the NIDKK-NCI Workshop on Pancreatitis-Diabetes-Pancreatic  
21 Cancer held on June 12-13, 2013 in Bethesda, Maryland.  
22

23 **Request to Produce No. 12:**

24 Produce any and all correspondence, communications and DOCUMENTS that  
25 refer to GLP-1 or DPP-4 inhibitor therapies, sent by YOU or anyone on YOUR behalf to,  
26  
27  
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1 or received by YOU, regarding any of the following individuals:

- 2 a. Dr. Peter Butler
- 3 b. Dr. Daniel J. Drucker
- 4 c. Dr. David D. Dore
- 5 d. Dr. Robert Elashoff
- 6 e. Dr. Michael Elashoff
- 7 f. Dr. Rajesh Garg
- 8 g. Dr. Belinda Gier
- 9 h. Dr. Fred Gorlick
- 10 i. Dr. Jacqueline Koehler
- 11 j. Dr. Aleksey Matveyenko
- 12 k. Dr. Robert Ratner
- 13 l. Dr. Sonal Singh
- 14 m. Dr. Jay S. Skyler
- 15 n. Dr. Susan Bonner-Weir

16  
17  
18  
19  
20 **Request to Produce No. 13:**

21 Produce any and all correspondence, communications and DOCUMENTS,  
22 including but not limited to any and all emails, that refer to any of the following  
23 individuals:

- 24 a. Dr. Peter Butler
- 25 b. Dr. Daniel J. Drucker

- c. Dr. David D. Dore
- d. Dr. Robert Elashoff
- e. Dr. Michael Elashoff
- f. Dr. Rajesh Garg
- g. Dr. Belinda Gier
- h. Dr. Fred Gorlick
- i. Dr. Jacqueline Koehler
- j. Dr. Aleksey Matveyenko
- k. Dr. Robert Ratner
- l. Dr. Sonal Singh
- m. Dr. Jay S. Skyler
- n. Dr. Susan Bonner-Weir

**Request to Produce No. 14:**

Produce any and all DOCUMENTS reflecting any payment or compensation paid by YOU or on YOUR behalf to any of the following individuals, or the organization or company employing them:

- a. Dr. Daniel J. Drucker
- b. Dr. David D. Dore
- c. Dr. Rajesh Garg
- d. Dr. Fred Gorelick
- e. Dr. Jacqueline Koehler

1 f. Dr. Robert Ratner

2 g. Dr. Jay S. Skyler

3 h. Dr. Susan Bonner-Weir

4 **Request to Produce No. 15:**

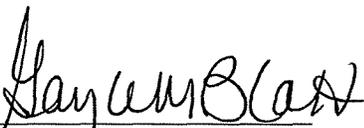
5 Produce any and all correspondence, communications and DOCUMENTS,  
6 including but not limited to attachments, data and articles, that refer to GLP-1 or DPP-4  
7 inhibitor therapies, sent by YOU or anyone on YOUR behalf to, or received by YOU  
8 from, the American Diabetes Association, or any of its officers, directors, advisors or  
9 staff.  
10  
11

12 **Request to Produce No. 16:**

13 Produce any and all DOCUMENTS reflecting YOUR communications to or from  
14 the pharmaceutical regulatory of Japan regarding GLP-1 or DPP-4 inhibitor therapies.  
15  
16

17 Dated: November 20, 2013

18 RESPECTFULLY SUBMITTED,

19 By: 

20 **GAYLE M. BLATT**

21 CASEY GERRY SCHENK FRANCAVILLA  
22 BLATT & PENFIELD, LLP

23 110 Laurel St.

24 San Diego, CA 92101

25 Phone: (619) 238-1811

26 Facsimile: (619) 544-9232

27 gmb@cglaw.com

28 *Plaintiff Co-Liaison Counsel*



Hasler

11/22/2013

US POSTAGE

PRIORITY MAIL  
ComBashRate

\$05.05



ZIP 92101  
011D11627221

**CASEY, GERRY, SCHENK, FRANCAVILLA,  
BLATT & PENFIELD LLP**

110 LAUREL STREET  
SAN DIEGO, CA 92101-1419

*To:*



Richard B. Goetz, Esq.  
O'Melveny & Myers, LLP  
400 South Hope Street  
Los Angeles, CA 90071

**WILLIAMS LEA | SYMPHONY**  
400 S. HOPE ST. ROOM 1616

### CALENDAR REQUEST

Job Number   
0 0 0 0 1 3 6 4 9 9 - 0 0 0

Requested Date  Requested By

Due Date  User ID

Case Number  Phone

Client Number  Office Floor

Matter Number  Room Number

Number of Documents

Client Name

Matter Name

Email Legal Team 1

Email Legal Team 2

Number of Pages including coversheet   Document sent to Calendar

Document Type

**Method of Service**

USPS Mail  
 Overnight Courier  
 Personally Served  
 Other

**Exception**

Digital media copy enclosure  
 Medical records  
 Originally signed documents

**Partial Scan**

Document larger than 100 pages  
 Bound document  
 Certified document  
 Exhibits

Postmark date-Date sent  Deliver Original To

Time Received to Mailroom

Special Instructions

# **EXHIBIT 9**

1 Michael K. Johnson  
2 **JOHNSON BECKER, PLLC**  
3 33 South Sixth Street, Suite 4530  
4 Minneapolis, Minnesota 55402  
5 Telephone: (612) 436-1800  
6 Facsimile: (612) 436-1801  
7 **Email: 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 **Email: 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**

15 UNITED STATES DISTRICT COURT  
16 SOUTHERN DISTRICT OF CALIFORNIA

17 IN RE INCRETIN-BASED  
18 THERAPIES PRODUCTS  
19 LIABILITY LITIGATION

20 *As to All Related and Member Cases*

CASE NO. 13md2452-AJB (MDD)  
MDL 2452

Magistrate: Hon. Mitchell D. Dembin  
Judge: Hon. Anthony J. Battaglia

22 **PLAINTIFFS' SECOND SET OF REQUESTS TO PRODUCE**  
23  
24 **TO DEFENDANT AMYLIN PHARMACEUTICALS, LLC**

25 To: Amylin Pharmaceuticals, LLC c/o O'Melveny & Myers LLP,  
26 610 Newport Center Drive, 17<sup>th</sup> Floor, Newport Beach, CA 92660

1 Pursuant to Rule 34 of the Federal Rules of Civil Procedure, Plaintiff in the above-  
2 referenced case requests Defendant Amylin Pharmaceuticals, LLC to produce and permit  
3 the Plaintiff to inspect and copy the documents listed below.

#### 4 **DEFINITIONS**

5 The following terms shall have the following meanings, unless the context requires  
6 otherwise:

7 1. "YOU," "YOUR," or "DEFENDANT" – means Amylin Pharmaceuticals,  
8 LLC, as well as its divisions, parents, subsidiaries, and each of their present and former  
9 officers, directors, employees, agents, and representatives.

10 2. "ELECTRONIC STORAGE DEVICE" – means any device capable of storing  
11 ESI for any period of time, including without limitation, disks, including hard disks and  
12 floppy disks, CD-ROMs, DVDs, network servers, shared servers, computers, magnetic  
13 tape, back-up tape, voice-mail, temporary files, telephones, and PDAs, whether currently  
14 on Defendant's premises or otherwise (e.g. at an employee's home or remote office).

15 3. "ELECTRONICALLY STORED INFORMATION" or "ESI" – means any  
16 information stored in an electronic medium, and shall include, without limitation, any  
17 information, including files, documents, images, video, metadata or any combination  
18 thereof stored, created, or used on any ELECTRONIC STORAGE DEVICE, disk, tape  
19 (including backup tapes and other backup media), or other computer or digital storage  
20 medium, microfilm, microfiche, floppy, or any other storage or recording medium. ESI  
21 includes without limitation electronic mail messages, information stored on web pages or  
22 web servers, and database records.

23 4. "RELATE" – or any variant thereof, including, but not limited to, the term  
24 "RELATING TO," shall be understood to apply if the data or information evidences,  
25 mentions, constitutes, contains, summarizes, describes, concerns, refers to, supports,  
26 contradicts or addresses the subject matter described in this set of demands in which the  
27 term "relate," or any variant thereof, appears.

1           5. “EVIDENCE” – or any variant thereof, including, but not limited to, the term  
2 “EVIDENCING,” shall be understood to apply if the data or information mentions,  
3 discusses, constitutes, concerns, supports, contradicts, or refers to the subject matter  
4 described in this set of demands in which the term “EVIDENCE,” or any variant thereof,  
5 appears.

6           6. “DOCUMENT” or “DOCUMENTS” – means any handwriting, typewriting,  
7 printing, photostating, photographing, photocopying, transmitting by electronic mail or  
8 facsimile, and every other means of recording upon any tangible thing, any form of  
9 communication or representation, including letters, words, pictures, sounds, or symbols,  
10 or combinations thereof, and any record thereby created, regardless of the manner in  
11 which the record has been stored; and shall include, without limitation, the original (and  
12 absent the original then a copy thereof), and all file copies and copies not identical to the  
13 original of any writing or record of every type, form, and description that is in the  
14 possession, custody, or control of the responding party, or which is no longer in the  
15 responding party’s possession but of which the responding party still has knowledge,  
16 whether or not said writings or records are claimed to be privileged or otherwise immune  
17 from discovery, including by way of illustration and not limitation, the following items:  
18 notes, correspondence, communications of any nature (including intra-company  
19 communications and correspondence), electronic mail messages, telegrams, cables,  
20 memoranda (including internal memoranda), notebooks of any nature, including  
21 laboratory and engineering reports; summaries, minutes, and records of telephone  
22 conversations, personal conversations or interviews; diaries, routing slips or memoranda,  
23 reports (including tests and analysis reports), books, manuals, publications, invoices,  
24 specifications, shipping papers, purchase orders, flow charts, schematics, diagrams,  
25 photographs of any nature, minutes or recordings of any meetings or conferences,  
26 including lists of persons attending meetings or conferences; transcripts of oral testimony  
27 or statements; labels, tags, fliers, brochures, pamphlets, advertisements, advertising  
28

1 layouts, circulars, trade letters, press releases, and translations; presentations, including  
2 boards, transparencies, storybooks and/or scripts; drafts of original or preliminary notes  
3 on, and marginal comments appearing on, any DOCUMENTS; whether those writings or  
4 records are on paper, magnetic disk, tape or other computer or digital storage medium,  
5 microfilm, floppy, or any other storage media or recording media.

6 7. "ADVERSE EVENT" – refers to any harmful or undesired experience related  
7 or potentially related to the use of BYETTA, including, without limitation, disability  
8 caused by use of the drug, life-threatening adverse drug experience that caused or placed  
9 the patient at risk of death, or unexpected adverse drug experiences not previously  
10 observed or anticipated.

11 8. "REPORTABLE EVENT" – means any information that YOU received or  
12 otherwise became aware of, from any source, that YOU believed that YOU were required  
13 to report to the Food and Drug Administration relating to an ADVERSE EVENT.

#### 14 **REQUESTS FOR PRODUCTION OF DOCUMENTS**

##### 15 **REQUEST FOR PRODUCTION NO. 1:**

16 Produce in electronic format complete copies of all Databases that YOU use(d) to  
17 track, trend, or record information regarding any ADVERSE EVENT that YOU  
18 associated with BYETTA, and attach source and other related documentation. This  
19 request includes, to the extent that the databases incorporate this information, any and all  
20 information regarding the nature and type of ADVERSE EVENTS; when they were  
21 received by YOU; what action YOU took in response to the ADVERSE EVENTS; who  
22 YOU contacted or communicated with regarding the ADVERSE EVENTS; any follow-  
23 up efforts or investigation YOU made to obtain further information regarding the  
24 ADVERSE EVENTS; if and when YOU and the Food and Drug Administration ("FDA")  
25 communicated regarding the ADVERSE EVENTS; whether the ADVERSE EVENT was  
26 in the form of a Medwatch Report, communication from a medical provider or consumer,  
27 an ADVERSE EVENT REPORT ("AER") or other form; what YOUR conclusions were

1 as to each ADVERSE EVENT; and the current status or final disposition of the  
2 ADVERSE EVENT or REPORTABLE EVENT.

3 **REQUEST FOR PRODUCTION NO. 2:**

4 Produce copies of each file that YOU established and maintained in response to  
5 each individual ADVERSE EVENT (commonly known as Adverse Event Report event  
6 files, source files, backup files, or any other files containing source documentation related  
7 to ADVERSE EVENTS) for BYETTA, including all DOCUMENTS and ESI contained  
8 therein EVIDENCING or RELATING to any and all information in YOUR possession,  
9 or references to information in YOUR possession related to the underlying ADVERSE  
10 EVENT, including what attempts, if any, YOU made to communicate with anyone,  
11 including, but not limited to health care providers, consumers, sales reps or person/entity  
12 who reported the AER, to gather further information regarding the ADVERSE EVENT,  
13 any analysis, investigation, internal communications, follow-up efforts, or evaluation  
14 YOU conducted, YOUR deliberations and decision-making processes used to determine  
15 whether the ADVERSE EVENT was or was not a REPORTABLE EVENT, related or  
16 unrelated, listed or not listed, associated or caused by BYETTA; any investigations YOU  
17 conducted to determine the cause of the event, and copies of all ADVERSE EVENT  
18 forms, including supplemental reports, MedWatch Reports, and other information  
19 submitted to the Food and Drug Administration.

20 **REQUEST FOR PRODUCTION NO. 3:**

21 To the extent not produced in response to the preceding request for production,  
22 produce all DOCUMENTS AND ESI EVIDENCING and/or RELATING to the  
23 following: any and all ADVERSE EVENTS YOU became aware of for BYETTA,  
24 including what the ADVERSE EVENTS consisted of, and when they were received by  
25 YOU; what action YOU took, if any, in response to each ADVERSE EVENT regarding  
26 BYETTA including any attempts to obtain further information from the health care  
27 providers who treated the person whom was allegedly injured by the drug; any  
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1 communications YOU made or received regarding each ADVERSE EVENT for  
2 BYETTA, including internal communications; the results of any investigations regarding  
3 each ADVERSE EVENT for BYETTA and/or the basis for the decision to not  
4 investigate; and what YOUR conclusions were as to each ADVERSE EVENT; and the  
5 current status or final disposition of the ADVERSE EVENT.

6 **REQUEST FOR PRODUCTION NO. 4:**

7 Produce all DOCUMENTS AND ESI EVIDENCING or RELATING to any  
8 ADVERSE EVENTS YOU received related to any PLAINTIFF in this matter, including  
9 all DOCUMENTS and ESI EVIDENCING or RELATING to what the ADVERSE  
10 EVENT consisted of; when it was received by YOU; what action YOU took in response  
11 to the ADVERSE EVENT; any and all communications YOU made or received regarding  
12 the ADVERSE EVENT, including internal communications; any follow-up efforts YOU  
13 made to obtain further information regarding the ADVERSE EVENT; whether and on  
14 what basis YOU decided to not investigate; whether the ADVERSE EVENT was in the  
15 form of a Medwatch Report, communication from a medical provider or consumer, an  
16 Adverse Event Report or other form; what YOUR conclusions were as to the ADVERSE  
17 EVENT; and the current status or final disposition of the ADVERSE EVENT.

18 **REQUEST FOR PRODUCTION NO. 5:**

19 To the extent not produced in response to the preceding request for production,  
20 produce all DOCUMENTS AND ESI EVIDENCING or RELATING to the following  
21 information for each individual REPORTABLE EVENT for BYETTA:

- 22 a. any information in YOUR possession or references to information in YOUR  
23 possession related to the REPORTABLE EVENT;
- 24 b. any attempts YOU made to communicate with anyone to gather further  
25 information regarding the ADVERSE EVENT;
- 26 c. any communications YOU made or received, including internal  
27 communications, regarding the REPORTABLE EVENT;

- 1 d. YOUR deliberations and decision-making processes used to determine  
2 whether the ADVERSE EVENT was or was not a REPORTABLE EVENT;  
3 e. any investigations YOU conducted to determine the cause of the event;  
4 f. any action YOU took as a result of the REPORTABLE EVENT to prevent  
5 recurrence of the REPORTABLE EVENT;  
6 g. experts and/or consultants whom YOU contacted regarding the ADVERSE  
7 EVENT;  
8 h. copies of all adverse event report forms, including supplemental reports, and  
9 other information submitted to the FDA;  
10 i. analysis of nature, severity and frequency of the ADVERSE EVENT;  
11 j. reporting rates analysis and trending of the ADVERSE EVENT.

12 **REQUEST FOR PRODUCTION NO. 6:**

13 Produce all DOCUMENTS AND ESI EVIDENCING or RELATING to any  
14 request by the Food and Drug Administration for YOU to conduct post-market  
15 surveillance of BYETTA; and any plans, reports, or other information YOU submitted to  
16 the Food and Drug Administration in response.

17 **REQUEST FOR PRODUCTION NO. 7:**

18 Produce all DOCUMENTS AND ESI EVIDENCING or referring to any and all  
19 data analysis or trends of adverse events that were reported to, or conducted by, YOU  
20 regarding BYETTA, including any studies, research or documents prepared to reflect any  
21 analysis or trend.

22 **REQUEST FOR PRODUCTION NO. 8:**

23 Produce all DOCUMENTS AND ESI EVIDENCING or referring to any and all  
24 written policies, procedures or standard operating procedures YOU had in place at the  
25 time YOU first began to market or distribute BYETTA regarding receiving, reviewing,  
26 investigating, evaluating, and/or documenting ADVERSE EVENTS YOU received for  
27 drugs that YOU marketed or distributed, including BYETTA. This includes for example,  
28

1 any questionnaires or follow-up procedure YOU developed to deal with specific types of  
2 injuries related to BYETTA such as, but not limited to, pancreatitis, pancreatic and  
3 thyroid cancers.

4 **REQUEST FOR PRODUCTION NO. 9:**

5 Produce all DOCUMENTS AND ESI EVIDENCING any and all written policies,  
6 procedures, or standard operating procedures YOU had in place during the entire period  
7 of time since BYETTA was first marketed anywhere regarding the timely identification,  
8 communication, investigation, and evaluation of ADVERSE EVENTS that may  
9 constitute REPORTABLE EVENTS; the review process for determining when an  
10 ADVERSE EVENT meets the criteria for being a REPORTABLE EVENT; the  
11 documentation and recordkeeping requirements for information YOU evaluated to  
12 determine whether ADVERSE EVENTS YOU received constituted REPORTABLE  
13 EVENTS, the documentation and recordkeeping requirements for all REPORTABLE  
14 EVENTS and information related thereto actually submitted to the FDA; and the  
15 documentation and recordkeeping requirements regarding any information that was  
16 evaluated for the purpose of preparing the submission of annual reports, PADERs and  
17 PSURs.

18 **REQUEST FOR PRODUCTION NO. 10:**

19 Produce all DOCUMENTS AND ESI EVIDENCING or RELATING to any and/or  
20 all changes or additions YOU made to the procedures and standards identified in the  
21 preceding request for production from January 2003 through the present.

22 **REQUEST FOR PRODUCTION NO. 11:**

23 To the extent not already produced, produce all DOCUMENTS AND ESI  
24 EVIDENCING or referring to any information provided to any of YOUR employees or  
25 agents who were responsible for following up with or communicating with health care  
26 providers regarding adverse events associated with BYETTA regarding the following:  
27 the potential for BYETTA to cause pancreatitis, pancreatic and/or thyroid cancer, any

1 information that these persons were to communicate to and/or obtain from the health care  
2 provider(s), and any training materials, scripts, questionnaires, and instructions that were  
3 to guide interactions with health care providers regarding adverse events for BYETTA.

4 **REQUEST FOR PRODUCTION NO. 12:**

5 Produce all DOCUMENTS AND ESI EVIDENCING any and/or all written  
6 policies, procedures or standard operating procedures YOU had in place during the entire  
7 period of time since BYETTA was first marketed anywhere regarding establishing and  
8 maintaining files for each ADVERSE EVENT that would contain any and/or all  
9 information in YOUR possession or references to information in YOUR possession  
10 related to the underlying ADVERSE EVENT, including all documentation of YOUR  
11 deliberations and decision-making processes used to determine if a drug-related death,  
12 serious injury, or injury of special interest was or was not a REPORTABLE EVENT, and  
13 copies of all adverse event report forms and other information submitted to the FDA.

14 **REQUEST FOR PRODUCTION NO. 13:**

15 Produce all DOCUMENTS AND ESI EVIDENCING or RELATING to any and/or  
16 all changes or additions YOU made to the procedures and standards identified in the  
17 preceding request for production during the entire period of time since BYETTA was first  
18 marketed anywhere.

19 **REQUEST FOR PRODUCTION NO. 14:**

20 Produce all DOCUMENTS AND ESI EVIDENCING or RELATING to  
21 communications and/or correspondence known as “Dear Doctor” or “Dear Healthcare  
22 Professional” letters prepared, generated, authored, and/or sent by YOU to health care  
23 professionals, including physicians, hospitals, pharmacies and clinics, in the United States  
24 and other countries, including any and all preliminary and final drafts of such letters, all  
25 minutes from company, departmental or directors meetings in which revisions or  
26 amendments to such communications and letters were discussed, as well as all editions or  
27 notations made by YOU, concerning BYETTA.

1 **REQUEST FOR PRODUCTION NO. 15:**

2 Produce all DOCUMENTS AND ESI EVIDENCING or RELATING to the  
3 organization of any division, segment, or office of DEFENDANT that participates in the  
4 receipt, collection, evaluation, analysis, trending, and/or reporting of information to any  
5 regulatory agency regarding ADVERSE EVENTS regarding BYETTA.

6 **REQUEST FOR PRODUCTION NO. 16:**

7 Produce all DOCUMENTS AND ESI EVIDENCING or RELATING to entities  
8 with whom YOU contract regarding the collection, processing, evaluating, investigation,  
9 follow-up, analysis, reporting and/or publication of ADVERSE EVENTS for BYETTA  
10 including but not limited to Functional Service Providers, Contract Research  
11 Organizations, vendors, and/or consultants.

12 Dated: December 13, 2013

13 RESPECTFULLY SUBMITTED,

14  
15 By: 

16 Michael K. Johnson

17 **JOHNSON BECKER, PLLC**

18 33 South Sixth Street, Suite 4530

19 Minneapolis, Minnesota 55402

20 Telephone: (612) 436-1800

21 Facsimile: (612) 436-1801

22 **Email: mjohnson@johnsonbecker.com**

23 Ryan L. Thompson

24 **WATTS GUERRA LLP**

25 5250 Prue Road, Suite 525

26 San Antonio, Texas 78240

27 Telephone: (210) 448-0500

28 Facsimile: (210) 448-0501

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Hunter J. Shkolnik

**NAPOLI, BERN, RIPKA & SHKOLNIK**

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6 hunter@napolibern.com

7 Tor A. Hoerman  
8 **TORHOERMAN LAW LLC**  
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# **EXHIBIT 10**

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15 **UNITED STATES DISTRICT COURT**  
16 **SOUTHERN DISTRICT OF CALIFORNIA**

17 **IN RE: INCRETIN-BASED**  
18 **THERAPIES PRODUCTS**  
19 **LIABILITY LITIGATION**

20 **Relates to: ALL CASES**

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

23 **MDL – 2452**

24 **Judge: Hon. Anthony J. Battaglia**

25 **PLAINTIFFS' AMENDED THIRD SET OF REQUESTS TO PRODUCE**  
26 **TO DEFENDANT AMYLIN PHARMACEUTICALS, LLC**

27 To: Amylin Pharmaceuticals, LLC c/o O'Melveny & Myers, LLP  
28 610 Newport Center Drive, 17<sup>th</sup> Floor, Newport Beach, CA 92660

Pursuant to Rule 34 of the Federal Rules of Civil Procedure, Plaintiffs request Defendant Amylin Pharmaceuticals, LLC to produce and permit the Plaintiffs to inspect and copy the documents listed below. By agreement of the parties, service of this amended Third Set of Requests to Produce has not restarted the 30-day limit for responding, inasmuch as it is identical to the requests served on January 7, 2014, but for

1 deletion of requests 4, 10, 29, 33, 96 and 100 of the prior set. Nonetheless, Defendant has  
2 requested a modest extension of time to respond, and the parties are currently negotiating  
3 the exact date on which Defendant's responses will be due.

#### 4 DEFINITIONS AND INSTRUCTIONS

5 1. "YOU," "YOUR," or "DEFENDANT" – means Amylin Pharmaceuticals,  
6 LLC, as well as its divisions, parents, subsidiaries, and each of their present and former  
7 officers, directors, employees, agents and representatives.

8 2. "ELECTRONIC STORAGE DEVICE" – means any device capable of  
9 storing ESI for any period of time, including without limitation, disks, including hard  
10 disks and floppy disks, CD-ROMs, DVDs, network servers, shared servers, computers,  
11 magnetic tape, back-up tape, voice-mail, temporary files, telephones, and PDAs, whether  
12 currently on Defendant's premises or otherwise (e.g. at an employee's home or remote  
13 office).

14 3. "ELECTRONICALLY STORED INFORMATION" or "ESI" – means any  
15 information stored in an electronic medium, and shall include, without limitation, any  
16 information, including files, documents, images, video, metadata or any combination  
17 thereof stored, created, or used on any ELECTRONIC STORAGE DEVICE, disk, tape  
18 (including backup tapes and other backup media), or other computer or digital storage  
19 medium, microfilm, microfiche, floppy, or any other storage or recording medium. ESI  
20 includes without limitation electronic mail messages, information stored on web pages or  
21 web servers, and database records.

22 4. "RELATE" – or any variant thereof, including, but not limited to, the term  
23 "RELATING TO," shall be understood to apply if the data or information evidences,  
24 mentions, constitutes, contains, summarizes, describes, concerns, refers to, supports,  
25 contradicts or addresses the subject matter described in this set of demands in which the  
26 term "relate," or any variant thereof, appears.

27 5. "DOCUMENT" or "DOCUMENTS" – means any handwriting, typewriting,  
28 printing, photostating, photographing, photocopying, transmitting by electronic mail or  
facsimile, and every other means of recording upon any tangible thing, any form of

1 communication or representation, including letters, words, pictures, sounds, or symbols,  
2 or combinations thereof, and any record thereby created, regardless of the manner in  
3 which the record has been stored; and shall include, without limitation, the original (and  
4 absent the original then a copy thereof), and all file copies and copies not identical to the  
5 original of any writing or record of every type, form, and description that is in the  
6 possession, custody, or control of the responding party, or which is no longer in the  
7 responding party's possession but of which the responding party still has knowledge,  
8 whether or not said writings or records are claimed to be privileged or otherwise immune  
9 from discovery, including by way of illustration and not limitation, the following items:  
10 notes, correspondence, communications of any nature (including intra-company  
11 communications and correspondence), electronic mail messages, telegrams, cables,  
12 memoranda (including internal memoranda), notebooks of any nature, including  
13 laboratory and engineering reports; summaries, minutes, and records of telephone  
14 conversations, personal conversations or interviews; diaries, routing slips or memoranda,  
15 reports (including tests and analysis reports), books, manuals, publications, invoices,  
16 specifications, shipping papers, purchase orders, flow charts, schematics, diagrams,  
17 photographs of any nature, minutes or recordings of any meetings or conferences,  
18 including lists of persons attending meetings or conferences; transcripts of oral testimony  
19 or statements; labels, tags, fliers, brochures, pamphlets, advertisements, advertising  
20 layouts, circulars, trade letters, press releases, and translations; presentations, including  
21 boards, transparencies, storybooks and/or scripts; drafts of original or preliminary notes  
22 on, and marginal comments appearing on, any DOCUMENTS; whether those writings or  
23 records are on paper, magnetic disk, tape or other computer or digital storage medium,  
microfilm, floppy, or any other storage media or recording media.

24 6. "ADVERSE EVENT" – refers to any harmful or undesired experience  
25 related or potentially related to the use of BYETTA, including, without limitation,  
26 disability caused by use of the drug, life-threatening adverse drug experience that caused  
27 or placed the patient at risk of death, or unexpected adverse drug experiences not  
28 previously observed or anticipated.



1 organization of the various departments, divisions and subdivisions, and the heads and/or  
2 employees of each such department, division or subdivision, and the relationship and/or  
3 overlap, if any, among and between departments, divisions and subdivisions.

4 8. All DOCUMENTS identifying the role of DEFENDANT with regard to  
5 BYETTA, including any agreements among and between YOU and any other entity  
6 relating to the manufacturing, marketing and/or sale of BYETTA, and all DOCUMENTS  
7 concerning any potential purchase of the rights to manufacture, market, and/or sell  
8 BYETTA by any entity, including, but not limited to, any communications with the  
9 potential purchaser and any internal communications regarding the potential purchase.

10 9. All DOCUMENTS concerning YOUR annual sales revenue and profits  
11 derived from BYETTA in the United States and broken down by State for every year  
12 since BYETTA was first marketed and sold in the United States.

13 10. All databases maintained by or on behalf of YOU that contain data  
14 concerning the number of prescriptions written by any physician relating to BYETTA.

15 11. All DOCUMENTS sufficient to identify any pharmaceutical product  
16 developed by or for YOU containing exenatide, other than BYETTA, whether or not  
17 ultimately submitted to a regulatory agency or marketed in any country.

18 12. All DOCUMENTS that comprise or reflect the policies and procedures that  
19 were or are in place for the storage, deletion, and back-up of DOCUMENTS, including  
20 emails, generated by YOUR employees and agents regarding BYETTA, and all  
21 DOCUMENTS concerning the steps taken by YOU to preserve all DOCUMENTS  
22 concerning, regarding, or pertaining to BYETTA.

23 13. All insurance policies, excess coverage policies, and any other type of  
24 insurance coverage, that YOU believe may potentially cover claims related to BYETTA  
25 for policy years 1995 until the present.

26 14. All DOCUMENTS identifying which clinical research companies and  
27 individuals were used to study BYETTA, together with any contracts whereby YOU  
28 engaged the services of such companies and individuals along with any study protocols

1 given to, used, or developed by such clinical research companies, and any study  
2 summaries and results provided by such clinical research companies.

3 15. All DOCUMENTS comprising or relating to any standard operating  
4 procedure and/or policy and procedure manuals relating to YOUR clinical and pre-  
5 clinical trials for BYETTA from 1995 until the present.

6 16. All DOCUMENTS that identify or list (including in summary format) any  
7 completed, proposed, planned, considered, or conceived pre-clinical studies as well as  
8 clinical trials that assess the association between BYETTA and cancers, including but not  
9 limited to pancreatic cancer and pancreatitis, as well as any other cancer.

10 17. All DOCUMENTS that identify any and all notebooks and electronic  
11 notebooks provided to clinical investigators or scientists that pertain to past, present, and  
12 future pre-clinical and clinical studies of BYETTA.

13 18. All DOCUMENTS comprising or concerning data collected during all  
14 phases of the BYETTA clinical and pre-clinical trials, including, but not limited to, all  
15 data concerning animal studies, *in vitro* studies, competitive studies, scientific studies,  
16 head-to-head studies, same assay studies, parallel studies, and double blind studies.

17 19. All study protocols developed by YOU or others on YOUR behalf relating to  
18 BYETTA, regardless of whether the study was ever completed, published or  
19 discontinued, or whether human patients were ever enrolled.

20 20. All DOCUMENTS from physicians and/or investigators concerning all  
21 BYETTA clinical or pre-clinical trials provided to YOU, whether provided to the FDA or  
22 not.

23 21. All DOCUMENTS containing any data or information relating to  
24 unpublished and discontinued studies (whether sponsored by YOU or not sponsored by  
25 YOU) involving BYETTA.

26 22. All DOCUMENTS containing any data or information relating to ongoing,  
27 past, future, or potential studies (whether sponsored by YOU or not sponsored by YOU)  
28 involving BYETTA.

1 23. All DOCUMENTS constituting minutes from meetings, summaries of the  
2 minutes of such meetings, agendas for such meetings, presentations made at any such  
3 meetings (in their native format) and/or summaries of such meetings with any and all  
4 physicians and investigators involved with clinical and pre-clinical trials for BYETTA.

5 24. All DOCUMENTS concerning any analysis or sub-analysis of clinical trial  
6 data and/or other safety and/or efficacy data used to determine specialty populations  
7 and/or other population criteria for the marketing, advertising, promotion, and/or  
8 targeting of BYETTA users.

9 25. All DOCUMENTS relating to BYETTA that were submitted to the FDA or  
10 received from the FDA.

11 26. All DOCUMENTS concerning any inquiries or investigations by  
12 governmental or regulatory organizations within the United States (either state or federal)  
13 related to BYETTA, including all DOCUMENTS submitted to or received from such  
14 organizations.

15 27. All correspondence or communications to or from any domestic or foreign  
16 regulatory agency and/or government relating to BYETTA and any English translations  
17 that exist.

18 28. All DOCUMENTS that concern or involve discussion about the potential or  
19 actual submission of BYETTA for approval and/or the approval of BYETTA in any  
20 country including, but not limited to, the U.S. This request includes, but is not limited to,  
21 communications regarding foreign governmental agencies and their drug approval  
22 procedures, rules and/or standards, any English translations that exist if the  
23 DOCUMENTS are written in any language other than English, and all DOCUMENTS  
24 pertaining to safety, adverse events, problems, and complications regarding BYETTA,  
25 including, but not limited to, adverse event reports and responses thereto, and post-  
26 approval clinical trials and any English translations that exist if the DOCUMENTS are  
27 written in any language other than English.

28 29. All DOCUMENTS concerning deferred approval to market, declined  
approval to market, declined approval for any indication, or approvals conditioned on

1 providing additional warnings with respect to BYETTA in any country. This request  
2 includes, but is not limited to, communications between the sponsor of BYETTA and the  
3 governmental agency involved, and any English translations that exist if the  
4 DOCUMENTS are written in any language other than English.

5 30. All DOCUMENTS pertaining to planned future IND (Investigational New  
6 Drug Application), NDA (New Drug Application), SNDA (Supplemental New Drug  
7 Application) and ANDA (Abbreviated New Drug Application) applications or  
8 submissions, or submissions for foreign regulatory agencies, related to BYETTA.

9 31. All DOCUMENTS comprising or regarding YOUR internal communications  
10 pertaining to BYETTA's past, present, and future anticipated market share and/or sales in  
11 the United States and/or worldwide.

12 32. All DOCUMENTS relating to, submitted to, created by, or concerning any  
13 committee that reviews and approves any advertising, sales and marketing materials  
14 relating to BYETTA.

15 33. All contracts or agreements with others relating to the promotion of  
16 BYETTA, including DOCUMENTS sufficient to identify all advertising agencies or  
17 public relations firms utilized by YOU in connection with BYETTA in the United States,  
18 and all DOCUMENTS concerning the relationship between YOU and any outside person  
19 or entity involved in the market analysis, marketing, advertising, or promotion of  
20 BYETTA.

21 34. All DOCUMENTS, including contracts, communications, invoices for  
22 services rendered, and any other DOCUMENTS relating to, demonstrating, or showing  
23 YOUR direct or indirect contact with third party contractors and/or vendors who provide  
24 computerized or other data on drug patient instructions for use by pharmacies. This  
25 request includes, but is not limited to, all records relating to, demonstrating, or showing  
26 whether YOU sought to ascertain what the third party contractors and/or vendors were  
27 stating about BYETTA, and any and all efforts to change any statements about BYETTA  
28 contained in patient information handouts generated by pharmacies using information  
generated by the third party contractors and/or vendors.

1 35. Video files (in video format) of all television advertisements, including  
2 drafts, for BYETTA, produced on DVD, and audio files (in audio format) of all radio  
3 advertisements, including drafts, for BYETTA on CD or DVD, as well as all  
4 DOCUMENTS showing or proving that a BYETTA advertisement was run on either  
5 television or radio, including but not limited to affidavits received from the media outlets,  
6 media buyers, or YOUR advertising agencies or public relations firms, and all  
7 DOCUMENTS that demonstrate what city, date and time each television or radio  
8 advertisement relating to BYETTA ran on television or radio.

9 36. All DOCUMENTS relating to point-of-purchase advertisement of whatever  
10 format for BYETTA, including copies of all print advertisements, including drafts, for  
11 BYETTA, all draft and final BYETTA question and answer brochures, copies of all  
12 outdoor advertisements for BYETTA, all DOCUMENTS relating to event advertising for  
13 BYETTA, and all DOCUMENTS relating to coupon programs for BYETTA.

14 37. Screenshots of all Internet based advertisements (including but not limited to  
15 Web sites, blogs, bulletin boards, and pod-casts) and e-commerce information relating to  
16 BYETTA sponsored by or on behalf of YOU, including every screen within any Website,  
17 copies of any Internet website (in a searchable format that can be navigated as if the site  
18 was operating live) tracking data relating to BYETTA, all DOCUMENTS or information  
19 relating to the marketing of BYETTA through any internet-based website, email  
20 campaign, or any other use of the internet or electronic communication, and copies in  
21 electronic/navigable format of any Web page or Website maintained by or on behalf of  
22 YOU that contains any content relating to BYETTA.

23 38. All DOCUMENTS relating to any Direct-to-Consumer marketing and/or  
24 advertising campaigns relating to BYETTA, relating to grassroots sponsorship for  
25 BYETTA, and all DOCUMENTS sufficient to identify YOUR thought leaders and/or key  
26 opinion leaders including, but not limited to, doctors and healthcare providers who were  
27 offered and/or received payment or honoraria from YOU for preparation of scientific  
28 papers, posters, medical articles, speeches, lectures, and/or presentations regarding  
BYETTA.

1 39. All DOCUMENTS that identify former and/or present sales representatives  
2 or detail persons responsible for, or involved with, the marketing or selling of BYETTA,  
3 including the territory each was responsible for.

4 40. All DOCUMENTS used in the training of YOUR sales force, sales  
5 representatives or detail persons who promoted or sold BYETTA at any point in time, and  
6 all DOCUMENTS concerning or regarding the training of YOUR sales force, sales  
7 representatives or detail persons who worked on BYETTA.

8 41. All audio files and video files (in native format) used in the training of your  
9 sales force, sales representatives or detail persons relating to BYETTA, produced on  
10 separate DVD, and all transcripts of any audio files and video files used in the training of  
11 your sales force, sales representatives or detail persons relating to BYETTA.

12 42. All audio communications (both in audio file format and a transcript of the  
13 same) between YOU and YOUR sales force, sales representatives or detail persons  
14 relating to BYETTA, and all email or other written communications between YOU and  
15 YOUR sales force relating to BYETTA.

16 43. All DOCUMENTS that reflect written procedures or guidelines for sales  
17 persons, sales representatives or detail people for recording information about doctor and  
18 healthcare provider detail visits relating to BYETTA.

19 44. All DOCUMENTS that contain information created by any sales  
20 representative or detail person concerning BYETTA that were created in relation to a  
21 meeting or conversation with any doctor, pharmacist or healthcare professional.

22 45. All databases maintained by or on behalf of YOU that contain sales call  
23 notes relating to BYETTA, including but not limited to all DOCUMENTS relating to the  
24 creation of and additions to “drop-down menus” in the call notes database(s) that are to be  
25 used by the sales force, sales representatives or detail persons instead of a data entry field  
26 to be entered by them.

27 46. All DOCUMENTS intended to be provided to prescribing physicians  
28 regarding BYETTA and its intended use, contraindications, potential complications,  
dosage, and potential need for patient monitoring and/or testing, including all

1 DOCUMENTS relating to materials left or intended to be left by sales representatives or  
2 detail persons in the offices of healthcare professionals relating to BYETTA, and all  
3 DOCUMENTS that were provided to physicians or other healthcare professionals that  
4 were intended for distribution to patients concerning the risks of BYETTA causing  
5 cancers, including but not limited to pancreatic cancer, and pancreatitis.

6 47. All DOCUMENTS that reflect warnings, objections or criticisms by any  
7 United States or foreign governmental or regulatory entity of YOUR marketing and/or  
8 promotional materials or practices for BYETTA, specifically including, but not limited to,  
9 all DDMAC letters received by YOU relating to BYETTA, and all internal  
10 communications relating to any DDMAC letter received by YOU relating to BYETTA.

11 48. All consulting agreements, engagement agreements, employment  
12 agreements, or any other agreement, however titled, relating in any way to the testing,  
13 research, development, and/or evaluation of BYETTA, including all DOCUMENTS  
14 regarding any post-marketing studies, seeding studies, cohort studies, case control studies,  
15 randomized studies, protocols, or surveillance conducted in the United States and  
16 worldwide pertaining to BYETTA; all DOCUMENTS regarding any on-going and future  
17 proposed post-marketing studies regarding BYETTA; and all DOCUMENTS comprising  
18 or regarding the retention and/or use of any third-parties who have analyzed or re-  
19 analyzed BYETTA and its causal connection or association with cancers, including but  
20 not limited to pancreatic cancer, and pancreatitis.

21 49. All DOCUMENTS relating to any Standard Operating Procedure (“SOP”)  
22 and policy and procedure manuals relating to YOUR pharmacovigilance group and its  
23 composition and responsibilities, and all DOCUMENTS relating to any SOP and policy  
24 and procedure manuals relating to YOUR post-marketing surveillance for BYETTA from  
25 1995 to the present.

26 50. All charts (to be produced in color) and other DOCUMENTS created by  
27 YOU relating to adverse event reports for BYETTA, including all charts and other  
28 DOCUMENTS that compare BYETTA to other therapeutic agents for the treatment of  
type 2 diabetes.

1 51. All DOCUMENTS concerning or relating to any studies, including but not  
2 limited to all phases, drafts, protocols, notes, comments, interim reports, final reports, and  
3 versions thereof, whether published or not, that raise questions about, suggest, indicate or  
4 demonstrate BYETTA's safety in relation to another drug(s).

5 52. All scientific, clinical, and medical literature concerning the potential  
6 association between therapeutic agents for the treatment of type 2 diabetes and any  
7 cancers, including but not limited to pancreatic cancer, and pancreatitis.

8 53. All DOCUMENTS comprising or regarding any communication with  
9 journals, authors, or publications about any articles or studies assessing a relationship or  
10 association between BYETTA and cancers, including but not limited to pancreatic cancer,  
11 and pancreatitis.

12 54. All DOCUMENTS comprising or regarding compensation, honoraria,  
13 grants, scholarships or gifts, offered or paid, to individuals or institutions for work  
14 associated with BYETTA, including, but not limited to, the promotion, marketing,  
15 research, pre-clinical and clinical trial investigation, and the authorship of articles related  
16 to or concerning BYETTA.

17 55. All DOCUMENTS and/or databases comprising, regarding, generated by, or  
18 sent to any committee, task force, or group YOU created or participated in to address or  
19 handle questions or concerns related to the potential association or causal connection  
20 between BYETTA and cancers, including but not limited to pancreatic cancer, and  
21 pancreatitis.

22 56. All internal communications and related DOCUMENTS concerning what  
23 information should be provided to consumers, physicians or other healthcare  
24 professionals concerning the risk of BYETTA causing cancers, including but not limited  
25 to pancreatic cancer, and pancreatitis, such DOCUMENTS including, but not limited to,  
26 approved informed consent forms; all correspondence and/or other communications  
27 prepared and/or sent in response to communications received from doctors, pharmacists,  
28 hospitals, healthcare providers and/or BYETTA users regarding complaints with  
BYETTA and/or adverse events with BYETTA, including any and all internal

1 communications; and all DOCUMENTS and/or information received or obtained from  
2 any source that relate in any way to any potential causal connection or association of  
3 BYETTA with cancers, including but not limited to pancreatic cancer, and pancreatitis.

4 57. All DOCUMENTS which were provided by YOU to or received by YOU  
5 from the FDA or any other regulatory agency that relate in any way to any potential  
6 causal connection or association of BYETTA with cancers, including but not limited to  
7 pancreatic cancer, and pancreatitis.

8 58. All labels or labeling, final and draft, for use on or in the box used to  
9 package BYETTA, whether submitted to the FDA or not.

10 59. All internal communications regarding final or draft labeling for use on or in  
11 the box used to package BYETTA.

12 60. All communications between YOU and the FDA regarding labels or  
13 labeling, final and draft, for use on or in the box used to package BYETTA.

14 61. All DOCUMENTS relating to any SOP and policy and procedure manuals  
15 relating to the content and format of labeling for BYETTA from 1995 to the present.

16 62. All draft package inserts pertaining to BYETTA, whether submitted to the  
17 FDA or not, from 1995 to the present.

18 63. All internal communications regarding package inserts for BYETTA, from  
19 1995 to the present.

20 64. All communications between YOU and the FDA regarding any and all  
21 BYETTA package inserts, from 1995 to the present.

22 65. All final package inserts approved to be placed within the BYETTA  
23 package, from 1995 to the present.

24 66. All package inserts intended for dissemination in any country other than the  
25 U.S. for BYETTA, including any English translations that exist.

26 67. All draft Core Data Sheets pertaining to BYETTA, whether submitted to the  
27 FDA or not, from 1995 to the present.

28 68. All internal communications regarding Core Data Sheets for BYETTA, from  
1995 to the present.

1           69. All communications between YOU and the FDA regarding any and all  
2 BYETTA Core Data Sheets, from 1995 to the present.

3           70. All final Core Data Sheets relating to BYETTA approved to be distributed,  
4 from 1995 to the present.

5           71. All DOCUMENTS relating to any SOP and policy and procedure manuals  
6 relating to the content and format of package inserts, patient information sheets, and other  
7 information pertaining to or concerning BYETTA that was or is intended for physicians  
8 and patients.

9           72. All draft patient information sheets and/or consumer information sheets  
10 pertaining to BYETTA, whether submitted to the FDA or not.

11           73. All internal communications regarding final or draft BYETTA patient  
12 information sheets and/or consumer information sheets, all communications between  
13 YOU and the FDA regarding any and all BYETTA patient information sheets and/or  
14 consumer information sheets.

15           74. All final patient information sheets and/or consumer information sheets  
16 regarding BYETTA intended for dissemination to patients.

17           75. All draft package inserts or patient information sheets pertaining to  
18 BYETTA that were prepared for any country other than the U.S. and any English  
19 translations that exist.

20           76. All final patient information sheets intended for dissemination in any country  
21 other than the U.S. regarding BYETTA and any English translations that exist.

22           77. All DOCUMENTS and/or information received or obtained from any source  
23 that relate in any way to any causal connection or association of BYETTA with cancers,  
24 including but not limited to pancreatic cancer, and pancreatitis, which were disclosed by  
25 YOU to consumers, potential consumers and YOUR customers.

26           78. All DOCUMENTS concerning and/or explaining YOUR relationship with  
27 retail pharmacies as it relates to BYETTA.

28           79. All DOCUMENTS and/or information received or obtained from any source  
that relate in any way to any causal connection or association of BYETTA with cancers,

1 including but not limited to pancreatic cancer, and pancreatitis, which were disclosed by  
2 YOU to Pharmacies for distribution to consumers, potential consumers and YOUR  
3 customers.

4 80. All DOCUMENTS and/or information received or obtained from any source  
5 that relate in any way to any causal connection or association of BYETTA with cancers,  
6 including but not limited to pancreatic cancer, and pancreatitis, which were provided by  
7 YOU to YOUR sales force, sales representatives, detail persons or any other of YOUR  
8 employees involved in any way in the sale or marketing of BYETTA.

9 81. All DOCUMENTS relating to any SOP and policy and procedure manuals  
10 relating to Dear Doctor or Health Advisory Letters concerning or regarding BYETTA,  
11 from 1995 to the present.

12 82. All draft Dear Doctor/Healthcare Provider Letters relating to BYETTA,  
13 whether or not ever sent.

14 83. All internal communications regarding final or draft Dear Doctor/Healthcare  
15 Provider Letters regarding BYETTA.

16 84. All communications between YOU and the FDA regarding any draft or final  
17 BYETTA Dear Doctor/Healthcare Provider Letter, and all final form Dear  
18 Doctor/Healthcare Provider Letters approved for dissemination to doctors and/or  
19 healthcare providers regarding BYETTA.

20 85. All DOCUMENTS and/or information received or obtained from any source  
21 that relate in any way to any causal connection or association of BYETTA with cancers,  
22 including but not limited to pancreatic cancer, and pancreatitis, which were disclosed by  
23 YOU to the medical community.

24 86. All Dear Doctor/Healthcare Provider Letters intended for dissemination in  
25 any country other than the U.S. regarding BYETTA and any English translations that  
26 exist.

27 87. All DOCUMENTS comprising or regarding YOUR internal communications  
28 pertaining to BYETTA and any label changes and/or decisions whether to send Dear  
Doctor/Healthcare Provider Letters.

1 88. All DOCUMENTS comprising or regarding YOUR internal communications  
2 pertaining to BYETTA and the need for physician monitoring and/or testing for cancers,  
3 including but not limited to pancreatic cancer, and pancreatitis.

4 89. All DOCUMENTS relating to, demonstrating, or showing that YOU or  
5 YOUR consultants contemplated or considered recommending that healthcare  
6 professionals test patients' renal and/or gastrointestinal health prior to placing a patient on  
7 BYETTA, and all DOCUMENTS relating to, demonstrating, or showing the outcome of  
8 any such considerations or discussions.

9 90. The IND/NDA and any SNDAs for BYETTA in native electronic searchable  
10 format as maintained by YOU.

11 91. YOUR Regulatory File as it relates to BYETTA, in the format and manner in  
12 which YOU maintain it.

13 92. All DOCUMENTS comprising or regarding correspondence with any  
14 regulatory agency and/or governmental entity in any country, including the United States,  
15 pertaining to safety, adverse events, problems, or complications that reference or relate in  
16 any way to pancreatic cancer with respect to BYETTA, including, but not limited to,  
17 adverse event reports and responses thereto, or post-approval clinical trials and any  
18 English translations that exist if the DOCUMENTS are written in any language other than  
19 English.

20 93. All internal communications and DOCUMENTS regarding adverse events  
21 related to BYETTA and pancreatic cancer.

22 94. All DOCUMENTS prepared but not filed with the FDA, as well as all  
23 information pertaining to planned or potential future IND, NDA, SNDA and ANDA  
24 applications or submissions for BYETTA.

25 95. ALL DOCUMENTS stating or discussing any document retention and/or  
26 document destruction and/or document archiving policy or policies maintained by YOU  
27 from 1995 to the present, including, but not limited to, the policies themselves and any  
28 communications regarding the policies and/or changes or potential changes thereto.

1           96. All DOCUMENTS related to any third party with whom YOU contracted or  
2 otherwise utilized to distribute BYETTA to doctors, pharmacies, retailers, health care  
3 providers, or patients in the United States, including DOCUMENTS sufficient to identify  
4 the nature of YOUR relationship with said third party, the extent of their distribution  
5 network and assigned territory, the document(s) controlling or otherwise guiding YOUR  
6 relationship with said third party, and all communications by and/or between YOU and  
7 said third party related to BYETTA.

8           97. All correspondence or DOCUMENTS comprising or referring to  
9 communications to or from the European Medicine Agency or any members of the  
10 European Medicine Agency regarding BYETTA.

11           98. All correspondence or DOCUMENTS comprising or referring to  
12 communications to or from the European Association for the Study of Diabetes or any  
13 members of the European Association for the Study of Diabetes regarding BYETTA.

14           99. All correspondence or DOCUMENTS comprising or referring to  
15 communications to or from the International Diabetes Foundation or any members of the  
16 International Diabetes Foundation regarding BYETTA.

17           100. All correspondence or DOCUMENTS comprising or referring to  
18 communications to or from the American Diabetes Association or any members of the  
19 American Diabetes Association regarding BYETTA.

20           101. All correspondence or DOCUMENTS comprising or referring to  
21 communications to or from the American Academy of Clinical Endocrinologists or any  
22 members of the American Academy of Clinical Endocrinologists regarding BYETTA.

23           102. All DOCUMENTS submitted to or received from any foreign regulatory  
24 agency and/or government concerning any inquiries or investigations by the regulatory  
25 agency or government related to the safety of BYETTA.

26           103. All DOCUMENTS comprising or referring to communications to or from  
27 laboratories or researchers that have conducted studies in any animal model regarding  
28 exenatide, AC2993, BYETTA, BYDUREON, JANUVIA, JANUMET, VICTOZA and/or  
any other GLP-1 agonist or DPP-4 inhibitor, including, but not limited to, all writings

1 pertaining to the protocols for each such study, amendments to protocols, status reports  
2 on studies, drafts of study reports and all other writings transmitted to or from YOU in  
3 connection with the laboratories or researchers conducting those studies.

4 104. All raw data, including cageside observations; necropsy notes, data and  
5 format; pathology notes; assistants' notes, data and forms; animal and organ weight  
6 records; consumption records; physical and palpation records; histology, serology and  
7 pathology records; photographs; transcripts; recordings in native format; scanning  
8 electron micrographs; and all drafts for each animal study undertaken for any purpose  
9 with respect to BYETTA. This includes, but is not limited to every primate study, every  
10 rodent study, and every other animal and cell system, in vivo and in vitro, studied by  
11 YOU.

12 105. All DOCUMENTS and raw data for each study of the effect of exenatide,  
13 sitagliptin, liraglutide and/or any other GLP-1 agonist or DPP-4 inhibitor on the human  
14 pancreas, undertaken or sponsored by YOU.

15 106. If not included in the foregoing, all Global Safety/Pharmacovigilance  
16 DOCUMENTS, raw data, summaries of data, commentary, correspondence, notes,  
17 memoranda, emails, and internal DOCUMENTS relating to YOUR compliance with  
18 postmarketing requirements in conjunction with post-approval FDA mandated clinical  
19 study where measurements of lipase and amylase were obtained and summarized.

20 107. All raw data from all published epidemiological studies dealing with or  
21 commenting on the risk of pancreatitis that were sponsored in whole or in part by YOU,  
22 including but not limited to pre-study design, bio-statistical issues such as statistical  
23 power, and pre-publication internal analysis of findings.

24 108. All DOCUMENTS, memoranda, notes, emails, and correspondence however  
25 designated that discuss the subject of exenatide, sitagliptin, liraglutide and/or any other  
26 GLP-1 agonist or DPP-4 inhibitor and the proliferation of abnormal or dysfunctional Beta  
27 cells.

28 109. All correspondence, communications or other DOCUMENTS between YOU  
or any of YOUR agents, employees, consultants or representatives and *JAMA Intern.*

1 *Med.* referring in any way to publication of articles that address the risk of acute  
2 pancreatitis in connection with GLP-1 and/or DPP-4 based therapies, including but not  
3 limited to an article authored by Dr. Sonal Singh, *et al.*

4 110. All DOCUMENTS referring in any way to publication in *JAMA Intern. Med.*  
5 of articles that address the risk of acute pancreatitis in connection with GLP-1 and/or  
6 DPP-4 based therapies, including but not limited to an article authored by Dr. Sonal  
7 Singh, *et al.*

8 111. All correspondence, communications or other DOCUMENTS between YOU  
9 or any of YOUR agents, employees, consultants or representatives and *JAMA Intern.*  
10 *Med.* referring in any way to publication of commentaries that address the risk of acute  
11 pancreatitis in connection with GLP-1 and/or DPP-4 based therapies, including but not  
12 limited to a commentary authored by Dr. Peter Butler.

13 112. All DOCUMENTS referring in any way to publication in *JAMA Intern.*  
14 *Med.* of commentaries that address the risk of acute pancreatitis in connection with GLP-  
15 1 and/or DPP-4 based therapies, including but not limited to a commentary authored by  
16 Dr. Peter Butler.

17 113. All correspondence, communications or other DOCUMENTS between YOU  
18 or any of YOUR agents, employees, consultants or representatives and *Gastroenterology*,  
19 and all DOCUMENTS referring in any way to publication of articles that address the risk  
20 of Pancreatitis, and Pancreatic and Thyroid Cancers With Glucagon-Like Peptide-I-Based  
21 Therapies, including but not limited to an article authored by Dr. Michael Elashoff, *et al.*

22 114. All correspondence, communications or other DOCUMENTS between YOU  
23 or any of YOUR agents, employees, consultants or representatives and *Diabetes*, and all  
24 DOCUMENTS referring in any way to publication of articles that address GLP-I receptor  
25 activation by exendin-4, expansion of pancreatic duct glands in rats and/or formation of  
26 dysplastic lesions and chronic pancreatitis in mice, including but not limited to an article  
27 authored by Belinda Gier, *et al.*

28 115. All correspondence, communications and other DOCUMENTS that refer to  
GLP-1 and/or DPP-4 based therapies, sent by YOU or others on YOUR behalf to, or

1 received from, Dr. Steven Kahn; the Diabetes Research Institute Foundation, University  
2 of Miami; the Lunenfield-Tanenbaum Research Institute; and/or the Joslin Diabetes  
3 Clinic.

4 116. All DOCUMENTS comprising or referring to any compensation in any form  
5 paid by YOU or others on YOUR behalf to Dr. Steven Kahn; the Diabetes Research  
6 Institute Foundation, University of Miami; the Lunenfield-Tanenbaum Research Institute;  
7 and/or the Joslin Diabetes Clinic.

8 117. All DOCUMENTS, including without limitation correspondence, contracts,  
9 consulting agreements, invoices, receipts and all other forms of payment information  
10 related to research on GLP-1 and/or DPP-4 based therapies funded in whole or in part by  
11 YOU or others on YOUR behalf, or for which YOU or others on YOUR behalf supplied  
12 products, facilities or other support, that was supervised or conducted by or on behalf of  
13 Dr. Steven Kahn; the Diabetes Research Institute Foundation, University of Miami; the  
14 Lunenfield-Tanenbaum Research Institute; and/or the Joslin Diabetes Clinic.

15 118. All DOCUMENTS, memoranda, notes, emails, and correspondence however  
16 designated that discuss the subject of exenatide, sitagliptin, liraglutide and/or any other  
17 GLP-1 agonist or DPP-4 inhibitor and the proliferation of abnormal or dysfunctional  
18 alpha ( $\alpha$ ) cells.

19 119. All DOCUMENTS and raw data including histology slides from a 1999  
20 rodent study with alpha-cells hyperplasia, undertaken or sponsored by YOU.

21 120. All DOCUMENTS and raw data including histology slides from any rodent  
22 study which showed increased ductal proliferation and acinar to ductal metaplasia.

23 121. All DOCUMENTS and raw data including histology slides from any non-  
24 human primate study which showed increased ductal proliferation and acinar to ductal  
25 metaplasia.

26 122. All DOCUMENTS and raw data including histology slides from any rodent  
27 study which showed a hemorrhagic pancreas with apoptosis-like necrosis.

28 123. All DOCUMENTS and raw data including histology slides from any non-  
human primate study which showed a hemorrhagic pancreas with apoptosis-like necrosis.

1 124. All DOCUMENTS and study records from any rodent study which recorded  
2 amylase levels.

3 125. All DOCUMENTS and study records from any rodent study which recorded  
4 lipase levels.

5 126. All DOCUMENTS and study records from any non-human primate study  
6 which recorded amylase levels.

7 127. All DOCUMENTS and study records from any non-human study which  
8 recorded lipase levels.

9 128. All DOCUMENTS, including but not limited to internal communications,  
10 grant applications and proposals, grant funding decisions and meetings or hearings about  
11 the same, phases, drafts, protocols, interim reports, final reports, and versions thereof,  
12 whether published or not, regarding the effect(s) of exenatide, sitagliptin, liraglutide  
and/or any other GLP-1 agonist or DPP-4 inhibitor on glucagon suppression.

13 129. All DOCUMENTS, including but not limited to internal communications,  
14 grant applications and proposals, grant funding decisions and meetings or hearings about  
15 the same, phases, drafts, protocols, interim reports, final reports, and versions thereof,  
16 whether published or not, regarding the short- and long-term effect(s) of glucagon  
17 suppression.

18 130. All DOCUMENTS, including but not limited to internal communications,  
19 grant applications and proposals, grant funding decisions and meetings or hearings about  
20 the same, phases, drafts, protocols, interim reports, final reports, and versions thereof,  
21 whether published or not, regarding a 2008 presentation regarding a “likely” causal  
22 connection between exenatide and pancreatitis.

23 131. All pre-clinical and clinical study results obtained by YOU or others on  
24 YOUR behalf relating to BYETTA, documenting calcitonin levels, regardless of whether  
25 the study was ever completed, published or discontinued, or whether human patients were  
ever enrolled.

26 132. All pre-clinical and clinical study results obtained by YOU or others on  
27 YOUR behalf relating to BYETTA, documenting thyroid histology, regardless of whether  
28

1 the study was ever completed, published or discontinued, or whether human patients were  
2 ever enrolled.

3 133. All correspondence, communications and other DOCUMENTS that refer to  
4 GLP-1 and/or DPP-4 based therapies, sent by YOU or others on YOUR behalf to, or  
5 received from, Professor Michael Nauck, Head of the Diabeteszentrum Bad Lauterberg,  
6 Harz, Germany.

7 134. All DOCUMENTS, memoranda, notes, emails, PowerPoint presentations,  
8 lists of attendees and correspondence, however designated, from a June 2009 meeting  
9 held at the American Diabetes Association's annual conference in New Orleans which  
10 discussed that acinar to ductal metaplasia and chronic pancreatitis seen in the Matveyenko  
11 study could suggest an increased risk of pancreatic cancer.

12 135. All DOCUMENTS, memoranda, notes, emails, PowerPoint presentations,  
13 lists of attendees and correspondence, however designated, from a September 2008  
14 pancreatitis working group which discussed, *inter alia*, external messaging and included a  
15 presentation which pointed to the mounting reports of pancreatitis in patients taking  
16 exenatide and the strengthening biological plausibility of exocrine pancreatic effects.

17 136. All DOCUMENTS concerning or relating to any studies, including but not  
18 limited to all phases, drafts, protocols, notes, comments, interim reports, final reports, and  
19 versions thereof, whether published or not, that raise questions about, suggest, indicate or  
20 demonstrate that GLP-1 receptors occur on pancreatic duct cells.

21 137. All DOCUMENTS concerning or relating to any studies, including but not  
22 limited to all phases, drafts, protocols, notes, comments, interim reports, final reports, and  
23 versions thereof, whether published or not, that raise questions about, suggest, indicate or  
24 demonstrate that GLP-1 agonists and/or DPP-4 inhibitors induce ductal cell proliferation  
25 in addition to Beta cell proliferation.

26 138. All DOCUMENTS concerning or relating to any studies, including but not  
27 limited to all phases, drafts, protocols, notes, comments, interim reports, final reports, and  
28 versions thereof, whether published or not, that raise questions about, suggest, indicate or  
demonstrate that GLP-1 agonists and/or DPP-4 inhibitors inhibit apoptosis of ductal cells.

1 139. All DOCUMENTS concerning or relating to any studies, including but not  
2 limited to all phases, drafts, protocols, notes, comments, interim reports, final reports, and  
3 versions thereof, whether published or not, that raise questions about, suggest, indicate or  
4 demonstrate that GLP-1 agonists and/or DPP-4 inhibitors inhibit apoptosis of islet cells.

5 140. All DOCUMENTS, memoranda, notes, emails, PowerPoint presentations,  
6 lists of attendees and correspondence, however designated, from an August 2012  
7 American Statistical Association meeting presentation by William DuMouchel, chief  
8 statistical scientist at Oracle Health Sciences.

9 141. All correspondence, communications and other DOCUMENTS that refer to  
10 GLP-1 and/or DPP-4 based therapies, sent by YOU or others on YOUR behalf to, or  
11 received from, chief medical officer Pia Caduff of the WHO's Uppsala Monitoring  
12 Centre.

13 142. All DOCUMENTS concerning or relating to any studies, including but not  
14 limited to all phases, drafts, protocols, notes, comments, interim reports, final reports, and  
15 versions thereof, whether published or not, that raise questions about, suggest, indicate or  
16 demonstrate an association between increased pancreatic weight and/or increased size of  
17 the exocrine pancreas with increasing dosage of BYETTA or exenatide, sitagliptin,  
18 liraglutide and/or any other GLP-1 agonist or DPP-4 inhibitor.

19 143. All DOCUMENTS, raw data and other evidence on which YOU and YOUR  
20 pathologists relied to conclude that hyperplasia of pancreatic ductal epithelium was not  
21 test article-related, as was concluded in Study No. 0997-139 Sponsor study No. REST  
22 00120.

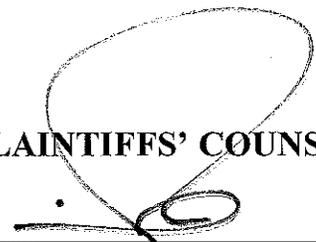
23 144. If not included in the foregoing, all DOCUMENTS, photographs, images,  
24 recordings in any format, and things maintained by Charles River Company pertaining to  
25 every primate study, including but not limited to, necropsy findings, and cage side  
26 observations of monkeys during the 273-day evaluation performed by employees of  
27 Sierra Biomedical.

28 145. If not included in the foregoing, all DOCUMENTS, photographs, images,  
recordings in any format, and things maintained by YOU or others on your behalf

1 pertaining to every primate study, including but not limited to, necropsy findings, and  
2 cage side observations of monkeys during the 91-day toxicity evaluation performed by  
3 employees of Oread, Inc.

4 146. All DOCUMENTS, raw data, summaries of data, commentary,  
5 correspondence, notes, memoranda, emails, and internal DOCUMENTS relating to the  
6 evaluation of amylase and lipase data from exenatide pre-clinical through post-marketing  
7 sources, including but not limited to studies undertaken in connection with NDA 21-919,  
8 Study BCB 108, Duration-2 and in any other context.

9  
10 DATED: January 30, 2014

  
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# **EXHIBIT 11**

likely that such efficacy will be shown until the vaccines are licensed and postmarketing surveillance commences.

Recent evidence suggests that EV71 vaccines do not provide cross-protection against all circulating genetic lineages of EV71 or against coxsackievirus A16.<sup>5</sup> Thus, the Chinese C4A-based vaccines may not generate protective immunity against EV71 in regions where other extant or newly emerged lineages circulate. Consequently, it may be necessary to develop multivalent vaccines to ensure that protection is provided against all EV71 strains.

Nevertheless, this is an exciting development in the global response to the emergence of EV71 as a cause of severe neurologic disease. It is also worth noting

that in the past 17 years, EV71 research and vaccine development have been primarily centered in Asia — a fact that not only reflects the predominance of EV71 epidemics in this region but also underscores the increasing importance of Asia as a center of medical research. Finally, if these vaccines prove to be effective in preventing EV71-associated neurologic disease, an important tool for controlling, or even eradicating, EV71 infection in regions where it is endemic may have been developed. If its promise is realized, a priceless gift will have been given to the children of the Asia-Pacific region and to the rest of the world.

Disclosure forms provided by the author are available with the full text of this article at NEJM.org.

From the Infectious Diseases and Immunology Department, Sydney Medical School, the University of Sydney, Sydney.

1. Solomon T, Lewthwaite P, Perera D, Cardoso MJ, McMinn PC, Ooi MH. Virology, epidemiology, pathogenesis, and control of enterovirus 71. *Lancet Infect Dis* 2010;10:778-90.
2. Ho M, Chen E-R, Hsu K-H, et al. An epidemic of enterovirus 71 infection in Taiwan. *N Engl J Med* 1999;341:929-35.
3. A guide to clinical management and public health response for hand, foot and mouth disease (HFMD). Geneva: World Health Organization, 2011 (<http://www.wpro.who.int/publications/docs/GuidancefortheclinicalmanagementofHFMD.pdf>).
4. Zhu FC, Meng FY, Li JX, et al. Efficacy, safety and immunology of an inactivated alum-adjunct enterovirus 71 vaccine in children in China: a multicenter, randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet* 2013;381:2024-32.
5. Chou AH, Liu CC, Chang JY, et al. Formalin-inactivated EV71 vaccine candidate induced cross-neutralizing antibody against subgenotypes B1, B4, B5 and C4A in adult volunteers. *PLoS One* 2013;8(11):e79783.  
DOI: 10.1056/NEJMp1400601  
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## Pancreatic Safety of Incretin-Based Drugs — FDA and EMA Assessment

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With approximately 25.8 million diabetic patients in the United States and 33 million in the European Union alone, the growing prevalence of diabetes worldwide poses a major public health challenge. Both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) are committed to ensuring the safety of drug products marketed for the treatment of diabetes, and post-marketing reports of pancreatitis and pancreatic cancer in patients taking certain antidiabetic

medications have been of concern to both agencies. Working in parallel, the agencies have reviewed nonclinical toxicology studies, clinical trial data, and epidemiologic data pertaining to blood glucose-lowering drug products (e.g., exenatide and sitagliptin) that stimulate postprandial insulin release by potentiating the incretin hormone pathways.

In keeping with the pathophysiological complexity of diabetes, several classes of blood glucose-lowering drugs, encompassing diverse mechanisms of

action, have been developed to treat the disease. The incretins (i.e., glucagon-like peptide 1 and glucose-dependent insulinotropic polypeptide) are intestinal hormones that stimulate the postprandial production of insulin and glucagon by the pancreas. In the past decade, drugs that act as incretin receptor agonists (e.g., exenatide) or that inhibit the proteolytic degradation of incretins (e.g., sitagliptin) have been approved by both the FDA and the EMA (see table), in part on the basis of clinical data establishing

Incretin-Based Drugs Approved by the Food and Drug Administration (FDA) and European Medicines Agency (EMA).*			
Drug	Incretin-Based Mechanism	Approval Date	
		FDA	EMA
Exenatide	GLP1 agonist	April 28, 2005	November 20, 2006
Sitagliptin	DPP4 inhibitor	October 16, 2006	March 21, 2007
Vildagliptin	DPP4 inhibitor	(Not approved by the FDA)	September 26, 2007
Saxagliptin	DPP4 inhibitor	July 31, 2009	October 1, 2009
Liraglutide	GLP1 agonist	January 25, 2010	June 30, 2009
Linagliptin	DPP4 inhibitor	May 2, 2011	August 24, 2011
Exenatide extended-release	GLP1 agonist	January 27, 2012	June 17, 2011
Alogliptin	DPP4 inhibitor	January 25, 2013	September 19, 2013
Lixisenatide	GLP1 agonist	(Not approved by the FDA)	February 1, 2013

\* GLP1 denotes glucagon-like peptide 1, an incretin; DPP4 denotes dipeptidyl peptidase 4, an exopeptidase that inactivates the incretins.

efficacy in improving glycemic control. The benefit–risk assessment also considered clinical advantages such as reduced risk for drug-related hypoglycemia and possible improvement in body-weight maintenance.

Within the past year, the FDA and the EMA independently undertook comprehensive evaluations of a safety signal arising from postmarketing reports of pancreatitis and pancreatic cancer in patients using incretin-based drugs. These investigations, now complete, included examination of data from a 2013 research report revealing a possible pancreatic safety signal.<sup>1,2</sup> Both agencies committed themselves to assessing the evidence pertinent to reported adverse events, as well as any factors that might confound safety analysis in the context of antidiabetic drugs. Although the disproportionate spontaneous reporting of adverse events is commonly interpreted as a safety signal, there are inherent limitations to the ability to establish causal relationships, including the eval-

uation of events with high background rates, long latency periods, or a possible contribution by the disease itself.

Using the extensive nonclinical assessments completed as part of all marketing applications for incretin-based drugs, the FDA re-evaluated more than 250 toxicology studies conducted in nearly 18,000 healthy animals (15,480 rodents and 2475 nonrodents). Microscopic examinations from these toxicology studies yielded no findings of overt pancreatic toxic effects or pancreatitis. The EMA conducted a similar review of the studies for the incretin-based drugs currently authorized for use in the European Union (see table). In addition, drug-induced pancreatic tumors were absent in rats and mice that had been treated for up to 2 years (their life span) with incretin-based drugs, even at doses that greatly exceed the level of human clinical exposure.

A potential limitation of these toxicology data lies in the use of only healthy animals. To address

this concern, the FDA required sponsors of marketed incretin-based drugs to conduct 3-month pancreatic toxicity studies in a rodent model of diabetes. These studies included extensive histopathological evaluation of the endocrine and exocrine pancreas, including analysis of ductal morphology and histochemical staining capable of disclosing pathological proliferation and apoptosis. Three of these studies have been completed and submitted for review by the FDA, and no treatment-related adverse effects on the pancreas were reported. In addition, approximately 120 pancreatic histopathology slides from one of the three sponsor-conducted studies were subjected to independent and blinded examination by three FDA pathologists. The FDA experts' conclusions regarding these slides were generally concordant with the sponsor's report.

As part of its evaluation of the postmarketing reports of pancreatic adverse events, the FDA also performed its own pancreatic

toxicology studies with exenatide. Rodent models of disease, each accompanied by a nondiseased control, included a mouse model with chemically induced pancreatitis, the Zucker diabetic fatty rat, and C57BL/6 mice fed a high-fat diet. Data from the studies of the pancreatitis mouse and diabetic rat models did not identify exenatide-related pancreatic injury. In the high-fat-diet mouse model, minimal-to-moderate exacerbation of background findings (e.g., acinar-cell hyperplasia, atrophy, and periductal inflammation or fibrosis) were detected after 12 weeks of treatment with exenatide; that mouse model has not been definitively qualified as a model of drug-induced pancreatic responses, but it merits further investigation.

Clinical safety databases reviewed by the FDA included data from more than 200 trials, involving approximately 41,000 participants, more than 28,000 of whom were exposed to an incretin-based drug; 15,000 were exposed to drug for 24 weeks or more, and 8500 were exposed for 52 weeks or more. A similar review was conducted by the EMA, including all studies performed with the incretin-based drugs authorized in the European Union. Small imbalances in the incidence of pancreatitis were reported in premarketing trials, although the overall number of events was small. A pooled analysis of data from 14,611 patients with type 2 diabetes from 25 clinical trials in the sitagliptin database provided no compelling evidence of an increased risk of pancreatitis or pancreatic cancer.<sup>3</sup> Clinical trials in which amylase and lipase levels had been

monitored in a systematic manner showed that incretin-based drugs may increase enzyme levels, but the mean levels were in the normal range. Furthermore, changes in enzyme levels were not associated with gastrointestinal adverse events (i.e., abdominal pain, nausea, and vomiting).

Two cardiovascular outcome trials in patients with type 2 diabetes who were treated with incretin-based drugs have been completed: the Saxagliptin Assessment of Vascular Outcomes Recorded (SAVOR) trial and the Examination of Cardiovascular Outcomes with Alogliptin versus Standard of Care (EXAMINE) trial. The SAVOR trial was a randomized, double-blind, placebo-controlled trial involving 16,492 patients. The EXAMINE trial was a randomized, double-blind, placebo-controlled trial involving 5380 patients. Reported rates of acute pancreatitis in the SAVOR and EXAMINE trials were low, with similar rates of events in the drug and placebo groups (22 and 16, respectively, in SAVOR; 12 and 8, respectively, in EXAMINE).<sup>4,5</sup> The reported incidence of pancreatic cancer was 5 and 12 cases, respectively, in the drug and placebo groups in the SAVOR trial, with no incidence of pancreatic cancer in either group in the EXAMINE trial.

The FDA and the EMA have also independently reviewed a number of observational studies to explore a possible association between incretin-based drugs and acute pancreatitis. Cohort and nested case-control studies, using a variety of large administrative claims databases, have yielded inconsistent results. These studies suffered, to different degrees,

from methodologic shortcomings, including limited power, inadequate outcome validation, incomplete covariate ascertainment, and inadequate confounding control.

Thus, the FDA and the EMA have explored multiple streams of data pertaining to a pancreatic safety signal associated with incretin-based drugs. Both agencies agree that assertions concerning a causal association between incretin-based drugs and pancreatitis or pancreatic cancer, as expressed recently in the scientific literature and in the media, are inconsistent with the current data. The FDA and the EMA have not reached a final conclusion at this time regarding such a causal relationship. Although the totality of the data that have been reviewed provides reassurance, pancreatitis will continue to be considered a risk associated with these drugs until more data are available; both agencies continue to investigate this safety signal. The FDA and the EMA believe that the current knowledge is adequately reflected in the product information or labeling, and further harmonization among products is planned in Europe. Ongoing strategies include systematic capture of data on pancreatitis and pancreatic cancer from cardiovascular outcome trials and ongoing clinical trials, which should facilitate meta-analyses, and accumulation of further knowledge regarding these signals in the future.

Disclosure forms provided by the authors are available with the full text of this article at [NEJM.org](http://NEJM.org).

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the Dutch Medicines Evaluation Board, Utrecht, the Netherlands (P.A.G.).

1. Butler AE, Campbell-Thompson M, Gurlo T, Dawson DW, Atkinson M, Butler PC. Marked expansion of exocrine and endocrine pancreas with incretin therapy in humans with increased exocrine pancreas dysplasia and the potential for glucagon-producing neuroendocrine tumors. *Diabetes* 2013;62:2595-604.
2. European Medicines Agency. Assessment report for GLP-1 based therapies. July 25, 2013 ([http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Report/2013/08/WC500147026.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Report/2013/08/WC500147026.pdf)).
3. Engel SS, Round E, Golm GT, Kaufman KD, Goldstein BJ. Safety and tolerability of sitagliptin in type 2 diabetes: pooled analysis of 25 clinical studies. *Diabetes Ther* 2013;4:119-45.
4. Scirica BM, Bhatt DL, Braunwald E, et al. Saxagliptin and cardiovascular outcomes in patients with type 2 diabetes mellitus. *N Engl J Med* 2013;369:1317-26.
5. White WB, Cannon CP, Heller SR, et al. Alogliptin after acute coronary syndrome in patients with type 2 diabetes. *N Engl J Med* 2013;369:1327-35.

DOI: 10.1056/NEJMp1314078

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# **EXHIBIT 12**

1 UNITED STATES DISTRICT COURT  
2 SOUTHERN DISTRICT OF CALIFORNIA

3 **IN RE: INCRETIN-BASED**  
4 **THERAPIES PRODUCTS**  
5 **LIABILITY LITIGATION**

) **MDL No. 13-md-2452-AJB(MDD)**

6 **Relates to: ALL CASES**

) **DECLARATION OF MICHAEL K.**  
) **JOHNSON, KENNETH W. PEARSON,**  
) **MAX KENNERLY, AND LINDA K.**  
) **LEIBFARTH**

9  
10 Michael K. Johnson, Kenneth W. Pearson, Max Kennerly, and Linda K. Leibfarth  
11 hereby declare under penalty of perjury that the following information is true and correct:

12 1. We are attorneys representing Plaintiffs in this litigation.

13 2. We personally met and conferred on February 18, 2014 in San Diego with  
14 counsel for Defendant Novo Nordisk, including Heidi Levine and Leeanne Neri; and  
15 counsel for Defendant Merck Sharp & Dohme, including Ana Reyes and Paul Boehm.

16 3. One of the issues discussed at the meet and confer was Plaintiffs' obligation  
17 to limit their discovery requests to matters relevant to general causation in accordance  
18 with Judge Battaglia's comments at the Status Conference held earlier the same day.

19 4. To resolve that issue, Defense counsel requested that Plaintiffs' counsel  
20 review their interrogatories and document requests, and remove those that could not  
21 reasonably bear on general causation issues. We agreed to do that and did so  
22 approximately a week later.

23 5. Defendants made no request at the meet and confer that Plaintiffs rewrite  
24 their requests to comply with Judge Battaglia's comments on limiting discovery to  
25 matters relevant to general causation. However, the subject of rewriting requests did  
26 come up in a different context during the meet and confer, as discussed below.

27 6. Defendants' raised concerns during the meet and confer about the recent  
28 sanctions imposed on the defendant in the *Pradaxa* litigation. Defendants explained that

1 they did not feel they could respond to Plaintiffs' discovery requests because they were  
2 concerned that any search they might make for responsive information might later be  
3 deemed inadequate if additional responsive information was found. One of the defense  
4 attorneys stated "We don't want to be the next *Pradaxa*." Defendants stated at various  
5 times that they could not and would not respond to any of Plaintiffs' discovery requests  
6 because of a fear of sanctions being imposed on them later, after the discovery of  
7 additional responsive information.

8 7. Much of the meet and confer was spent discussing Defendants' *Pradaxa*  
9 concerns. Among other things, Defendants asked Plaintiffs to rewrite their discovery  
10 requests so that each one was targeted so specifically that it would be almost impossible  
11 for Defendants to perform an inadequate search for the requested information. That  
12 proposal was rejected as impractical, in part because Plaintiffs do not know what  
13 documents and information Defendants have, and cannot prepare requests precisely  
14 targeting things they don't even know about. Defendants were asked how they expected  
15 Plaintiffs to be able to specifically target discovery requests when even Defendants, with  
16 their superior knowledge of their own documents, were afraid to commit to saying any  
17 search was complete. Defendants were not able to answer that question.

18  
19 I declare under penalty of perjury that the foregoing is true and correct.

20 Executed on March 18, 2014.

*/s/ Michael K. Johnson*  
Michael K. Johnson

*/s/ Kenneth W. Pearson*  
Kenneth W. Pearson

*/s/ Max Kennerly*  
Max Kennerly

*/s/ Linda K. Leibfarth*  
Linda K. Leibfarth