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

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

19 *This Documents Relates to All Cases*

CASE NO. 3:13-MD-02452-AJB-MDD

**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**

**(FILED CONCURRENTLY WITH  
DECLARATIONS OF AMY J.  
LAURENDEAU, ELIZABETH M.  
RAY, STEPHEN P. SWINTON AND  
PROPOSED ORDER)**

Hon. Anthony J. Battaglia

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1 **I. INTRODUCTION**

2 Pursuant to the Court’s August 14, 2014 Order Granting Joint Motion for  
3 Entry of Amended Protective Order (Doc. No. 530) and the Court’s  
4 December 23, 2014 Order Granting Parties’ Joint Motion for Extension of Time to  
5 File a Motion to Seal (Doc. No. 870), Defendants Amylin Pharmaceuticals, LLC  
6 (“Amylin”) and Eli Lilly and Company (“Lilly”) (collectively “Defendants”)  
7 respectfully move the Court to strike the expert reports of David Madigan, Ph.D.  
8 (Doc. No. 850) and G. Alexander Fleming, M.D. (Doc. No. 852) (together the  
9 “Expert Reports”) from the public docket.<sup>1</sup> The reports incorporate, reference, and  
10 rely upon Defendants’ confidential materials, which were properly designated as  
11 “confidential” or “attorneys’ eyes only” pursuant to the Parties’ agreed-upon  
12 Protective Order. These materials include discussions of confidential regulatory  
13 submissions, meeting minutes from internal safety committees, and confidential  
14 internal email exchanges. Such Rule 26(a)(2) expert reports are not typically filed  
15 with the Court, and the case for not having such documents on the public docket is  
16 even more compelling here, where: (1) Plaintiffs failed to provide the requisite  
17 notice pursuant to the Protective Order; (2) Dr. Fleming is a Competitor as defined  
18 in the Protective Order;<sup>2</sup> and (3) the Confidential Documents themselves relate to  
19 fraud on the FDA claims that the Court has repeatedly ruled are not relevant to  
20 preemption.

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21 <sup>1</sup> Defendants Merck Sharp & Dohme Corp. (“Merck”) and Novo Nordisk Inc.  
22 (“Novo”) join in this Motion to Strike From The Public Docket Plaintiffs’  
23 Expert Reports Regarding Preemption, and are simultaneously filing motions to  
seal based upon disclosure of their confidential documents.

24 <sup>2</sup> In addition to the fact that Plaintiffs did not notify Defendants before disclosing  
25 their Confidential Documents to a Competitor per the Protective Order’s  
26 directive, Dr. Fleming served as a consultant to both Amylin and Novo on the  
27 very GLP-1-based agents at issue in this litigation. Amylin and Novo have  
28 raised with Plaintiffs’ counsel their concerns regarding Dr. Fleming’s  
designation and the scope of his expert report in light of his consulting work  
and nondisclosure agreements with Amylin and Novo. Given these  
circumstances, further motion practice regarding Dr. Fleming’s designation  
may be forthcoming.

1 In the alternative, Defendants respectfully move the Court to seal certain  
2 portions of the Expert Reports.<sup>3</sup> As set forth below, and as explained in the  
3 accompanying Declarations of Amy J. Laurendeau and Elizabeth M. Ray, there is  
4 good cause to maintain such material (and detailed discussions thereof) under seal.  
5 Attached as Exhibits A and B to the Declaration of Stephen P. Swinton filed  
6 concurrently herewith are Defendants’<sup>4</sup> proposed public versions of Plaintiffs’  
7 Expert Reports which reflect carefully limited redactions of Defendants’  
8 confidential material.<sup>5</sup>

9 The Protective Order reflects the Parties’ mutual understanding and  
10 agreement that the materials at issue in this litigation—“not only those items or  
11 things which are expressly designated as Confidential, but also all copies, excerpts,  
12 and summaries thereof, as well as testimony, oral communications, and other work  
13 product containing Confidential information or information derived therefore”—  
14 reflect confidential and proprietary regulatory submissions, trade secrets, and  
15 manufacturing information that should not be subject to disclosure (hereinafter  
16 “Confidential Documents”).<sup>6</sup> The Protective Order underscores the fact that,  
17 outside this litigation, the Defendants are fierce competitors—both with each other  
18 and with companies not part of this MDL—in a highly competitive market for  
19

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20 <sup>3</sup> Plaintiffs cite, but do not attach or quote from, additional confidential-  
21 designated documents throughout the Expert Reports and in Exhibit B to  
22 Dr. Fleming’s report. While those documents have not been filed or otherwise  
23 disclosed, such that a motion to seal would be presently warranted, Defendants  
24 reserve their rights to seek to seal those documents should Plaintiffs seek to  
25 disclose them and would request the opportunity to brief any such request.

23 <sup>4</sup> For the Court’s convenience, the redacted documents also reflect those  
24 redactions advocated by Merck and Novo in their separate Motions to Seal.

25 <sup>5</sup> While the Declarations of Amy J. Laurendeau and Elizabeth M. Ray each  
26 address specific portions of the Expert Reports, Amylin and Lilly, as alliance  
27 partners, share a common interest in the confidential nature of their documents  
28 and each relies upon and adopts the rationale offered by the other.

27 <sup>6</sup> See Protective Order at § 1(f). The Confidential Documents at issue in this  
28 motion constitute Confidential Discovery Material as defined by the Protective  
Order. See Protective Order at § 1(c); see also, *infra*, note 11.

1 diabetes medicines. Simply put, the Protective Order is designed to ensure that  
2 Confidential Documents are not subject to unfettered disclosure so as to protect the  
3 Defendants from the risk of significant competitive harm. For the reasons that  
4 follow, and as set forth in the accompanying Declarations, there is good cause to  
5 keep these materials confidential.

## 6 **II. ARGUMENT**

### 7 **A. Plaintiffs' Expert Reports Should Be Stricken From The Public** 8 **Docket.**

9 The Court should strike Plaintiffs' Expert Reports from the public docket.  
10 By default, "disclosures under Rule 26(a)(1) or (2) ... *must not be filed*[" Fed. R.  
11 Civ. P. 5(d)(1) (emphasis added). The two exceptions to the rule are (1) when such  
12 disclosures are used in a proceeding or (2) when the Court orders filing. *Id.* In this  
13 case the Court's Scheduling Order directed the parties to "serve and file" their  
14 preemption expert reports. *See* October 24, 2014 Order Granting Joint Motion for  
15 Modification of Scheduling Order and Following Status Conference, Document  
16 No. 740, 3:13-md-02452-AJB-MDD. Defendants respectfully submit that the  
17 Court clarify that Expert Reports in this case need only be served on opposing  
18 counsel, and not filed, per the standard practice.

19 To begin with, there is no need to file Expert Reports at this stage of the  
20 proceeding. If and when Plaintiffs seek to rely on the Expert Reports in support of  
21 or in opposition to any motion, Plaintiffs may attach the reports (or excerpts of the  
22 reports) to their pleadings. Moreover, Plaintiffs' Expert Reports discuss a large  
23 number of Confidential Documents that Defendants produced pursuant to the  
24 Protective Order. Striking the Expert Reports from the public docket avoids the  
25 need for the Court to consider numerous motions to seal relating to the Expert  
26 Reports.

27 Moreover, although Defendants supported the Court's current Scheduling  
28 Order, Defendants had no indication that Plaintiffs would seek to publish their

1 Confidential Documents in connection with Rule 26(a)(2) disclosures.<sup>7</sup> To begin  
2 with, Plaintiffs did not provide notice of intent to disclose Confidential Documents  
3 via their Expert Reports as required by the Protective Order. Paragraph 10(b)  
4 requires that a party “who intends to attach Confidential Discovery Materials to a  
5 court filing shall, to the extent circumstances allow, provide the Producing Party  
6 two days advance written notice of their intent to do so. . .” Had Plaintiffs  
7 provided the requisite notice, Defendants would have had an opportunity to ask the  
8 Court to clarify that the Parties’ reports should not be filed pursuant to  
9 Rule 5(d)(1).

10 Even more troubling, Plaintiffs’ expert, Dr. Fleming, is Defendants’  
11 competitor in the marketplace of diabetes medicines. He is Co-Founder,  
12 Chairman, and Chief Medical Officer of Exsulin, a pharmaceutical company  
13 “developing peptide-based drugs targeted at regenerating the insulin-producing  
14 islets in patients with both Type 1 and Type 2 diabetes.”<sup>8</sup> Accordingly, pursuant to  
15 paragraph 5(d) of the Protective Order, Plaintiffs were obliged to provide “fourteen  
16 days’ advance notice in writing ... identifying with particularity the Confidential  
17 Discovery Materials to be disclosed and stating the purpose of such disclosure”  
18 before they even showed Dr. Fleming Defendants’ Confidential Documents.

19  
20 <sup>7</sup> Subsequently, Defendants invited Plaintiffs’ counsel to join them on a call to  
21 the Clerk to clarify whether the parties should actually file their reports, but  
22 Plaintiffs’ counsel did not respond.

23 <sup>8</sup> See generally Fleming Expert Report at 3 (noting that just four days before his  
24 report was filed in this litigation, Dr. Fleming published a patent for “Ursolic  
25 Acid Salts for Treating Diabetes and Obesity”). Dr. Fleming also is or has  
26 recently been a Member of the Advisory Board for Poxel SAS, which, two days  
27 after his report was filed, announced positive results for its antidiabetic agent  
28 Imeglimin, “the first in a new chemical class of oral anti-diabetic agents,” in a  
Phase 2b trial. See generally Poxel Announcement, available at  
<http://goo.gl/2ULasg> (last accessed January 2, 2015); see also Company  
Overview of Poxel SAS, Bloomberg Businessweek, available at  
<http://goo.gl/fXxbNq> (last accessed January 2, 2015). Poxel is also currently  
developing, *inter alia*, a small molecule GLP-1 Receptor Agonist. Poxel  
Corporate Presentation (January 2014), available at <http://goo.gl/axsYo5> (last  
accessed January 2, 2015).

1 Plaintiffs provided no such notice. Again, had Defendants known, they would  
2 have asked the Court to clarify that the Parties' expert reports should not be filed  
3 pursuant to Rule 5(d)(1).

4 Finally, Plaintiffs' Expert Reports focus on material that Defendants  
5 supposedly did not disclose to the FDA. However, the Court has twice made clear  
6 that "Plaintiffs' assertions that there were 'reasons to believe [pancreatic] cancers  
7 were not correctly reported and were under-reported' and that information was  
8 'withheld by Defendants from the FDA' are fraud-on-the-FDA claims expressly  
9 preempted by *Buckman*."<sup>9</sup> Defendants had little reason to expect that Plaintiffs  
10 would attempt to publish their Confidential Documents in this manner, particularly  
11 when the Court explicitly stated that such an analysis "would not change" whether  
12 Plaintiffs claims were preempted.<sup>10</sup>

13 Accordingly, Defendants now respectfully move the Court to strike the  
14 Parties' expert reports from the public docket. To avoid a repeat of this situation,

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15 <sup>9</sup> *E.g.*, Order Denying Plaintiffs' Motion to Compel Discovery of Adverse Event  
16 Source Documents and Databases, Document 554, 3:13-md-02452-AJB-MDD,  
17 4.

18 <sup>10</sup> *See id.* at 5; *see also, e.g.*, Fleming Expert Report at 35, n57 ("Plainly, that  
19 assessment should have been, and should be, provided to FDA . . ."); *id.* at 40  
20 ("The manufacturers have or could have had access to a multitude of scientific  
21 evidence . . . *some* of this evidence is already in the possession of the FDA...")  
22 (emphasis added); *id.* at 82 (" . . . EMA likely did not yet have some of the non-  
23 clinical and clinical data that the FDA was also missing, as discussed above.");  
24 *id.* at 86-87 (" . . . it appears likely that the FDA did not have the Signal  
25 Assessment . . ."; "The letter makes it clear that Amylin failed to disclose to the  
26 FDA . . ."; "The manufacturers had the signal assessment . . . but it appears the  
27 FDA did not . . ."); *id.* at 105 ("As a further example, FDA did not appear to  
28 have each manufacturer's clinical trial pancreatic cancers..."); *accord* Fleming  
Expert Report at 41 ("This information, which I also understand was not in the  
possession of FDA..."); *id.* at 61-66 ("[the] witness admits that this information  
was not in the FDA's possession"; "The spreadsheet submitted to FDA did not  
contain information on the studies . . ."; "The NEJM article specifically cites the  
clinical data . . . but [the] clinical data did not include the three cases of  
pancreatic cancer..."; "it is unlikely that this information was considered by  
FDA . . ."); *id.* at 94 (" . . . even putting aside [the manufacturer's] inappropriate  
analysis . . . and their failure to include the pancreatic cancer case..."); *id.* at  
102, n245 ("I found it worrisome that the regulatory personnel for the  
manufacturers were unable to even identify *who* makes such a determination,  
much less *how* it is done.").

1 Defendants respectfully urge the Court to revise its October 24, 2014 Order  
2 Granting Joint Motion for Modification of Scheduling Order and Following Status  
3 Conference (Doc. No. 740) to make clear that, henceforth, the Parties should serve  
4 (but not file) all future expert reports, with respect to both preemption and general  
5 causation, on the dates scheduled.

6 **B. Confidential Documents May Be Maintained Under Seal Where**  
7 **Defendants Show That “Good Cause” Exists To Do So.**

8 Should the Court nonetheless wish to leave the Parties’ expert reports on the  
9 public docket, governing Ninth Circuit law makes clear that confidential  
10 documents may be maintained under seal where there exists “good cause” to do so.  
11 *See Kamakana v. Honolulu*, 447 F.3d 1172, 1179 (9th Cir. 2006) (stating the good  
12 cause standard will “suffice [] to warrant preserving the secrecy of sealed  
13 discovery material attached to nondispositive motions”) (citing *Foltz v. State Farm*  
14 *Mut. Auto. Ins. Co.*, 331 F.3d 1122, 1135 (9th Cir. 2003) and *Phillips v. General*  
15 *Motors Corp.*, 307 F.3d 1206, 1213 (9th Cir. 2002)) (noting that the Ninth Circuit  
16 has “carved out an exception to the presumption of access” to judicial records for a  
17 “sealed discovery document [attached] to a non-dispositive motion,” such that the  
18 “usual presumption of the public’s right of access is rebutted”); *see also* Fed. R.  
19 Civ. P. 26(c); Protective Order, § 11(c). Because Plaintiffs’ Expert Reports discuss  
20 Defendants’ Confidential Documents, good cause exists to maintain the portions of  
21 Plaintiffs’ Expert Reports that discuss, incorporate, and reference Defendants’  
22 Confidential Documents under seal.

23 Pursuant to the “good cause” standard of Rule 26(c) of the Federal Rules of  
24 Civil Procedure, a trial court has broad discretion to permit sealing of court  
25 documents for, *inter alia*, the protection of “a trade secret or other confidential  
26 research, development, or commercial information.” Fed. R. Civ. P. 26(c)(1)(G);  
27 *see also Benedict v. Hewlett-Packard Co.*, 2014 U.S. Dist. LEXIS 7368, at \*4  
28 (N.D. Cal. Jan. 21, 2014). Moreover, a myriad of other reasons can constitute

1 “good cause.” Fed. R. Civ. P. 26(c); *Phillips*, 307 F.3d at 1211; *Foltz*, 331 F.3d at  
2 1130. The bottom line is that “good cause” requires a party to show that specific  
3 prejudice or harm may result from public disclosure of the documents at issue.  
4 *Phillips*, 307 F.3d at 1210-11; *Foltz*, 331 F.3d at 1130. Moreover, “good cause” to  
5 seal is generally found where the disclosure of proprietary information could cause  
6 a party competitive injury. *Model Drug, Inc. v. Amerisourcebergen Drug Corp.*,  
7 2013 U.S. Dist. LEXIS 169496, 5 (E.D. Cal. Nov. 26, 2013).

8 **C. Here, The Risk of Substantial Competitive Harm Demonstrates**  
9 **That Good Cause Exists To Maintain the Portions of Plaintiffs’**  
10 **Expert Reports Disclosing Confidential Documents Under Seal.**

11 By its very nature, the significance of the “Confidential” designation, as  
12 defined in the Parties’ Protective Order, encompasses all of the “good cause”  
13 principles outlined above. Indeed, designating a document as Confidential reflects  
14 the fact that the material contains, *inter alia*, sensitive business or scientific  
15 material, trade secrets, or other proprietary information not available to the  
16 public.<sup>11</sup> If Plaintiffs wish to challenge a document’s confidentiality designation,  
17 the agreed-upon Protective Order provides the means to do so. Otherwise,

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18 <sup>11</sup> See Protective Order § 1(d) (providing that the term “Confidential” means “(1)  
19 sensitive business or scientific material or information which in the ordinary  
20 course is neither made available to the general public or the industry at large,  
21 and/or which the Producing Party would not normally reveal to third parties, or  
22 would cause third parties to maintain in confidence, such as sales, technical  
23 product details, commercial, financial, budgeting and/or accounting  
24 information, or marketing studies; or (2) information that the Producing Party  
25 reasonably believes constitutes a trade secret under applicable statutory and  
26 case law; or (3) other information which in the ordinary course is neither made  
27 available to the general public or the industry at large and to which access is  
28 restricted and efforts have been made to prevent the information from being  
broadly disseminated; or (4) other information that the Producing Party  
reasonably believes constitutes such highly sensitive technical or proprietary  
business information of such Producing Party that its disclosure might result in  
an unfair competitive, financial or commercial advantage to the Party receiving  
the information (the “Receiving Party”) or competitors or disadvantage to the  
Producing Party, such as research, development information, testing data and  
analysis, information about existing and potential customers, business  
strategies, decisions and/or negotiations, and/or confidential and proprietary  
information about affiliates, parents, subsidiaries and third parties with whom  
the Parties to this action have had business relationships.”

1 Plaintiffs are fully able, subject to the agreed-upon Protective Order, to use  
2 confidential documents for permissible purposes. However, Plaintiffs should not  
3 be able to circumvent the Protective Order and strip confidential materials of  
4 confidentiality by using them in the Expert Reports.

5 Indeed, substantial competitive harm could result from disclosure of  
6 Defendants' Confidential Documents, which comprise, *inter alia*, discussions of  
7 confidential regulatory submissions, meeting minutes from internal safety  
8 committees, and confidential internal email exchanges. It is axiomatic in the  
9 pharmaceutical industry that there exist competitors who can derive some  
10 commercial benefit from data access. *See, e.g., Public Citizen Health Research*  
11 *Group v. NIH*, 209 F. Supp. 2d 37, 47 (D.D.C. 2002). In this MDL alone, there are  
12 four marketplace competitors, in addition to the numerous other manufacturer-  
13 competitors in the diabetes arena not involved in the instant litigation. Indeed,  
14 competitors routinely attempt to acquire safety and efficacy data by petitioning  
15 FDA under the Freedom of Information Act ("FOIA"). *See* Orrin Hatch,  
16 *Refinements Are Needed To Stop Abuses*, ABA Journal 556, 557 (May 1983)  
17 (noting that 85% of the FOIA requests received by FDA are initiated by  
18 pharmaceutical companies, "many of whom are seeking their competitors  
19 secrets"). FDA, for its part, recognizes that safety and efficacy data constitute  
20 "confidential commercial information," and are, therefore, exempt from FOIA  
21 disclosure requirements. *See* 39 Fed. Reg. 44602, 44634 (Dec. 24, 1974) (release  
22 of data upon request would allow "me-too" drugs to be marketed immediately); *see*  
23 *also* 21 C.F.R. § 314.430 (discussed *infra* at note 11).

24 **D. Good Cause To Seal The Portions of Plaintiffs' Expert Reports**  
25 **Disclosing Confidential Documents Also Exists Because FDA**  
26 **Recognizes That The Documents Are Proprietary and**  
**Confidential.**

27 Many of the Confidential Documents disclosed in Plaintiffs' Expert Reports  
28 are or relate to regulatory materials that FDA recognizes as confidential by

1 regulation and guidance documents. It is “indisputable” that “most” of a  
2 company’s application to FDA (and amendments thereto) are trade secrets, “the  
3 disclosure of which to a competitor ... would be extremely damaging” to the  
4 applicant’s interests. *Biovail Labs., Inc. v. Anchen Pharms., Inc.*, 463 F. Supp. 2d.  
5 1073, 1083 (C.D. Cal. 2006). Where FDA would not make such information  
6 available to an applicant’s competitors for review and comment — neither should  
7 the court. *Id.* at 1084; *see also Andrx Pharms., LLC v. GlaxoSmithKline, plc*, 236  
8 F.R.D. 583, 586 (S.D. Fla. 2006) (“Courts dress technical information with a heavy  
9 cloak of judicial protection because of the threat of serious economic injury to the  
10 discloser of scientific information”); *Serono Lab. v. Shalala*, 35 F. Supp. 2d 1, 2  
11 (D. D.C. 1999) (“In a field as competitive and technical as the pharmaceutical  
12 industry, success or failure will turn in large measure on innovation and the  
13 members of the industry justifiably hoard their trade secrets as jealously as a miser  
14 hoards his gold.”).

15 Several of the Confidential Documents relate to analyses that would be  
16 included in Periodic Safety Update Reports (“PSURs”)<sup>12</sup> provided to FDA. FDA  
17 recognizes PSURs as proprietary and confidential. *See* FDA Guidance for  
18 Industry: Addendum to E2C Clinical Safety Data Management: Periodic Safety  
19 Update Reports for Marketed Drugs, February 2004, p. 7 (attached as Ex. B to Ray  
20 Declaration); *see also* 21 C.F.R. § 314.430 (enumerating types of data and  
21 circumstances under which “safety and effectiveness data” may become public,  
22 none of which applies here).<sup>13</sup>

23  
24 <sup>12</sup> Periodic Safety Update Reports present the worldwide safety experience of a  
25 medicinal product at defined intervals after a medication has been approved.  
26 *See* U.S. Food and Drug Administration Guidance for Industry – E2C Clinical  
27 Safety Data Management: Periodic Safety Update Reports for Marketed Drugs,  
28 p. 2, attached as Ex. A to Ray Declaration.

<sup>13</sup> 21 C.F.R. § 314.430 (a) provides, in relevant part, “For purposes of this section,  
safety and effectiveness data include all studies and tests of a drug on animals  
and humans and all studies and tests of the drug for identity, stability, purity,  
potency, and bioavailability.” 21 C.F.R. § 314.430 (f) further explains: (f) All

~footnote continued on next page~

1           Moreover, these protected communications with FDA reflect the  
2 confidential process that Defendants use to evaluate, analyze, and synthesize post-  
3 marketing safety data. FDA mandates no set procedure or methodology for the  
4 evaluation of safety data for pharmacovigilance purposes. *See* U.S. Food and Drug  
5 Administration Guidance for Industry – E2C Clinical Safety Data Management:  
6 Periodic Safety Update Reports for Marketed Drugs (attached as Ex. A to Ray  
7 Declaration). Rather, “judgment should be used in such situations to determine  
8 whether the data reflect a meaningful change in [Adverse Drug Reactions]  
9 occurrence or safety profile and whether an explanation can be proposed to such a  
10 change (e.g., population exposed, duration of exposure).” *See id.* at 4.  
11 Accordingly, each company’s methodology reflects a proprietary process, and  
12 documents that reflect that process, leading to the preparation of confidential  
13 PSUR and other submissions, deserve the same level of confidentiality that the  
14 agency accords the finished submissions.

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17           safety and effectiveness data and information which have been submitted in an  
18 application and which have not previously been disclosed to the public are  
19 available to the public, upon request, at the time any one of the following events  
occurs unless extraordinary circumstances are shown:

20           (1) No work is being or will be undertaken to have the application approved.

21           (2) A final determination is made that the application is not approvable and all  
legal appeals have been exhausted.

22           (3) Approval of the application is withdrawn and all legal appeals have been  
exhausted.

23           (4) A final determination has been made that the drug is not a new drug.

24           (5) For applications submitted under section 505(b) of the act, the effective date  
25 of the approval of the first abbreviated application submitted under section  
26 505(j) of the act which refers to such drug, or the date on which the approval of  
an abbreviated application under section 505(j) of the act which refers to such  
drug could be made effective if such an abbreviated application had been  
submitted.

27           (6) For abbreviated applications submitted under section 505(j) of the act, when  
28 FDA sends an approval letter to the applicant.

1 Other Confidential Documents contain information related to “safety and  
2 effectiveness data” from Defendants’ studies, which FDA also recognizes as  
3 proprietary and confidential. For these reasons the Court should find that “good  
4 cause” exists to maintain the seal of the portions of Plaintiffs’ Expert Reports that  
5 incorporate and reference Defendants’ Confidential Documents.

6 **E. Unsealing the Confidential Documents, Which Lack Appropriate**  
7 **Context, Would Prejudice the Defendants and Potentially Harm**  
8 **Patients – Further Demonstrating That Good Cause Exists To**  
9 **Maintain the Materials’ Confidentiality.**

10 In addition to the trade-secret and competitive issues that attend the  
11 Confidential Documents, Defendants will be prejudiced and patients potentially  
12 harmed, if Plaintiffs’ cherry-picked selections are unsealed. First, diabetes is a  
13 public health crisis, and FDA has recognized that incretin-based therapies are an  
14 important treatment for managing the disease. Numerous medical societies have  
15 stated that the available data do not justify withholding incretin-based therapies  
16 from diabetic patients. *See American Diabetes Association, ADA/EASD/IDF*  
17 *Statement Concerning the Use of Incretin Therapy and Pancreatic Disease*, 2  
18 (June 28, 2013) (noting there is insufficient information regarding incretin-based  
19 therapies and pancreatic disease to modify current treatment recommendations)  
20 (attached as Ex. C to Ray Declaration). There is a strong public interest in  
21 ensuring that patients and their physicians have access to accurate safety data about  
22 such therapies and that no-one is confused by preliminary and incomplete  
23 statements in documents taken out of context.

24 Second, the pancreatic safety of incretin-based therapies is an issue that has  
25 the attention of the popular press. *See, e.g., Andrew Pollack, A Lone Voice Raising*  
26 *Alarms*, N.Y. Times, May 31, 2013, at B1 (attached as Ex. D to Ray Declaration).  
27 Indeed, both FDA and EMA have recognized the media’s focus on the issue: “Both  
28 agencies agree that assertions concerning a causal association between incretin-  
based drugs and pancreatitis or pancreatic cancer, as expressed recently in the

1 scientific literature and in the media, are inconsistent with the current data.” See  
2 Amy G. Egan et al., *Pancreatic Safety of Incretin-Based Drugs—FDA and EMA*  
3 *Assessment*, 370;9 N Engl J Med 794, 796 (2014) (attached as Ex. E to Ray  
4 Declaration). Publication of partial safety information creates an atmosphere in  
5 which patients can become frightened off their medications and which interferes  
6 with the doctor-patient relationship. Cf. Judyth Pendell, *The Adverse Side Effects*  
7 *of Pharmaceutical Litigation*, AEI-Brookings Joint Center For Regulatory Studies  
8 (2003) (reporting physicians’ refusal to prescribe and patients’ refusal to take  
9 appropriately prescribed medications after learning medications were subject to  
10 product liability litigation) (attached as Ex. F to Ray Declaration). Disclosure of  
11 the portions of Plaintiffs’ Expert Reports that discuss, incorporate, and reference  
12 Defendants’ Confidential Documents, which consist of internal materials that  
13 discuss incomplete, preliminary safety evaluations, would prejudice Defendants  
14 and harm patients by raising undue alarm about a potential safety issue that FDA  
15 has recently discredited.<sup>14</sup>

16 Third, the Confidential Documents discussed, incorporated, and referenced  
17 in Plaintiffs’ Expert Reports are miscellaneous internal emails, letters, single-case  
18 data, and confidential advisory panel summaries that do not represent the full  
19 safety review and analysis that Defendants undertook to assess the pancreatic  
20 safety of Byetta. Divorced from materials that put context around the Confidential  
21 Documents and provide the final results of investigations addressed in the  
22 Confidential Documents, disclosure of the portions of Plaintiffs’ Expert Reports

23 <sup>14</sup> As has been described, the FDA and EMA recently and jointly published an  
24 article expressing their view that “current knowledge [regarding pancreatitis  
25 and pancreatic cancer] is adequately reflected in the product information or  
26 labeling” of incretin-based drugs. For its part, FDA’s conclusion was based on  
27 an independent, year-long, “comprehensive evaluation” of “multiple streams of  
28 data.” Such data included data from “more than 200 [clinical] trials, involving  
approximately 41,000 participants,” and “more than 250 toxicology studies  
conducted in nearly 18,000 healthy animals[.]” See Amy G. Egan et al.,  
*Pancreatic Safety of Incretin-Based Drugs—FDA and EMA Assessment*, 370;9  
N Engl J Med 794, 796 (2014) (attached as Ex. E to Ray Declaration).

1 that discuss, incorporate and reference Defendants' Confidential Documents would  
2 provide selective, distorted information to patients who take Byetta (and other  
3 incretin-based therapies) and their physicians.

4 **III. CONCLUSION**

5 For the foregoing reasons, Plaintiffs' Expert Reports should be stricken from  
6 the public docket consistent with Rule 5(d). Alternatively, because Defendants  
7 have made a particularized showing — sufficient under the “good cause” standard  
8 — Plaintiffs' Expert Reports should remain partially sealed in the form of the  
9 carefully limited proposed redactions shown on the versions of the reports  
10 attached.

11  
12 Dated: January 6, 2015

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**SIGNATURE ATTESTATION**

Pursuant to Section 2.f.4 of the Court’s CM/ECF Administrative Policies, I hereby certify that authorization for the filing of this document has been obtained from each of the other signatories shown above and that all signatories have authorized placement of their electronic signature on this document.

s/Stephen P. Swinton  
stephen.swinton@lw.com

1 **CERTIFICATE OF SERVICE**

2 I am employed in the County of San Diego, State of California. I am over  
3 the age of 18 years and not a party to this action. My business address is  
4 Latham & Watkins LLP, 12670 High Bluff Drive, San Diego, CA 92130.

5 On January 6, 2015, I served the following document described as:

6 **DEFENDANTS AMYLIN PHARMACEUTICALS, LLC AND  
7 ELI LILLY AND COMPANY’S MOTION TO STRIKE FROM THE  
8 PUBLIC DOCKET OR, IN THE ALTERNATIVE, TO SEAL  
9 PLAINTIFFS’ EXPERT REPORTS REGARDING PREEMPTION**

10 **DECLARATION OF ELIZABETH M. RAY IN SUPPORT OF  
11 DEFENDANTS AMYLIN PHARMACEUTICALS, LLC AND  
12 ELI LILLY AND COMPANY’S MOTION TO STRIKE FROM THE  
13 PUBLIC DOCKET OR, IN THE ALTERNATIVE, TO SEAL  
14 PLAINTIFFS’ EXPERT REPORTS REGARDING PREEMPTION**

15 **DECLARATION OF AMY J. LAURENDEAU IN SUPPORT OF  
16 DEFENDANTS AMYLIN PHARMACEUTICALS, LLC AND  
17 ELI LILLY AND COMPANY’S MOTION TO STRIKE FROM THE  
18 PUBLIC DOCKET OR, IN THE ALTERNATIVE, TO SEAL  
19 PLAINTIFFS’ EXPERT REPORTS REGARDING PREEMPTION**

20 **DECLARATION OF STEPHEN P. SWINTON IN SUPPORT OF  
21 DEFENDANTS AMYLIN PHARMACEUTICALS, LLC AND  
22 ELI LILLY AND COMPANY’S MOTION TO STRIKE FROM THE  
23 PUBLIC DOCKET OR, IN THE ALTERNATIVE, TO SEAL  
24 PLAINTIFFS’ EXPERT REPORTS REGARDING PREEMPTION**

25 by serving a true copy of the above-described document in the following manner:

26 **BY ELECTRONIC FILING**

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27 I am familiar with the United States District Court, Southern District of  
28 California’s practice for collecting and processing electronic filings. Under that  
practice, documents are electronically filed with the court. The court’s CM/ECF  
system will generate a Notice of Electronic Filing (NEF) to the filing party, the  
assigned judge, and any registered users in the case. The NEF will constitute  
service of the document. Registration as a CM/ECF user constitutes consent to  
electronic service through the court’s transmission facilities. Under said practice,  
all parties to this case have been served electronically.

1 I declare that I am employed in the office of a member of the Bar of  
2 California, or permitted to practice before, this Court at whose direction the service  
3 was made and declare under penalty of perjury under the laws of the State of  
4 California that the foregoing is true and correct.

5 Executed on January 6, 2015, at San Diego, California

6  
7 /s/ Stephen P. Swinton  
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