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8 **UNITED STATES DISTRICT COURT**
9 **SOUTHERN DISTRICT OF CALIFORNIA**

10
11 **IN RE INCRETIN-BASED**
THERAPIES PRODUCTS
12 **LIABILITY LITIGATION**

13 *As to All Related and Member Cases*
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Case No. 13md2452-AJB (MDD)

MDL 2452

**DECLARATION OF AMY J.
LAURENDEAU IN SUPPORT OF
MOTION PURSUANT TO THE
COURT'S MAY 13, 2014 ORDER
TO SEAL EXHIBITS ATTACHED
TO PLAINTIFFS' RESPONSE TO
DEFENDANTS' MOTION FOR
SUMMARY JUDGMENT ON
PREEMPTION**

1 I, Amy J. Laurendeau, declare as follows:

2 1. I am an attorney duly licensed to practice in the State of California,
3 and I am a partner at the law firm of O'Melveny & Myers, LLP, counsel of record
4 for Defendant Amylin Pharmaceuticals, LLC ("Amylin") in this litigation. I am
5 making this declaration in support of Defendants' Motion to Seal Exhibits Attached
6 to Plaintiffs' Opposition to Defendants' Motion for Summary Judgment on
7 Preemption. I have personal knowledge of the facts set forth herein or am informed
8 and believe that such facts are true based on my review of the documents
9 referenced below and relevant regulatory standards and, if called to testify, I could
10 and would testify competently hereto.

11 2. Many of the exhibits Plaintiffs attached as exhibits to their Opposition
12 contain Amylin's confidential and proprietary information. As demonstrated
13 below, compelling reasons exist to seal these confidential documents. While this
14 declaration and the concurrent Declaration of Elizabeth M. Ray each addresses
15 specific documents, Amylin and Defendant Eli Lilly and Company as alliance
16 partners share a common interest in the confidential nature of their documents and
17 each relies upon and adopts the rationale offered by the other.

18 3. I have reviewed Exhibits A through E, G, and H to the Declaration of
19 John M. Restaino in Opposition to Defendants' Motion for Summary Judgment
20 Based on Preemption (the "Restaino Declaration"), as well as Exhibits A and G
21 through R to the Declaration of Neal L. Moskow in Opposition to Defendants'
22 Motion for Summary Judgment Based on Preemption (the "Moskow Declaration").

23 4. Exhibits A and B to the Restaino Declaration have been designated by
24 the parties as "Confidential" pursuant to the Protective Order entered in this
25 litigation. These exhibits are designated as "Confidential" because they contain
26 portions of draft clinical study reports pertaining to Byetta®, which are nearly
27 identical to the final versions of the same reports that were submitted to the FDA.
28 The studies that Amylin commissions and submits to the FDA are confidential and

1 proprietary. Even after the approval of a drug, study reports are not disclosed by
2 the FDA. The only aspect of a study that is publicly available would be the design
3 of the study, as described in the FDA's Summary Basis of Approval ("SBA"). The
4 FDA makes the SBA publicly available through a Freedom of Information Act
5 request, but does not make other components of the study available. Final study
6 reports are not subject to Freedom of Information Act Requests. Further, I am
7 informed and believe that: (1) Amylin treats clinical study reports as confidential
8 and proprietary and takes measures to protect such reports from disclosure to the
9 public or to competitors; and (2) Amylin does not routinely have access to clinical
10 study reports that its competitors submit to the FDA.

11 5. Exhibit O to the Moskow Declaration has been designated by the
12 parties as "Attorneys' Eyes Only" pursuant to the Protective Order. Exhibits C and
13 D to the Restaino Declaration and Exhibits G through J and M, N and P to the
14 Moskow Declaration have been designated by the parties as "Confidential"
15 pursuant to the Protective Order. These exhibits consist of private, confidential e-
16 mail communications among Amylin employees and, in some cases, with
17 employees of other companies, including Eli Lilly and Company, with whom
18 Amylin has confidentiality and/or non-disclosure agreements. Each of these e-mail
19 communications contains confidential commercial information and/or
20 competitively sensitive proprietary information on a broad range of subjects,
21 including discussions and analyses of studies, clinical trial subjects, clinical trial
22 results, and individual case reports. I am informed and believe that: (1) Amylin
23 treats communications such as these as confidential and takes measures to protect
24 such communications from disclosure to the public or to competitors; and (2)
25 Amylin does not routinely have access to similar communications of its
26 competitors.

27 6. Exhibit H to the Restaino Declaration has been designated by the
28 parties as "Attorneys' Eyes Only" pursuant to the Protective Order. This exhibit is

1 an internal document that was created for internal use among Amylin and Lilly
2 personnel. It discusses confidential commercial information and/or competitively
3 sensitive proprietary information regarding clinical trial results and reported
4 adverse events. I am informed and believe that: (1) Amylin treats documents such
5 as this as confidential and takes measures to protect them from disclosure to the
6 public or to competitors; and (2) Amylin does not routinely have access to similar
7 documents prepared by its competitors.

8 7. Exhibit E to the Restaino Declaration and Exhibit R to the Moskow
9 Declaration have been designated by the parties as “Confidential” pursuant to the
10 Protective Order. These exhibits consist of materials submitted confidentially to
11 and maintained confidentially by the FDA that discuss confidential commercial
12 information and/or competitively sensitive proprietary information regarding
13 clinical trial results, reported adverse events, and epidemiological studies. I am
14 informed and believe that: (1) Amylin treats materials such as this as confidential
15 and takes measures to protect them from disclosure to the public or to competitors;
16 and (2) Amylin does not routinely have access to similar materials that its
17 competitors submit to the FDA.

18 8. Exhibits K and Q to the Moskow Declaration have been designated by
19 the parties as “Confidential” pursuant to the Protective Order. These exhibits are
20 letters submitted confidentially to the FDA that discuss and analyze postmarketing
21 studies of Byetta®. Each exhibit contains confidential commercial information
22 and/or competitively sensitive proprietary information, including Amylin’s analysis
23 of postmarketing studies of Byetta®. I am informed and believe that Amylin treats
24 communications such as these as confidential and takes measures to protect them
25 from disclosure to the public or to competitors.

26 9. Exhibit G to the Restaino Declaration and Exhibit A to the Moskow
27 Declaration have been designated by the parties as “Confidential” pursuant to the
28 Protective Order. These exhibits are confidential because they are internal Amylin

1 company documents that discuss the development, testing, and/or safety of
2 Byetta®. I am informed and believe that: (1) Amylin treats internal company
3 documents such as these as confidential and takes measures to protect them from
4 disclosure to the public or to competitors; and (2) Amylin does not routinely have
5 access to similar documents prepared by its competitors.

6
7 I declare under penalty of perjury under the laws of the United States
8 that the foregoing is true and correct. Executed on May 29, 2014 at Newport
9 Beach, California.

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11 _____
12 Amy J. Laurendeau