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

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

21 *This Document Relates to All Cases*

Case No. 3:13-MD-02452-AJB-MDD

**DEFENDANT NOVO NORDISK
INC.'S MOTION TO STRIKE FROM
THE PUBLIC DOCKET OR, IN THE
ALTERNATIVE, TO SEAL
PLAINTIFFS' EXPERT REPORTS
REGARDING PREEMPTION
(FILED CONCURRENTLY WITH
DECLARATION OF HEIDI LEVINE
AND PROPOSED ORDER)**

Judge: Hon. Anthony J. Battaglia

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1 Pursuant to the Court’s August 14, 2014 Order Granting Parties’ Joint
2 Motion for Entry of Amended Protective Order (Doc. No. 530) and the Court’s
3 December 23, 2014 Order Granting Parties’ Joint Motion for Extension of Time to
4 File a Motion to Seal (Doc. No. 870), Defendant Novo Nordisk Inc. (“NNI”) joins
5 in Defendants Amylin Pharmaceuticals, LLC (“Amylin”) and Eli Lilly and
6 Company’s (“Lilly”) Motion to Strike From the Public Docket or, in the
7 Alternative, to Seal Plaintiffs’ Expert Reports Regarding Preemption (“Amylin and
8 Lilly’s Motion”). For the reasons stated in that motion, the Court should strike the
9 expert reports from the public docket, which obviates the need to consider any
10 motions to seal relating to the reports. In the alternative, NNI respectfully moves
11 the Court to seal certain portions of Dr. Fleming’s Expert Report (the “Expert
12 Report”).¹ As set forth below, and as explained in the accompanying Declaration of
13 Heidi Levine (the “Levine Declaration”), Plaintiffs’ Expert Report discusses and
14 references various NNI materials that have been designated as confidential in this
15 litigation. There is good cause to maintain such material (and detailed discussions
16 thereof) under seal, as shown in the proposed limited redactions by NNI in the
17 reports attached to Amylin and Lilly’s Motion, to protect NNI from the risk of
18 significant competitive harm.²

19 ////

20 ////

21
22 ¹ Dr. Fleming cites to, but does not attach, numerous confidential NNI
23 documents. To the extent a confidential document was discussed, incorporated, or
24 referenced in the Report, it is addressed in the attached Declaration of Heidi Levine
25 and both the document and discussion of its contents should remain confidential.
26 Additionally, Dr. Fleming reviewed, but does not attach or discuss, additional
documents listed in Appendix B to the Report. To the extent a confidential
document was reviewed but not filed nor its contents disclosed such that a motion
to seal would be presently warranted, NNI reserves its rights to seek to seal the
document should Plaintiffs seek to disclose it and requests the opportunity to brief
any such request.

27 ² A more detailed discussion of the Expert Report and the reasons that certain
28 portions should be sealed is provided in the Levine Declaration.

1 **I. INTRODUCTION**

2 Plaintiffs' Expert Report, a 108 page report from Dr. Alexander Fleming,
3 incorporates, references, and relies upon NNI's confidential materials. These
4 materials, all of which detail NNI's proprietary evaluation of pancreas and
5 pancreatic cancer safety data, form the foundation of Plaintiffs' Expert Report.
6 These materials include internal, non-public analyses of data. The materials were
7 designated "confidential" or "attorneys' eyes only" pursuant to the Parties' agreed-
8 upon Protective Order.³

9 As an initial matter, both Dr. Fleming's Report and Plaintiffs' Expert Report
10 from Dr. David Madigan should be stricken from the public docket because, as
11 established in Amylin and Lilly's Motion, such Rule 26(a)(2) expert reports are not
12 typically filed with the Court. The case for not having such documents on the
13 public docket is even more compelling here, where (1) Plaintiffs failed to provide
14 the requisite notice pursuant to the Protective Order; (2) Dr. Fleming is a
15 Competitor within the meaning of the Protective Order;⁴ and (3) the Confidential
16 Documents themselves relate to alleged fraud on the FDA—claims this Court has
17 repeatedly ruled are not relevant to preemption.

18 Further, the Protective Order reflects the Parties' mutual understanding and
19 agreement that the materials at issue in this litigation reflect confidential and
20 proprietary regulatory submissions, trade secrets, and manufacturing information

21 ³ See Order Granting Joint Motion for Entry of Amended Protective Order,
22 Document 564, 3:13-md-02452-AJB-MDD (hereinafter "Protective Order"); see
23 also Original Protective Order, Document 31-2 in *Moses Scott, et al. v. Merck, et*
al., 3:12-cv-02549-AJB-MDD.

24 ⁴ In addition to the fact that Plaintiffs did not notify Defendants before
25 disclosing their Confidential Documents to a Competitor per the Protective Order's
26 directive, Dr. Fleming served as a consultant to both Amylin and NNI on the very
27 GLP-1-based agents at issue in this litigation. Amylin and NNI have raised with
28 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 NNI. Given these circumstances, further motion practice
regarding Dr. Fleming's designation may be forthcoming.

1 that should not be subject to disclosure (hereinafter “Confidential Documents”).
2 This includes “not only those items or things which are expressly designated as
3 Confidential, but also all copies, excerpts, and summaries thereof, as well as
4 testimony, oral communications, and other work product containing Confidential
5 information or information derived therefore.”⁵ The Protective Order underscores
6 the fact that, outside this litigation, the Defendants are fierce competitors—both
7 with each other and with companies not part of this MDL—in a highly competitive
8 market for diabetes medicines. Simply put, the Protective Order is designed to
9 ensure that Confidential Documents are not subject to unfettered disclosure so as to
10 protect the Defendants from the risk of significant competitive harm. For the
11 reasons that follow, and as set forth in the accompanying Declaration, there is good
12 cause to keep these materials confidential.

13 **II. ARGUMENT**

14 **A. Plaintiffs’ Expert Reports Should Be Stricken From The Public** 15 **Docket.**

16 NNI joins in Amylin and Lilly’s Motion to Strike From the Public Docket or,
17 in the Alternative, to Seal Plaintiffs’ Expert Reports Regarding Preemption
18 (“Amylin and Lilly’s Motion”) and refers the Court to Section II. A. of Amylin and
19 Lilly’s Motion.

20 **B. Confidential Documents and Information May Be Maintained** 21 **Under Seal Where Defendants Show That “Good Cause” Exists To Do So.**

22 Should the Court nonetheless wish to make available on the public docket
23 Plaintiffs’ expert reports, governing Ninth Circuit law makes clear that confidential
24 documents and information may be maintained under seal where there exists “good
25 cause” to do so. *See Kamakana v. Honolulu*, 447 F.3d 1172, 1179 (9th Cir. 2006)

26 ⁵ *See* Protective Order at § 1(f). The Confidential Documents at issue in this
27 motion constitute Confidential Discovery Material as defined by the Protective
28 Order. *See* Protective Order at § 1(c); *see also, infra*, note 6.

1 (stating the good cause standard will “suffice to warrant preserving the secrecy of
2 sealed discovery material attached to nondispositive motions”) (citing *Foltz v. State*
3 *Farm Mut. Auto. Ins. Co.*, 331 F.3d 1122, 1135 (9th Cir. 2003) and *Phillips v.*
4 *General Motors Corp.*, 307 F.3d 1206, 1213 (9th Cir. 2002)) (noting that the Ninth
5 Circuit has “carved out an exception to the presumption of access” to judicial
6 records for a “sealed discovery document [attached] to a non-dispositive motion,”
7 such that the “usual presumption of the public’s right of access is rebutted”); *see*
8 *also* Fed. R. Civ. P. 26(c); Protective Order, § 11(c). Here, good cause exists to
9 maintain NNI’s Confidential Documents and the portions of Plaintiffs’ Expert
10 Report that discusses, incorporates, and references NNI’s Confidential Documents
11 under seal.

12 Pursuant to the “good cause” standard of Rule 26(c) of the Federal Rules of
13 Civil Procedure, a trial court has broad discretion to permit sealing of court
14 documents for, *inter alia*, the protection of “a trade secret or other confidential
15 research, development, or commercial information.” Fed. R. Civ. P. 26(c)(1)(G);
16 *see also Benedict v. Hewlett-Packard Co.*, 2014 U.S. Dist. LEXIS 7368, 4 (N.D.
17 Cal. Jan. 21, 2014). Moreover, a myriad of other reasons can constitute “good
18 cause.” Fed. R. Civ. P. 26(c); *Phillips*, 307 F.3d at 1211; *Foltz*, 331 F.3d at 1130.
19 The bottom line is that “good cause” requires a party to show that specific prejudice
20 or harm may result from public disclosure of the documents at issue. *Phillips*, 307
21 F.3d at 1210-11; *Foltz*, 331 F.3d at 1130. Moreover, “good cause” to seal is
22 generally found where the disclosure of proprietary information could cause a party
23 competitive injury. *Model Drug, Inc. v. Amerisourcebergen Drug Corp.*, 2013 U.S.
24 Dist. LEXIS 169496, 5 (E.D. Cal. Nov. 26, 2013).

25 **C. Here, The Risk of Substantial Competitive Harm Demonstrates**
26 **That Good Cause Exists To Maintain the Confidential Documents And Any**
27 **Discussion of Such Documents in the Expert Report Under Seal.**

28 By its very nature, the significance of the “Confidential” designation, as
defined in the Parties’ Protective Order, encompasses all of the “good

1 cause” principles outlined above. Indeed, designating a document as Confidential
2 reflects the fact that the material contains, *inter alia*, sensitive business or scientific
3 material, trade secrets, or other proprietary information not available to the public.⁶

4 If Plaintiffs wish to challenge a document’s Confidential designation, the
5 agreed-upon Protective Order provides the means to do so. Otherwise, Plaintiffs
6 are fully able, subject to the agreed-upon Protective Order, to use Confidential
7 Documents for permissible purposes. However, Plaintiffs should not be able to
8 circumvent the Protective Order and strip materials of confidentiality by using them
9 in an expert report, which they then propose to file publicly on the Court’s docket.

10 Indeed, substantial competitive harm could result from disclosure of NNI’s
11 Confidential Documents and information, which include, *inter alia*, data analyses,
12 draft presentations discussing internal safety analyses, and internal analyses of non-
13 clinical data. It is axiomatic in the pharmaceutical industry that there exist
14 competitors who can derive some commercial benefit from access to their
15 competitors’ data. *See, e.g., Public Citizen Health Research Group v. NIH*, 209 F.
16 Supp. 2d 37, 47 (D.D.C. 2002). In this MDL alone, there are four marketplace

17
18 ⁶ *See* Protective Order § 1(d) (providing that the term “Confidential” means
19 “(1) 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, and/or
21 which the Producing Party would not normally reveal to third parties, or would
22 cause third parties to maintain in confidence, such as sales, technical product
23 details, commercial, financial, budgeting and/or accounting information, or
24 marketing studies; or (2) information that the Producing Party reasonably believes
25 constitutes a trade secret under applicable statutory and case law; or (3) other
26 information which in the ordinary course is neither made available to the general
27 public or the industry at large and to which access is restricted and efforts have
28 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 competitors, in addition to the numerous other manufacturer-competitors in the
2 diabetes arena not involved in the instant litigation. Indeed, competitors routinely
3 attempt to acquire safety and efficacy data by petitioning FDA under the Freedom
4 of Information Act (“FOIA”). *See* Orrin Hatch, *Refinements Are Needed To Stop*
5 *Abuses*, ABA Journal 556, 557 (May 1983) (noting that 85% of the FOIA requests
6 received by FDA are initiated by pharmaceutical companies, “many of whom are
7 seeking their competitors secrets”). FDA, for its part, recognizes that safety and
8 efficacy data constitute “confidential commercial information,” and are, therefore,
9 exempt from FOIA disclosure requirements. *See* 39 Fed. Reg. 44602, 44634 (Dec.
10 24, 1974) (release of data upon request would allow “me-too” drugs to be marketed
11 immediately); *see also* 21 C.F.R. § 314.430 (discussed *infra* at note 11).

12 **D. Good Cause To Seal The Confidential Documents And Portions of**
13 **the Expert Report Discussing Same Also Exists Because FDA Recognizes That**
14 **The Documents and Information Are Proprietary and Confidential.**

15 Some of the Confidential Documents and information in the Expert Report
16 relates to regulatory submissions that FDA recognizes as confidential by regulation
17 and guidance documents. It is “indisputable” that “most” of a company’s
18 application to FDA (and amendments thereto) are trade secrets, “the disclosure of
19 which to a competitor ... would be extremely damaging” to the applicant’s
20 interests. *Biovail Labs., Inc. v. Anchen Pharms., Inc.*, 463 F. Supp. 2d. 1073, 1083
21 (C.D. Cal. 2006). Where FDA would not make such information available to an
22 applicant’s competitors for review and comment, neither should the court. *Id.* at
23 1084; *see also* *Andrx Pharms., LLC v. GlaxoSmithKline, plc*, 236 F.R.D. 583, 586
24 (S.D. Fla. 2006) (“Courts dress technical information with a heavy cloak of judicial
25 protection because of the threat of serious economic injury to the discloser of
26 scientific information”); *Serono Lab. v. Shalala*, 35 F. Supp. 2d 1, 2 (D. D.C. 1999)
27 (“In a field as competitive and technical as the pharmaceutical industry, success or
28 failure will turn in large measure on innovation and the members of the industry
justifiably hoard their trade secrets as jealously as a miser hoards his gold.”).

1 Several of the Confidential Documents and information in the Expert Report
2 relate to analyses that would be included in Periodic Safety Update Reports
3 (“PSURs”)⁷ provided to FDA. FDA recognizes PSURs as proprietary and
4 confidential. *See* FDA Guidance for Industry: Addendum to E2C Clinical Safety
5 Data Management: Periodic Safety Update Reports for Marketed Drugs, February
6 2004 (attached as Ex. B to the Ray Declaration, attached to Amylin and Lilly’s
7 Motion); *see also* 21 C.F.R. § 314.430 (enumerating types of data and
8 circumstances under which “safety and effectiveness data” may become public,
9 none of which applies here).⁸

10
11 ⁷ Periodic Safety Update Reports present the worldwide safety experience of a
12 medicinal product at defined intervals after a medication has been approved. *See*
13 U.S. Food and Drug Administration Guidance for Industry – E2C Clinical Safety
14 Data Management: Periodic Safety Update Reports for Marketed Drugs, p. 2,
15 attached as Ex. A to the Levine Declaration.

16 ⁸ 21 C.F.R. § 314.430 (a) provides, in relevant part, “For purposes of this
17 section, safety and effectiveness data include all studies and tests of a drug on
18 animals and humans and all studies and tests of the drug for identity, stability,
19 purity, potency, and bioavailability.” 21 C.F.R. § 314.430 (f) further explains: (f)
20 All safety and effectiveness data and information which have been submitted in an
21 application and which have not previously been disclosed to the public are available
22 to the public, upon request, at the time any one of the following events occurs
23 unless extraordinary circumstances are shown:

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

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

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

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

(5) For applications submitted under section 505(b) of the act, the
effective date of the approval of the first abbreviated application submitted under
section 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.

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

1 Moreover, these documents and Dr. Fleming’s discussion of such documents
2 reflect the confidential process that NNI uses to evaluate, analyze, and synthesize
3 post-marketing safety data. FDA does not mandate a set procedure or methodology
4 for the evaluation of safety data for pharmacovigilance purposes. *See* U.S. Food
5 and Drug Administration Guidance for Industry – E2C Clinical Safety Data
6 Management: Periodic Safety Update Reports for Marketed Drugs (attached as Ex.
7 A to the Ray Declaration, attached to Amylin and Lilly’s Motion). Rather,
8 “judgment should be used in such situations to determine whether the data reflect a
9 meaningful change in [Adverse Drug Reactions’] occurrence or safety profile and
10 whether an explanation can be proposed to such a change (e.g., population exposed,
11 duration of exposure).” *See id.* at 4. Accordingly, each company’s methodology
12 reflects a proprietary process, and documents reflecting that process, leading to the
13 preparation of confidential PSUR and other submissions, such as Development
14 Safety Update Report, deserve the same level of confidentiality that the agency
15 accords the finished submissions.

16 Other Confidential Documents referenced and discussed within the Expert
17 Report contain information related to “safety and effectiveness data” from
18 Victoza® studies, which FDA also recognizes as proprietary and confidential. For
19 these reasons, the Court should find that “good cause” exists to maintain the
20 designation and seal of NNI’s Confidential Documents and portions of the Expert
21 Report discussing those documents.

22 **E. Unsealing the Confidential Documents and Related Excerpts of the**
23 **Expert Report, Which Lacks Appropriate Context, Would Prejudice NNI and**
24 **Potentially Harm Patients—Further Demonstrating That Good Cause Exists**
To Maintain the Documents’ and Report’s Confidentiality.

25 In addition to the trade-secret and competitive issues that attend the
26 Confidential Documents and related excerpts in the Expert Report, NNI will be
27 prejudiced and patients potentially harmed, if Plaintiffs’ cherry-picked selections
28 are unsealed and taken out of context. First, diabetes is a national and global public

1 health crisis, and FDA has recognized that incretin-based therapies are an important
2 treatment for managing the disease. Numerous medical societies have stated that
3 the available data do not justify withholding incretin-based therapies from diabetic
4 patients. *See American Diabetes Association, ADA/EASD/IDF Statement*
5 *Concerning the Use of Incretin Therapy and Pancreatic Disease*, 2 (June 28, 2013)
6 (noting there is insufficient information regarding incretin-based therapies and
7 pancreatic disease to modify current treatment recommendations) (attached as Ex.
8 C to the Ray Declaration, attached to Amylin and Lilly’s Motion). There is a
9 strong public interest in ensuring that patients and their physicians have access to
10 accurate safety data about such therapies and that no-one is confused by
11 preliminary and incomplete statements in documents taken out of context.

12 Second, the pancreatic safety of incretin-based therapies is an issue that has
13 the attention of the popular press. *See, e.g., Andrew Pollack, A Lone Voice Raising*
14 *Alarms*, N.Y. Times, May 31, 2013 at B1 (attached as Ex. D to the Ray Declaration,
15 attached to Amylin and Lilly’s Motion). Indeed, both FDA and EMA have
16 recognized the media’s focus on the issue: “Both agencies agree that assertions
17 concerning a causal association between incretin-based drugs and pancreatitis or
18 pancreatic cancer, as expressed recently in the scientific literature and in the media,
19 are inconsistent with the current data.” *See Amy G. Egan et al., Pancreatic Safety*
20 *of Incretin-Based Drugs—FDA and EMA Assessment*, 370; 9 N Engl J Med 794,
21 796 (2014) (attached as Ex. E to the Ray Declaration, attached to Amylin and
22 Lilly’s Motion). Publication of partial safety information creates an atmosphere in
23 which patients can become frightened off their medications and which interferes
24 with the doctor-patient relationship. *Cf. Judyth Pendell, The Adverse Side Effects of*
25 *Pharmaceutical Litigation*, AEI-Brookings Joint Center For Regulatory Studies
26 (2003) (reporting physicians’ refusal to prescribe and patients’ refusal to take
27 appropriately prescribed medications after learning medications were subject to
28 product liability litigation) (attached as Ex. F to the Ray Declaration, attached to

1 Amylin and Lilly’s Motion). Disclosure of the Confidential Documents, which
2 contain internal materials that discuss incomplete, preliminary safety evaluations,
3 would prejudice NNI and harm patients by raising undue alarm about a potential
4 safety issue that FDA has recently discredited.⁹

5 Third, the Confidential Documents and discussion of same in the Expert
6 Report do not present the full safety review and analysis that NNI undertook to
7 assess the pancreatic safety of Victoza®. The Confidential Documents and
8 discussion of same in the Expert Report would provide selective, distorted
9 information to patients who take Victoza® (and other incretin-based therapies) and
10 their physicians.

11 **III. CONCLUSION**

12 For the foregoing reasons, Plaintiffs’ Expert Report should be stricken from
13 the public docket consistent with Rule 5(d). Alternatively, because NNI has made a
14 particularized showing—sufficient under the “good cause” standard—NNI’s
15 Confidential Documents should remain sealed and, accordingly, discussions of

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22 _____
23 ⁹ As has been described, the FDA and EMA recently and jointly published an
24 article expressing their view that “current knowledge [regarding pancreatitis and
25 pancreatic cancer] is adequately reflected in the product information or labeling” of
26 incretin-based drugs. For its part, FDA’s conclusion was based on an independent,
27 year-long, “comprehensive evaluation” of “multiple streams of data.” Such data
28 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 the Ray Declaration, attached to Amylin and Lilly’s Motion).

1 same within Plaintiffs' Expert Report should remain sealed in the form of the
2 carefully limited proposed redactions shown on the version of the Report attached
3 to Amylin and Lilly's Motion.

4 Dated: January 6, 2015

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