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9
10 **UNITED STATES DISTRICT COURT**
11 **SOUTHERN DISTRICT OF CALIFORNIA**
12

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

16 *As to All Related and Member Cases*
17

Case No. 13-md2452-AJB (MDD)

MDL 2452

**DECLARATION OF AMY J.
LAURENDEAU IN SUPPORT OF
DEFENDANTS AMYLIN
PHARMACEUTICALS, LLC AND
ELI LILLY AND COMPANY'S
MOTION TO STRIKE FROM
THE PUBLIC DOCKET OR, IN
THE ALTERNATIVE, TO SEAL
PLAINTIFFS' EXPERT
REPORTS REGARDING
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 Strike From The
6 Public Docket Or, In The Alternative, To Seal Plaintiffs' Expert Reports Regarding
7 Preemption. I have personal knowledge of the facts set forth herein and, if called to
8 testify, I could and would testify competently hereto.

9 2. Many sections of Dr. Madigan's and Dr. Fleming's expert reports
10 discuss and disclose Amylin's confidential and proprietary information, the content
11 of documents produced by Amylin containing such information, or deposition
12 testimony designated by Amylin as confidential. As demonstrated below, good
13 cause exists to seal these sections of Dr. Madigan's and Dr. Fleming's reports.
14 While this Declaration and the Declaration of Elizabeth M. Ray each address
15 specific sections of the Madigan and Fleming reports (and the documents to which
16 they relate), Amylin and Eli Lilly and Company ("Lilly") as alliance partners share
17 a common interest in the confidential nature of their documents and each relies
18 upon and adopts the rationale offered by the other.

19 3. I have reviewed Dr. Madigan's report, Dr. Fleming's report, and the
20 documents produced by Amylin referenced in these reports. I have also reviewed
21 the deposition testimony of Orville Kolterman, M.D. and John Buse, M.D., Ph.D.
22 cited in these reports.

23 4. The confidential sections of Dr. Madigan's report that Amylin seeks to
24 maintain under seal are as set forth below:

25 a. **Madigan report at page 3, ¶ 8:** This section of Dr. Madigan's
26 report discusses Amylin's internal pharmacovigilance and safety analyses regarding
27 pancreatic cancer and confidential communications between Amylin and Lilly
28 employees regarding preliminary safety data relating to a potential pancreatic

1 cancer safety signal. Further, this section is based in part on AMYLN00240832, a
2 document produced by Amylin and designated “Confidential” pursuant to the
3 Protective Order entered in this litigation (the “Protective Order”). This document
4 is an internal Amylin company document that reflects Amylin’s internal
5 pharmacovigilance and safety analyses of potential safety signals for Byetta.

6 b. **Madigan report at page 10, ¶ 33:** This section of Dr.
7 Madigan’s report discusses Amylin’s internal pharmacovigilance and safety
8 analyses regarding pancreatic cancer. Further, this section is based on
9 AMYLN03058141, a document produced by Amylin and designated
10 “Confidential” pursuant to the Protective Order. This document consists of excerpts
11 of a draft internal Amylin company document that summarizes and analyzes
12 adverse event data for Byetta and competitor products.

13 5. The confidential sections of Dr. Fleming’s report that Amylin seeks to
14 maintain under seal are as set forth below:

15 a. **Fleming report at page 37, first full sentence and n.59:**
16 These sections of Dr. Fleming’s report disclose the content of AMYLN05310370, a
17 document produced by Amylin and designated “Confidential - Attorney’s Eyes
18 Only” pursuant to the Protective Order. This document is a confidential submission
19 by Astrazeneca PLC (“Astrazeneca”) to the European Medicines Agency (“EMA”)
20 that, *inter alia*, analyzes proposed labeling changes and summarizes and evaluates
21 safety data pertaining to pancreatitis and pancreatic cancer. Amylin’s parent
22 corporation is BMS Holdco, Inc. (“BMS”), a wholly owned subsidiary of Zeneca,
23 Inc., whose corporate parent is AstraZeneca.

24 b. **Fleming report at page 41, first sentence in ¶ 3:** This
25 section of Dr. Fleming’s report discloses information regarding Amylin’s clinical
26 trial results. Further, this section is based on AMYLN05123059, a document
27 produced by Amylin and designated “Confidential” pursuant to the Protective
28 Order. This document is an internal Amylin and Lilly company report that

1 summarizes and analyzes blinded adverse event data related to patients in Byetta's
2 clinical trial program. Dr. Fleming's report cites this document at page 66, footnote
3 161 of his report.

4 c. **Fleming report at page 46, sentence citing n.74:** This
5 section of Dr. Fleming's report discloses information regarding Amylin's clinical
6 trial results. Further, this section is based on AMYLN01856403, a document
7 produced by Amylin and designated "Confidential" pursuant to the Protective
8 Order. This document is a letter from a clinical trial investigator to Amylin
9 describing an adverse event in a clinical trial patient and reflecting the patient's
10 identification number and personal health information.

11 d. **Fleming report at page 50, second paragraph and**
12 **nn.89-90; page 51, sentence citing n.96:** These sections of Dr. Fleming's report
13 disclose comments made by an advisory panel of medical and scientific consultants
14 who reviewed preliminary Byetta safety data and is based in part on
15 AMLYN00039110, a document produced by Amylin and designated
16 "Confidential" pursuant to the Protective Order. This document is an internal
17 Amylin and Lilly company report that summarizes a meeting held by the advisory
18 panel, including comments made by panel members about their impressions of
19 preliminary Byetta safety data.

20 e. **Fleming report at page 51, sentence citing n.93 and**
21 **n.93:** These sections of Dr. Fleming's report disclose testimony provided by Dr.
22 Kolterman that Amylin has designated as confidential. Amylin designated this
23 testimony as confidential because it pertains to Amylin's analysis and evaluation of
24 safety data regarding Byetta. Attached hereto as **Exhibit A** is a true and correct
25 copy of a letter dated January 5, 2015 submitted by counsel for Amylin to
26 Plaintiffs' counsel designating testimony from Dr. Kolterman's deposition as
27 confidential under the Protective Order.

28

1 f. **Fleming report at page 53, sentence citing n.103:** This
2 section of Dr. Fleming's report discloses information regarding Amylin's
3 preclinical trial results for Bydureon. Further, this section is based on
4 AMYLN02643315, a document produced by Amylin and designated "Confidential
5 - Attorney's Eyes Only" pursuant to the Protective Order. This document is an
6 internal Amylin company document that summarizes Amylin's observations in
7 preclinical testing for exenatide.

8 g. **Fleming report at page 66, sentence citing n.161:** This
9 section of Dr. Fleming's report discloses information regarding Amylin's clinical
10 trial results for Byetta and is based on AMYLN05123059, a document described in
11 further detail above. *See supra* at ¶ 5.b.

12 h. **Fleming report at pages 67-68, sentence citing n.164:**
13 This section of Dr. Fleming's report discusses Amylin's internal pharmacovigilance
14 and safety analyses regarding pancreatic cancer and is based on AMYLN00240832,
15 a document described in further detail above. *See supra* at ¶ 4.a.

16 i. **Fleming report at page 74, sentences citing nn. 177-**
17 **178:** These sections of Dr. Fleming's report disclose testimony provided by Dr.
18 Buse that Amylin has designated as confidential. Amylin designated this testimony
19 as confidential because it pertains to Amylin's analysis and evaluation of safety
20 data regarding Byetta. Attached hereto as **Exhibit B** is a true and correct copy of a
21 letter dated November 5, 2014 submitted by counsel for Amylin to Plaintiffs'
22 counsel designating testimony from Dr. Buse's deposition as confidential under the
23 Protective Order.

24 j. **Fleming report at pages 75-76, sentences citing nn.**
25 **185-186 and first sentence in first full paragraph of page 76:** These sections of
26 Dr. Fleming's report discloses the content of AMYLN05278007, a document
27 produced by Amylin and designated "Confidential - Attorney's Eyes Only"
28 pursuant to the Protective Order. This document is a confidential submission by

1 Astrazeneca to the EMA that, *inter alia*, discusses information concerning protocols
2 and results for studies on Byetta and pancreatic cancer or thyroid cancer.

3 k. **Fleming report at pages 96-98, portions disclosing**
4 **content of BY00360566 and BY00364270:** These sections of Dr. Fleming's report
5 disclose the content of BY00360566 and BY00364270, documents produced by
6 Amylin and designated "Confidential" under the Protective Order. These
7 documents are letters submitted confidentially to, and maintained confidentially by,
8 the FDA that discuss and analyze labeling supplements for Byetta. Each document
9 reflects confidential commercial information and/or competitively sensitive
10 proprietary information, including the results of a clinical study and the process by
11 which Amylin decided to include the proposed labeling.

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13 I declare under penalty of perjury under the laws of the United States
14 that the foregoing is true and correct. Executed on January 6, 2015 at Newport
15 Beach, California.

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18 Amy J. Laurendeau
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EXHIBIT A



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January 5, 2015

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Re: In re: Incretin-Based Therapies Products Liability Litigation, 13md2452-AJB (MDD) Deposition of Orville Kolterman, M.D. – Confidentiality Designations - Amylin Pharmaceuticals

Dear Counsel:

Amylin Pharmaceuticals is designating the following portions of Dr. Orville Kolterman's November 5, 2014 deposition as confidential under the Protective Order in this case:

Begin Designation (Page:Line)	End Designation (Page:Line)
44:16	45:11
46:21	47:8
47:18	48:17
49:23	50:2
52:16	53:4
53:11	53:16
54:5	55:1
55:16	56:20
57:13	59:6
59:16	61:2
62:14	62:24
64:19	64:23
66:3	73:19
74:6	76:8

77:15	78:4
80:10	83:7
83:13	84:23
85:12	86:2
92:16	97:12
99:11	99:25
104:7	105:14
109:9	112:9
113:24	115:2
116:18	119:12
122:3	126:11
127:3	127:17
128:6	138:1
139:6	140:6
144:19	146:20
160:8	163:24
166:17	167:20
169:3	170:16
172:14	172:19
173:16	175:12
179:16	184:14
185:12	186:12
194:17	200:23
204:9	206:8
209:8	211:1
223:14	236:2
242:8	244:20
249:23	253:3
257:16	260:8
262:24	263:15
264:11	279:1
279:18	281:10
283:20	284:14
285:23	291:2
296:22	302:7
304:14	306:14
310:19	317:1
326:19	329:18
332:25	334:15
335:13	337:3
341:7	342:16
344:1	344:12

366:20	367:25
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Amylin asks that the court reporter designate these passages as Confidential. As provided for in the Protective Order, these confidentiality designations will apply to any video or other recordings of the designated testimony. Further, all Confidential Discovery Materials produced by Amylin and used as exhibits or as the subject of testimony during this deposition retain the same designation as when produced by Amylin.

Sincerely,

/s/ Houman Ehsan

Houman Ehsan
Partner
of O'MELVENY & MYERS LLP

cc: Stephen D. Raber, Esq. (sraber@wc.com)
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EXHIBIT B



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November 5, 2014

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Re: In re: Incretin-Based Therapies Products Liability Litigation, 13md2452-AJB (MDD) Deposition of John Buse, M.D., Ph.D. – Confidentiality Designations - Amylin Pharmaceuticals

Dear Counsel:

Amylin Pharmaceuticals is designating the following portions of Dr. John Buse's September 23, 2014 deposition as confidential under the Protective Order in this case:

Begin Designation (Page:Line)	End Designation (Page:Line)
46:20	47:9
54:21	55:11
57:1	57:11
142:14	143:7
198:22	201:20
202:17	202:20

Amylin asks that the court reporter designate these passages as Confidential. As provided for in the Protective Order, these confidentiality designations will apply to any video or other recordings of the designated testimony. Further, all Confidential Discovery Materials

produced by Amylin and used as exhibits or as the subject of testimony during this deposition retain the same designation as when produced by Amylin.

Sincerely,

/s/ Houman Ehsan

Houman Ehsan
Partner
of O'MELVENY & MYERS LLP

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