IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: GLUGAGON-LIKE : CIVIL ACTION

PEPTIDE-1 RECEPTOR AGONISTS

(GLP-1 RAS) PRODUCTS

LIABILITY LITIGATION

: MDL No. 3094 : 24-md-3094

THIS DOCUMENT RELATES TO:

HON. KAREN SPENCER MARSTON

ALL ACTIONS/ALL CASES :

CASE MANAGEMENT ORDER NO. 11

QUALIFIED PROTECTIVE ORDER & SEALING PROCESS ORDER

AND NOW, this 12th day of July 2024, having considered the parties' Joint Motion for Entry of Proposed Protective Order and Proposed Order Regarding Filing Documents Under Seal (Doc. No. 167), the Court finds as follows:

- 1. A "party seeking a protective order over discovery material must demonstrate that good cause exists for the order." *In re Avandia Mktg. Sales Practices & Prods. Liab. Litig.*, 924 F.3d 662, 671 (3d Cir. 2019) (quotation marks omitted); *see also Sprinturf, Inc. v. Sw. Recreational Indus., Inc.*, 216 F.R.D. 320, 323 (E.D. Pa. 2003) ("Protective orders stipulated between the parties are not guaranteed judicial approval" and "must still meet the requirements of Rule 26(c), which requires demonstrating the existence of confidential information and good cause as to why such information should not be disclosed.").
- 2. "Good cause means that disclosure will work a clearly defined and serious injury to the party seeking closure," and the injury "must be shown with specificity." *In re Avandia*, 924 F.3d at 671. In determining whether good cause exists, the court considers: (1) whether the disclosure will violate any private interests; (2) whether disclosure of the information will cause a party embarrassment; (3) whether the information is being sought for a legitimate purpose or



for an improper purpose; (4) whether the sharing of information among the litigants will promote fairness and efficiency; (5) whether confidentiality is being sought over information important to public health and safety; (6) whether a party benefitting from the order of confidentiality is a public entity or official; and (7) whether the case involves issues important to the public. *Id.* at 671–72.

3. In their joint motion, the parties seek to protect certain discovery that includes: (1) personal information, including personal health information, and (2) private, proprietary commercial information. (*Id.* at 1.) The Court agrees that public disclosure of this information would harm the privacy interests of the individuals and businesses discussed in the documents. In particular, disclosure of private health information could cause embarrassment to Plaintiffs and non-parties, and disclosure of proprietary business information could cause commercial harm to Defendants. The discovery is relevant to the cases involved in this MDL, and its production will promote fairness and efficiency during consolidated discovery. And to date, no party is a public entity or official. Last, the Court finds that although the cases involved in this MDL, which claim personal injuries arising from a group of widely used medications, are likely important to the public and involve issues of public health and safety, this factor weighs only

¹ Specifically, the parties have indicated that during discovery, discovery is likely to encompass: "(i) non-public financial information; (ii) proprietary development and business plans; (iii) personnel records; (iv) competitive information regarding contractual relationships, (v) protected health information, (vi) information subject to a preexisting confidentiality obligation; (vii) information requested by another party to be kept confidential; and (vii) non-public information submitted to regulatory agencies that otherwise could be subject to a designation as Confidential under this Order." (Doc. No. 167 at 4–5; Doc. No. 167-1 at 7–8.) In addition, it may require discovery of: (i) "highly sensitive information, the disclosure of which to a competitor could result in significant competitive or commercial disadvantage to the designating person," (ii) "highly sensitive documents detaining research and development, projects, profit and loss statements, pricing, revenue, cost, contractual relationships with third parties, product design and manufacturing and/or the identification of suppliers," and (iii) information of a "highly commercially or competitively sensitive nature that in-house counsel for a Receiving Party should not be able to access the materials." (Doc. No. 167 at 5 (quotation marks omitted); Doc. No. 167-1 at 9–10.)

marginally in favor of public disclosure of the private personal, health, and business information that will be exchanged during discovery.

4. Having weighed the public and private interest factors, the Court finds that good cause exists for entering the parties' stipulated confidentiality order. See Landau v. Zong, Civil Action No. 3:15-CV-1327, 2018 WL 1251844, at *1-2 (M.D. Pa. Mar. 12, 2018) (entering qualified protective order to prohibit the parties from disclosing personal health information for any purpose other than the litigation and to require the return or destruction of any such information at the end of the litigation); Grant Heilman Photography, Inc. v. Pearson, Civil Action No. 11-cv-4649, 2012 WL 1521954, at *6 (E.D. Pa. Apr. 30, 2012) (finding that the defendant had "a strong interest in keeping its non-public financial information, sales and marketing projections, and forecasts confidential" and that "disclosure of such information would significantly impair [the defendant's] competitiveness in the market"); Howard v. Rustin, Civil Action No. 06-200, 2007 WL 2811828, at *23 (W.D. Pa. Sept. 24, 2007) (entering a qualified protective order to prohibit the parties from disclosing the protected health information for any purpose other than the litigation and to require the return or destruction of any such information at the end of the litigation); Castle v. Crouse, No. 03-5252, 2004 WL 1151710 at *3 (E.D. Pa. May 24, 2004) ("As to claimants' personal information, such as name, address, . . . and other personal identifying information, no one disputes the strong privacy interest at stake. We agree with both parties that good cause exists at this time to enter a protective order as to this information."); Sprinturf, Inc. v. Sw. Recreational Indus., Inc., 216 F.R.D. 320, 324 (E.D. Pa. 2003) (concluding that the defendants demonstrated the requisite "good cause" to protect "confidential and sensitive" business information, including the defendants' proprietary

information regarding the development of a product line, and explaining that the defendants

showed that the release of such information "could result in competitive disadvantage").

For those reasons, it is **ORDERED** that the motion (Doc. No. 167) is **GRANTED**, and

the parties' proposed Qualified Protective Order which is attached to this Order as Exhibit A is

APPROVED.

IT IS FURTHER ORDERED that the parties proposed Sealing Process Order, which is

attached this Order as Exhibit B, is also APPROVED and shall govern the sealing of documents

in this MDL.

IT IS SO ORDERED.

/s/Karen Spencer Marston

KAREN SPENCER MARSTON, J.

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EXHIBIT A

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: GLUCAGON-LIKE

PEPTIDE-1 RECEPTOR AGONISTS

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ALL ACTIONS/ALL CASES

HON. KAREN SPENCER MARSTON

QUALIFIED PROTECTIVE ORDER

The undersigned counsel for Plaintiffs and Defendants Novo Nordisk A/S, Novo Nordisk North America Operations A/S, Novo Nordisk US Holdings Inc., Novo Nordisk US Commercial Holdings Inc., Novo Nordisk Inc., Novo Nordisk Research Center Seattle, Inc., Novo Nordisk Pharmaceutical Industries LP, and Eli Lilly and Company (collectively "Defendants"), hereinafter referred to collectively as "Parties," and individually as a "Party," in the above-captioned action, agree that the Parties may be required to produce or disclose in this Proceeding information subject to confidentiality limitations on disclosure under applicable law or rule.

Therefore, the Parties hereby stipulate to the following negotiated terms, subject to the Court's approval, and the Court hereby ORDERS that the following procedures shall be followed in the MDL Proceedings (as defined below) to facilitate orderly and efficient discovery while minimizing the potential for unauthorized use of information subject to protection under this order.

1. Scope.

a. This Order governs documents (including electronically stored information ("ESI"), as defined below), the information contained therein, and other Information produced or

Disclosed (as defined below) during this litigation, which includes any related actions that have been or will be originally filed in this Court, transferred to this Court, or removed to this Court and assigned to this Court (collectively, "the MDL Proceedings"). Parties in any current and future product liability cases pending in state court (together with the MDL Proceedings, "the Actions") may avail themselves of discovery conducted in the MDL Proceedings by expressly agreeing to be bound by the terms of this Order and provide an executed Acknowledgement and Agreement, attached here as Exhibit A.

- b. This Protective Order is binding upon all Parties in the Actions, including (as applicable) their respective corporate parents, subsidiaries, and affiliates, including their successors, and their respective attorneys, principals, representatives, directors, officers, employees, and others as set forth in this Protective Order including all signatories to Exhibit "A."
- c. If additional parties are added other than parents, subsidiaries, or affiliates of current parties to the Actions, their ability to receive a Document protected by this Protective Order will be subject to their being bound, by agreement and written notice to all other parties or by Court Order, to this Protective Order.
- d. This Order authorizes the exchange of information protected by HIPAA, as amended by the HITECH Act, including all applicable Privacy and Security Rules. This Order constitutes a Qualified Protective Order, as that term is defined in the Privacy and Security Rules.
- e. Nothing herein shall be construed as an admission or concession by any Party that designated Protected Material constitutes material, relevant, or admissible evidence in this matter.
- f. The Definitions set forth in Paragraph 2 are included to facilitate the production of information in a manner that preserves appropriate protections for Protected

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Material. Nothing in the Definitions shall be interpreted to affect the substantive rights or responsibilities of the Parties.

- 2. **<u>Definitions.</u>** In this Order, the terms set forth below shall have the following meanings:
- a. "Challenging Person or Entity" means a Party or Non-Party that challenges the designation of information or items under this Stipulated Protective Order.
- b. "Competitor" means any company that manufactures, develops, or sells any product with a glucagon-like peptide-1 (GLP-1) receptor agonist or glucose-dependent insulinotropic polypeptide (GIP) receptor agonist intended to treat the same conditions or indications as the products in the Actions (a "Competing Product").
- c. "Counsel" means all members, partners and employees of a law firm of which the attorney or counsel is a member, partner or employee, Outside Counsel of Record and In-House Counsel (as well as their support staff).
- d. "Court" means the Honorable Judge currently assigned to this Action or any other judge to which the Actions may be assigned, including Court staff and persons designated by the judge to assist or participate in such proceedings.
- e. "Designating Person or Entity" means a Party or Non-Party that designates information or items that it produced in disclosures or in responses to discovery as "Confidential," "Highly Confidential Attorney's Eyes Only," or "Highly Confidential Attorney's Eyes Only Outside Counsel Only," pursuant to paragraphs 3 and 4, below. Non-Parties who so elect may avail themselves of, and agree to be bound by, the terms and conditions of this Protective Order and thereby become a potential Designating Person or Entity for the purposes of this Protective Order.

- f. "Document" or "Documents" shall be understood to include ESI and shall be defined as described in the Federal Rule of Civil Procedure 34(a)(1)(A).
- g. "Testimony" means all depositions, declarations, or other pre-trial testimony taken or used in the Actions.
- h. "Information" means the content of Documents or Testimony; or other content exchanged among the Parties, whether orally or in writing; as well as any matter derived from or based on any of the foregoing.
- i. "In-House Counsel" means attorneys who are officers (e.g., General Counsel or equivalent) or employees of a Party. In-House Counsel does not include Outside Counsel, as defined below.
- j. "Outside Counsel" means attorneys who are not employees of a Party, but are retained to represent or advise a Party, or are affiliated with a law firm that has been retained to represent or advise a Party, or contract or temporary attorneys who have been retained, through an agency or directly, by a law firm that has been retained on behalf of a Party.
- k. "Outside Experts or Consultants" means experts or consultants who are not employees of a Party. The term "Outside Experts or Consultants" also includes court-appointed experts and special masters.
 - 1. "Party" means any party to the Actions.
- m. "Producing Person or Entity" means a Party or Non-Party that produces documents or ESI or makes disclosures in the Actions.
- n. "Protected Material" means "Confidential Discovery Material," "Highly Confidential Attorneys' Eyes Only Discovery Material," or "Highly Confidential Attorneys' Eyes Only Outside Counsel Only Discovery Material" as defined in Sections 3 and 4.

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- o. "Receiving Party" shall mean any Party that receives Documents—either directly, or indirectly via counsel—during the course of discovery in the Actions.
- p. "Disclose," "Disclosed," or "Disclosure" means to reveal, divulge, give, or make available Documents, Testimony, Information, or any part of any of the foregoing.
- "Protected Health Information" ("PHI") has the same scope and definition q. as set forth in the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH Act"), including all applicable regulations and guidance issued by the Secretary of the United States Department of Health and Human Services (collectively "HIPAA Rules"), including specifically 42 C.F.R. Part 2, and 45 C.F.R. §§ § 164.506(c)(3), 164.512(e)(1)(ii)(B), 164.512(e)(1)(v), as well as all state laws and regulations regarding the privacy and security of personal information (collectively with the HIPAA Rules, "Privacy and Security Rules") as well as the definitions and guidance set forth in 45 C.F.R. § 160.103 and § 164.501. Without limiting the generality of the foregoing, PHI includes, but is not limited to, health information, including demographic information, relating to: the past, present, or future physical or mental health or condition of an individual; and the provision of health care to an individual, which identifies or reasonably could be expected to identify the individual. PHI includes information that contains the following identifiers of a patient:
 - i. names;
 - ii. all geographic subdivisions smaller than a State, including street address,city, county, precinct, and zip code;
 - iii. all elements of dates (except year) directly related to an individual, including birth date and age;

- iv. telephone numbers;
- v. fax numbers;
- vi. electronic mail addresses;
- vii. social security numbers;
- viii. medical record numbers;
 - ix. health plan beneficiary numbers;
 - x. account numbers;
 - xi. certificate/license numbers;
- xii. vehicle identifiers and serial numbers, including license plate numbers;
- xiii. device identifiers and serial numbers;
- xiv. web universal resource locaters ("URLs");
- xv. internet protocol ("IP") address numbers;
- xvi. biometric identifiers, including finger and voice prints;
- xvii. full face photographic images and any compatible images;
- xviii. any other unique identifying number; characteristic, or code; and
- xix. any other information that the Producing Person or Entity knows could be used alone or in combination with other information to identify an individual who is subject of the information.

3. Confidential Discovery Materials.

a. Any Designating Person or Entity may designate as "Confidential Discovery Materials" all Documents, Testimony, Information, or portions of any of the foregoing that the Designating Person or Entity believes in good faith are subject to protection under Federal Rule of Civil Procedure 26(c)(1) or other applicable law or rule. Confidential Discovery Materials

may include Documents; materials; depositions or other Testimony; Information revealed or exchanged in a discovery response, conferral, or other things; or portions of any of the foregoing; and the Information contained in any of the foregoing or otherwise Disclosed.

- b. Without prejudice to the rights any Party otherwise holds to seek production, object to production, or seek de-designation of any Documents or Information, Confidential Discovery Materials may include, without limitation, Documents or Information that fall within the categories listed below, but any individual Document or Information in these categories can only be designated Confidential Discovery Material to the extent the Designating Party has a good faith belief that it satisfies the definition in 3.a:
 - Non-public financial or commercially sensitive information, such as information concerning the Designating Person or Entity's assets, liabilities, business operations, performance, structure, business practices, business plans, business ventures, financial projections, or financial and business analyses;
 - ii. Proprietary licensing, distribution, marketing, design, development, research, and manufacturing information regarding products and medicines, whether previously or currently marketed or under development, or any information constituting intellectual property or trade secrets (not to include disseminated marketing materials or material that, on its face, was published to the general public).
 - iii. Personnel records, including non-public compensation information about the Designating Person or Entity's employees;

- iv. Competitive information concerning the Designating Person or Entity's contractual relationships;
- v. Protected Health Information (unless identifying information is redacted);
- vi. Information that the Designating Person or Entity is under a preexisting obligation to a third-party to treat as confidential;
- vii. Information that the Designating Person or Entity has in good faith been requested by another Party or non-Party to so designate on the grounds that such other Party or non-Party considers such material to contain information that is confidential or proprietary to such Party or non-Party; and
- viii. Information that otherwise would be subject to designation under this

 Order but that has been submitted to a governmental or regulatory agency,
 provided that the governmental or regulatory submission is exempt from
 public disclosure.
- c. All material, data, and information excerpted from Confidential Discovery Materials are protected to the same extent as the underlying Confidential Discovery Materials, provided that the same are not publicly available or otherwise subject to the exclusions herein.
- d. Specifically excluded from the definition of "Confidential Discovery Material" are any Documents or Information that the Designating Party or Entity has made public at any time.
- e. If counsel for any Party becomes aware that Documents or Information designated as "Confidential Discovery Material" pursuant to this Order have been designated as "not confidential" by order of any court other than the MDL Court, that counsel shall notify counsel

for Plaintiff Leadership and/or Defendants and shall meet and confer regarding the impact of that order on the Documents or Information designated "Confidential Discovery Material" pursuant to this Order.

f. Protected Health Information, as defined in Section 2, including the names of any person or persons reporting adverse experiences of patients and the names of any patients that are not redacted shall be treated as Confidential, regardless of whether the document containing such names is designated as Protected Material.

4. Highly Confidential – Attorneys' Eyes Only Materials.

- a. Any Designating Person or Entity may designate as "Highly Confidential Attorneys' Eyes Only Materials" any Confidential Discovery Materials, as defined above, that the Designating Person or Entity believes in good faith contain highly sensitive information, the disclosure of which to a competitor could result in significant competitive or commercial disadvantage to the Designating Person or Entity. Each Defendant will make good faith efforts to use Highly Confidential Attorney's Eyes Only designations as narrowly as is reasonably necessary to protect its interests under Rule 26(c) or other applicable law or rule.
- b. Without prejudice to the rights any Party otherwise holds to seek production, object to production, or seek de-designation of any Documents or Information, Highly Confidential Attorney's Eyes Only Materials may include, without limitation, highly sensitive Documents detailing research and development, projections related to FDA regulatory approvals, current and future business plans, financial analyses and projections, profit and loss statements, pricing, revenue, cost, contractual relationships with third parties, product design and manufacturing, and/or the identification of suppliers, to the extent such materials satisfy provision 4.a above.

c. Further, and also without prejudice to the rights any Party otherwise holds to seek production, object to production, or seek de-designation, a subset of Highly Confidential – Attorney's Eyes Only Discovery Material may be additionally designated as Highly Confidential – Attorney's Eyes - Outside Counsel Only Discovery Material if the Designating Person or Entity reasonably and in good faith believes it is of such a highly commercially or competitively sensitive nature that persons employed by or working for a Competitor should not be able to access or review the Information. The "Outside Counsel Only" designation and attendant restrictions applies in connection with paragraph 7.b.i.8 and does not otherwise impact or alter the rights, limits, or obligations attendant to Highly Confidential – Attorneys' Eyes Only Materials. Each Defendant will make good faith efforts to use Highly Confidential – Attorney's Eyes - Outside Counsel Only designations as narrowly as is reasonably necessary to protect its interests under Rule 26(c) or other applicable law or rule.

5. <u>Designations of Protected Material.</u>

- a. <u>Designation of Documents.</u> A Designating Person or Entity may designate Documents as Confidential Discovery Material, Highly Confidential Attorneys' Eyes Only Discovery Material, or Highly Confidential Attorneys' Eyes Outside Counsel Only Discovery Material by placing a stamp or marking on the Documents "Confidential," "Highly Confidential Attorneys' Eyes Only," or "Highly Confidential Attorneys' Eyes Outside Counsel Only," respectively. Such markings shall not obscure, alter, or interfere with the legibility of the original document.
 - i. All copies, duplicates, extracts, excerpts (hereinafter referred to collectively as "copies") of Protected Material shall be marked with the

- same confidential stamp or marking as contained on the original, unless the original confidential stamp or marking already appears on the copies.
- ii. If a Document containing Protected Material is produced in native format,
 the Producing Party shall include "Confidential," "Highly Confidential –
 Attorneys' Eyes Only," or "Highly Confidential Attorneys' Eyes –
 Outside Counsel Only" in the file name of the produced Document.
- b. <u>Designation of Deposition Transcripts.</u> During depositions, Protected Material may be used or marked as exhibits, but shall remain subject to this Order and may not be shown or otherwise Disclosed to the witness unless such witness is a Qualified Person as described below, or upon agreement by the Designating Person or Entity, or by Court order.
 - i. If deposition Testimony or exhibits contain or refer to Protected Material, or if they contain or refer to Documents, Testimony, or Information intended in good faith to be designated as Protected Material, the Designating Person or Entity, by and through counsel, shall either:
 - On the record at the deposition, designate the Testimony or exhibit(s) as Protected Material, or
 - 2. No later than thirty (30) days after receiving a final copy of the deposition transcript, inform the deposing counsel and counsel for other Parties that the Testimony or exhibit(s) constitute Protected Material; during the thirty-day period, the entire deposition testimony, transcript, and exhibits shall be treated as Protected Material under this Order.

- 3. Except as otherwise provided in paragraph 9 below, no designation of a deposition transcript or its exhibits at any time shall interfere with or delay the ability of any expert retained by Plaintiffs who has signed Exhibit A to review such transcript or exhibits.
- ii. For thirty (30) days following the Designating Person or Entity's receipt of the final transcript, deposition Testimony that describes or refers to Documents or Information designated as Highly Confidential Attorneys Eyes Only or as Highly Confidential Attorneys Eyes Only Outside Counsel Only shall be treated as either Highly Confidential Attorneys Eyes Only or as Highly Confidential Attorneys Eyes Only Outside Counsel Only under the terms of this Order, in accordance with the designation of the Document(s) or Information described by or referred to in such Testimony.
- iii. If the Designating Person or Entity designates deposition Testimony as Protected Material in accordance with paragraph 5.b.i.1 or 5.b.i.2, such designation shall supersede those described above in paragraph 5.b.ii. For the avoidance of doubt, an order of this Court resolving a Designation Motion or otherwise ruling on the designation of deposition Testimony whose designation was previously controlled by paragraph 5.b.ii. shall govern.
- iv. When a Designating Person or Entity designates testimony as Protected Material during the deposition, counsel for that Designating Person or

Entity may exclude from the deposition all persons who are not Qualified Persons under this Order.

- v. When a Designating Person or Entity seeks to designate portions of a deposition transcript or its exhibits for protection, the Designating Person or Entity is responsible for ensuring that each page of the transcript or exhibit page is marked by the Court Reporter with the legend "Confidential," "Highly Confidential Attorneys' Eyes Only," or Highly Confidential Attorneys Eyes Only Outside Counsel Only.
- c. Written Pleadings, Motion Papers, and Discovery Materials. A Designating Person or Entity may designate as Protected Material portions of interrogatories and interrogatory answers, responses to requests for admission and the requests themselves, requests for production of documents and things and responses to such requests, pleadings, motions, affidavits, and briefs, to the extent that any of the foregoing contain Protected Material. To the extent any Party designates such materials as confidential, that Party shall serve both redacted and unredacted versions of the document, and shall make good faith efforts to use Protected Material designations as narrowly as is reasonably necessary to protect their interests under Rule 26(c).
- d. <u>Designation of Other Protected Material</u>. With respect to Protected Material produced in some form other than as described above, including, without limitation, compact discs or DVDs or other tangible items, the Designating Person or Entity must affix in a prominent place on the exterior of the container or containers in which the Information or item is stored the words "Confidential," "Highly Confidential Attorneys' Eyes Only," or "Highly Confidential Attorneys Eyes Only Outside Counsel Only." If only portions of the Information or item warrant

protection, the Designating Person or Entity, to the extent practicable, shall identify the portions that constitute Protected Material.

e. With respect to Documents or Information produced or Disclosed by a non-party, a Receiving Party may designate the Documents or Information as Protected Material pursuant to this Order, provided that the Documents or Information satisfy the requirements for Protected Material described above. A Party so designating material produced by a non-party shall notify all other Parties within fourteen (14) days of receipt of such Document or Information that the same or portions thereof constitute or contain Protected Material. In order to avoid disruption, and in furtherance of this Court's management of this litigation, transfers to this Court of any motions related to compliance with a FRCP 45 subpoena issued by this Court are encouraged pursuant to FRCP 45(f).

6. Required Treatment of Protected Material.

- a. A Receiving Party may use Protected Material that is Disclosed or produced by another Party or by a Non-Party in these Actions only for prosecuting, defending, or attempting to settle the Actions, including any appeal(s), so long as such use is permitted herein, and for no other purpose. Any Protected Material may be Disclosed only to the categories of persons and under the conditions described in this Order unless the Court orders otherwise.
- b. Except as specifically provided in this Order, the Parties and their counsel shall keep all Protected Material Disclosed or produced to them within their exclusive possession and control, shall take all necessary and prudent measures to maintain the confidentiality of such materials and information, and shall not permit unauthorized dissemination of such materials to anyone.

- c. Nothing in this Order shall preclude a Party from introducing into evidence at an evidentiary hearing, in connection with a motion, at trial, or in another proceeding in these Actions, any Protected Material that is admissible under applicable law. The Parties shall meet and confer regarding the procedures for use of Protected Material in connection with an evidentiary hearing, a motion, or trial, unless otherwise agreed, and may move the Court for entry of an appropriate order.
- d. To the extent any Party anticipates a dispute about the use of Protected Material at trial, the Parties shall meet and confer in good faith within the time allotted for filing objections to the other Parties' exhibit lists, unless another time period is agreed upon and ordered by the Court, regarding that dispute, including the need, if any, for procedures for limiting access to trial testimony and sealing exhibits and portions of transcripts.
- e. Access to and disclosure of Protected Material shall be limited to those persons designated as Qualified Persons, below.
- f. Protected Material shall not be used for any business, competitive, or any purpose other than preparing for or litigating the Actions without the express written consent of counsel for the Designating Person or Entity or by order of the Court.
 - i. Nothing in this Protective Order shall limit any Designating Person or Entity's use of its own documents or shall prevent any Designating Person or Entity from disclosing its own Protected Material to any person for any purpose. Documents that have been made public by the Designating Person or Entity automatically lose their status as Protected Material. Any Party may move to de-designate Documents or Information designated as Protected Material that are responsive, or contextual to Documents

- marked as Protected Material, that have been made public by the Designating Person or Entity.
- ii. Disclosures described in the above sub-paragraphs shall not affect any Protected Material designation made pursuant to the terms of this Protective Order so long as the disclosure is made in a manner that is reasonably calculated to maintain the confidentiality of the designated Information, Testimony, and/or Document.
- g. To avoid security risks inherent in certain current technologies and to facilitate compliance with the terms of this Order, and unless otherwise ordered by the Court or agreed upon in writing by the Designating Person or Entity whose Protected Material is at issue, all Qualified Persons with access to Protected Material shall comply with the following as expressly limited by paragraph 6. g.(iii) below:
 - i. Undertaking reasonable and necessary efforts to secure the confidentiality of Protected Material by implementing industry standard best practices for data security. By way of example, such efforts include:
 - 1. Transmitting Protected Material through secure means.
 - 2. Storing Protected Material in secure locations that apply standard industry practices regarding data security, including but not limited to application of access control rights to those persons authorized to access Protected Material under this Order or with a reputable service provider that takes reasonable and necessary steps to ensure that the storage is secure, including use of a secure hosting facility that uses

- encrypted web-enabled software that allows for secure and protected sharing and collaboration and may not be accessed by individuals who are not authorized to review Protected Material.
- 3. No Protected Material, including excerpts from Protected Material, may be inputted into any public internet search engine or into any public, non-compartmentalized generative artificial intelligence system (e.g. ChatGPT, Google Bard, etc.).
- ii. If the Receiving Party discovers a breach of security relating to the Protected Material of a Producing Person or Entity, the Receiving Party shall: (1) provide written notice to the Producing Person or Entity of the breach within five (5) days of the Receiving Party's discovery of the breach; (2) take reasonable efforts to investigate, respond to, and stop or reverse the breach; (3) provide the Producing Person or Entity with assurance reasonably satisfactory to the Receiving Party that the breach shall not recur; (4) provide sufficient information about the breach that the Producing Person or Entity can ascertain the size, scope, and impact of the breach; and (5) reasonably cooperate with the Producing Person or Entity and law enforcement in investigating and responding to any such security incident.
- iii. Notwithstanding the foregoing provisions, Qualified Persons, as defined in the following paragraph, shall not be prohibited from transmitting

Protected Material to any other Qualified person through electronic mail, as attachments to an electronic mail in the form of separate PDF files or zip files, through secure tools provided by a reputable service provider as described herein, or via FTP file transfer, provided that Qualified Persons undertake reasonable and necessary efforts to secure the confidentiality of Protected Material.

- 7. **Qualified Persons with Respect to Protected Material**. Protected Material may be disclosed only to the following persons (referred to as "Qualified Persons" throughout this Order):
 - a. <u>Disclosure of "Confidential" Information or Items.</u>
 - i. Unless otherwise ordered by the Court or permitted in writing by the Designating Person or Entity, a Receiving Party may Disclose any Information or item designated "Confidential" only to:
 - the Receiving Party's Outside Counsel of Record in this
 Action, as well as employees of said Outside Counsel of
 Record to whom it is reasonably necessary to disclose the
 information for this litigation;
 - 2. notwithstanding Section 8 of this order, the officers, directors, and employees (including In-House Counsel) of the Receiving Party to whom disclosure is reasonably necessary for this litigation and who have signed the "Acknowledgment and Agreement to Be Bound" (Exhibit A);

- 3. Outside Experts and Consultants and their staff retained to assist the Parties in the conduct of these Actions, subject to the provisions of Section 9 and so long as the Outside Experts or Consultants have signed an Exhibit A;
- 4. the Court and its personnel;
- 5. persons or entities that provide litigation support services retained by a Party or a Party's outside counsel including but not limited to court reporters and their staff, professional jury or trial consultants, and vendors, as well as their employees and subcontractors, to whom disclosure is reasonably necessary for this litigation and who have signed a copy of Exhibit A;
- 6. any mediator, arbitrator, or neutral engaged by the Parties or authorized by the Court for purposes of mediation, arbitration, or other dispute resolution and who have signed Exhibit A;
- 7. during their depositions or trial testimony (subject to the trial provision set forth in Paragraph 6(d)), witnesses in the Actions to whom disclosure is made in good faith, provided that the deponent or witness has signed or signs Exhibit A. Pages of transcribed deposition testimony or exhibits to depositions designated as Protected Material must be

- separately bound by the court reporter and may not be Disclosed to anyone except as permitted under this Order;
- 8. A plaintiff's current or former healthcare provider, or a Defendant's current or former employee, to whom disclosure is reasonably necessary at a deposition provided that: (1) the witness has been asked to sign Exhibit A; (2) the witness has agreed on the record (or absent agreement, has been admonished on the record) to maintain the confidentiality of any Protected Material intended to be used at the deposition; (2) no copies of the Protected Material shall be left in the possession of the witness; and (3) copies of that Protected Material shall not be attached to or included with any original or copy of the transcript of that deposition provided to the witness. Counsel present at the deposition should make a good faith effort to obtain the witness's agreement on the record to maintaining confidentiality and no counsel shall make efforts to dissuade the witness from agreeing on the record to maintaining the confidentiality of any such Documents. Regardless of whether any deponent signs Exhibit A, this Order will apply to any deponent who is shown or examined about Protected Material and the deponent cannot take any exhibits with them nor can he/she

- reveal any Information they learned from the Protected

 Material shown to them; and
- 9. the author or recipient of a document containing the Information.
- ii. Any current employee of a Designating Person or Entity may be examined at trial or upon deposition concerning any Information designated "Confidential" by such Designating Person or Entity.
- iii. The Parties shall meet and confer regarding the disclosure of Protected Material to any deponent or witness who does not fall within subsections 7(a)(i)(1) through 7(a)(9) above.
- b. <u>Disclosure of "Highly Confidential Attorneys' Eyes Only" Information or Documents.</u>
 - i. Unless otherwise ordered by the Court or permitted in writing by the Designating Person or Entity, a Receiving Party may disclose any Information or item designated "Highly Confidential – Attorneys' Eyes Only" only to:
 - A Receiving Party's Outside Counsel of Record in this
 Action, as well as employees of said Outside Counsel of
 Record to whom it is reasonably necessary to disclose the
 Information for this litigation;
 - Outside Experts and Consultants and their staff retained to assist the Parties in the conduct of these Actions, subject to

- the provisions of Section 9 and so long as the Outside Experts or Consultants have executed an Exhibit A;
- 3. the Court and its personnel;
- 4. persons or entities that provide litigation support services retained by a Party or a Party's Outside Counsel including but not limited to court reporters and their staff, professional jury or trial consultants, and Professional Vendors, as well as their employees and subcontractors, to whom Disclosure is reasonably necessary for this litigation; and
- 5. during their depositions or trial testimony (subject to the trial provision set forth in Paragraphs 6.c. and 6.d., witnesses in the Action reasonably believed to have authored or received a copy of a Document containing the Information and to whom Disclosure is reasonably necessary for the purposes of the litigation provided that the deponent or witness signs Exhibit A.
- any mediator, arbitrator, or neutral engaged by the Parties or authorized by the Court for purposes of mediation, arbitration, or other dispute resolution and who have signed Exhibit A;
- 7. up to four In-House Counsel at any one time at each

 Defendant designated by each Defendant subject to the

following limitations that each such designated In-House Counsel:

- a. Has as their primary responsibility oversight of the defense or prosecution of litigation matters on behalf of a Defendant;
- b. Has no primary role or primary responsibility for (a)
 any commercial business strategy or commercial
 business decision-making, including but not limited
 to sales, marketing, research and development, and
 intellectual property, or (b) patent prosecution
 matters;
- c. Is identified by name and role by each Defendant to the Designating Person or Entity no less than seven
 (7) days prior to obtaining access to any Highly Confidential Attorneys' Eyes Only designated information to enable the Designating Person or Entity to object to the designation and to permit the Defendant and Designating Person or Entity to meet and confer with respect to the objection;
- d. Will not use any Highly Confidential Attorneys'
 Eyes Only designated Information other than in their role overseeing the defense of prosecution of litigation in these Actions on behalf of a Defendant;

- e. Will not be able to access or review, under any circumstances, any Information that is designated by
 a Designating Person or Entity as Highly
 Confidential Attorneys Eyes Outside Counsel
 Only; and
- f. Will, in the event that the attorney leaves the designated role, relinquish all copies of Highly Confidential Attorneys' Eyes Only information received in connection with these Actions to another designated attorney if the Actions are ongoing such that the attorney leaving the designated role no longer has access to or possession of the information; upon an attorney leaving the designated role, the Party has the opportunity to identify another attorney to take that designated role, provided that attorney meets the criteria referenced herein.
- ii. Pages of transcribed deposition testimony or exhibits to depositions that are designated as Protected Material must be separately bound by the court reporter and may not be Disclosed to anyone except as permitted under this Order.
- iii. Any current employee of a Designating Person or Entity may be examined at trial or upon deposition concerning any Information designated "Highly

Confidential – Attorneys' Eyes Only" by such Designating Person or Entity.

8. <u>Filing of Confidential and/or Highly Confidential Information</u>. To the extent a Party wishes or is required to file Protected Material with the Court, the Party shall proceed according to the terms of the agreed Sealing Order or as otherwise ordered by the Court.

9. Non-Disclosure to Competitors.

- a. Except as permitted in Section 7(b)(i)(7), without express written consent or Court order, in no event shall any Disclosure of a Defendant's Highly Confidential Attorney's Eyes Only information or Highly Confidential Attorney's Eyes Only Outside Counsel Only information be made to any person who, upon reasonable and good faith inquiry, could be determined to be: (1) a current employee of a Competitor; or (2) a former employee, or current or former contractor or consultant of a Competitor for any period of time within the six (6) months prior to the formation of the MDL whose work relates to the same subject matter as the Actions. Regarding current or former contractors and consultants of a Competitor, disclosure may be made to those contractors and consultants who merely provide lectures or presentations to the public (such as speaker programs or grand rounds) so long as the contractor or consultant does not also participate in the design, development, or manufacturing of Competing Products for that Competitor.
- b. To the extent that any expert or consultant engaged by a Receiving Party or appointed by the Court seeks to become an employee of, or advisor to, a Competitor, that expert or consultant shall take appropriate precautions to

- ensure that no Protected Material influences the work of that expert or consultant, and that no Protected Material is disclosed to that Competitor or its employees.
- c. If, within two (2) years of the time at which they last reviewed the Defendants'

 Protected Material, any expert or consultant engaged by a Receiving Party or
 appointed by the Court seeks to become an employee of, or advisor to, a

 Competitor, the expert or consultant shall disclose such intent to such

 Defendant no later than fourteen (14) days prior to taking such a position.
- d. Any expert or consultant engaged by a Receiving Party for purposes of advising on or litigating these Actions or appointed by the Court, to whom a Defendant's Protected Material is Disclosed, shall—in addition to signing Exhibit A—further confirm in writing that they understand and acknowledge that they are such an expert or consultant for purposes of this paragraph, which shall be provided to the Defendant upon request.
- e. No expert or consultant engaged by a Receiving Party for purposes of advising on or litigating these Actions or appointed by the Court, to whom a Defendant's Protected Material is disclosed, may disclose such Protected Material to a Competitor of that Defendant or in a matter inconsistent with any applicable Protective Orders in these Actions.

10. Challenges to Designations.

a. **Burden.** The Designating Person or Entity bears the burden of establishing confidentiality.

- b. **Waiver.** Apart from Section 6.f.i, nothing in this Order shall constitute a waiver of any Party's right to object to the designation or non-designation of Documents, Testimony, or Information as Protected Material.
- c. Challenges. If a Party contends that any Document, Testimony, or Information has been erroneously or improperly designated as Protected Material, or has been improperly redacted, the material at issue shall be treated as Protected Material under the terms of this Order until:
 - i. The Parties reach a written agreement, or
 - ii. This Court issues an order determining that the material is not confidential and shall not be given confidential treatment.

If counsel for a Receiving Party objects to a designation of Protected Material, said counsel shall advise counsel for the Designating Person or Entity, in writing, of such objections, and identify the specific Protected Material (by Bates number, if possible) to which each objection pertains (the "Designation Objections").

d. **Meet and Confer.** Upon receipt of written Designation Objections, Counsel for the Designating Person or Entity shall have fifteen (15) days to meet and confer in good faith and respond in writing as to whether the designations will be maintained or withdrawn. Before the expiration of the period of fifteen (15) days, the Designating Person or Entity shall provide the basis for the confidential treatment of the challenged material. During that period of fifteen (15) days, the Receiving Party that issued those Designation Objections shall not issue any additional Designation Objections to the same Designating Person or Entity that would cause the total number of pending Designation Objections to exceed 100.

e. **Judicial Intervention.** If the Receiving Party and the Designating Person or Entity are unable to resolve the dispute regarding the Designation Objections, the Party challenging the designation may file a motion with the Court seeking an order to de-designate (i.e., to rule to be not confidential) the Protected Material subject to the Designation Objection (the "Designation Motion"). Until the Court rules on the Designation Objections, all parties shall continue to treat the materials as Confidential Information and/or Highly Confidential – Attorneys' Eyes Only Information under the terms of this Order. A person or entity not a Party in this Proceeding may also challenge a designation at any time by way of the same procedure set forth in this paragraph.

11. Redactions.

- a. To protect against unauthorized Disclosure of Protected Material, and to comply with all applicable state and federal laws and regulations, the Producing Party may redact from produced documents, materials and other things, the following items:
 - i. The names, street addresses, Social Security numbers, tax identification numbers, and other personal identifying information of patients and other individuals in clinical studies or adverse event reports, only to the extent the Producing Party has a good faith belief that the redaction is required by applicable privacy laws. For the avoidance of doubt, a Producing Party shall not redact under this sub-provision medical conditions, names of doctors, or broader geographic information such as state or province.
 - ii. The Social Security numbers, tax identification numbers, and other personal identifying information of non-parties in any records only to the

- extent required by applicable privacy laws. For the avoidance of doubt, Defendants shall not redact employee names.
- iii. To the extent a Producing Party intends to redact personal identifying or other information on the basis of a law or rule other than U.S. healthcare privacy laws, the Producing Party shall confer with Requesting Party regarding the basis for the good faith belief that the redaction is required by applicable law. If the Parties are unable to agree as to the applicability of the law to the production, the Producing Party shall file an appropriate motion for a protective order addressing the applicability of the law with the Court and not be required to produce any affected documents until after the Court rules on the dispute.
- b. If a Designating Person or Entity seeks to redact information on the grounds that the information is (1) competitively sensitive Protected Material, and (2) relates solely to products that are not: (a) intended to treat diabetes or obesity; or (b) intended to treat side effects attributed to the diabetes or obesity products at issue in this litigation, the Designating Person or Entity shall provide notice in writing to each Receiving Party identifying the nature of the information that the Designating Person or Entity seeks to redact. Defendants shall apply redactions pursuant to this paragraph, if any, to the narrowest extent possible necessary to protect their privacy interests, and in such a way that the nature of the information redacted is apparent on the face of the document. If the Designating Person or Entity and the Receiving Party cannot reach agreement regarding whether proposed categories of redactions meet criteria (1) and (2) above, they will submit the dispute to the Court. For the avoidance of doubt, absent any separate express

written agreement among the Parties or order of the Court, Defendants may not redact material on the basis of relevance or scope objections.

- c. If a Producing Party redacts information under this section, the reason for any such redaction (e.g., "Redacted PII") shall be included in the redaction box on the face of the produced documents, materials, and other things.
- d. Notwithstanding any of the foregoing provisions, nothing contained herein shall be construed as a waiver of a Party's ability to challenge such redactions pursuant to the procedures set forth in Section 10 herein. The burden as to the propriety of any redaction remains on the Designating Person or Entity at all times.

12. Subpoena by Other Courts or by Agencies

- a. If another court or an administrative agency requests, subpoenas, or orders the disclosure of Protected Material from a Party that has obtained such material under the terms of this Order, the Party so requested, subpoenaed, or ordered shall notify the Designating Person or Entity by electronic mail transmission, express mail, or overnight delivery to counsel of record for the Designating Person or Entity not later than ten (10) days prior to producing or disclosing any Protected Material, and shall furnish such counsel with a copy of the requests, subpoena, or order. The recipient of the Subpoena shall not disclose any Protected Material pursuant to the Subpoena prior to the date specified for production of the Subpoena.
- b. Upon receipt of this notice, the Designating Person or Entity may, in its sole discretion and at its own cost, move to quash or limit the request, subpoena, or order, otherwise oppose the Disclosure of the Protected Material, or seek to obtain confidential treatment of such Protected Material, to the fullest extent available under law, by the person or entity issuing the request, subpoena, or order.

13. Disposition of Protected Material.

- a. Within ninety (90) calendar days of a request by the Designating Person or Entity and after the final disposition of any of the Actions (including without limitation any appeals and after the time for filing all appellate proceedings has passed), each Receiving Party in such Action, including its employees, attorneys, consultants, and experts, must use good faith efforts to destroy all Protected Material with respect to that Action or otherwise shall comply with an applicable order of the Court, subject to the exception described herein.
- b. The destruction of Protected Material under this paragraph shall include, without limitation, originals, copies, duplicates, abstracts, compilations, summaries, and any other format reproducing or capturing any of the Protected Material. Nothing in this provision limits a Receiving Party from maintaining their work product.
- c. Upon request of the Producing Party, the Receiving Party must submit a written certification to the Producing Party (and, if not the same person or entity, to the Designating Person or Entity) within 90 days of such request that (1) states that good faith efforts have been made to assure that all Protected Material has been destroyed, and (2) affirms that the Receiving Party has not retained any originals, copies, duplicates, abstracts, compilations, summaries, or any other format reproducing or capturing any of the Protected Material.
- d. As an exception to the above requirements, and unless otherwise ordered by the Court, Outside Counsel may retain: (a) copies of pleadings or other papers that have filed with the Court and that are Protected Material or that reflect, reference, or contain Protected Material; (b) their work product; and (c) transcripts and exhibits thereto. The terms and provisions of this Order shall continue to apply to any such materials retained by counsel.

14. Order Survives Termination of Action. After the termination of any of the Actions by entry of a final judgment or order of dismissal, the provision of this Order shall continue to be binding. This Order is, and shall be deemed to be, an enforceable agreement between the Parties, their agents, and their attorneys. The Parties agree that the terms of this Order shall be interpreted and enforced by this Court.

15. Production or Disclosure of Confidential Material.

- a. Except as discussed in Section 6.f.i *supra*, inadvertent disclosure, without the required confidentiality designation, of any Document, Testimony, or Information that constitutes Protected Material shall not be deemed a waiver in whole or in part of the Producing Party's claim of confidentiality, either as to specific documents and information disclosed or as to the same or related subject matter. In the event that a Designating Person or Entity makes such a production, that Party shall inform the receiving Party or Parties in writing of the production and the specific material at issue promptly after its discovery and shall promptly reproduce the Protected Material with the required legend. Challenges to such designations shall proceed in the same manner as in paragraph 10 above.
- 16. <u>Contact with Physicians</u>. The following paragraph will govern the parties' interactions with an MDL Plaintiff's prescribing and treating physicians. An "MDL Plaintiff's prescribing or treating physician" is a physician who has provided medical care to one or more patients who have filed a lawsuit (or whose representative has filed a lawsuit) pending in this Proceeding.
- a. Plaintiffs' counsel may engage in *ex parte* communications with any MDL Plaintiff's prescribing or treating physician.

- b. Defendants' counsel will not knowingly engage in ex parte communications with any MDL Plaintiff's prescribing or treating physician. Defendants' counsel shall not retain physician-experts who are identified in Plaintiff Fact Sheets or otherwise as an MDL Plaintiff's prescribing or treating physicians at the time of their retention. If a Defendant's counsel becomes aware that one of their retained physician-experts is also an MDL Plaintiff's prescribing or treating physician, that Defendant shall provide notice to Plaintiffs' counsel within twenty-one (21) days. That notice shall include the Plaintiff's name and a statement that Defendant's retention of the physician-expert occurred before the Defendant became aware of his or her status as an MDL Plaintiff's prescribing or treating physician. Having timely provided such notice, Defendants may continue to use such a physician as a consulting or testifying expert in these Actions generally or in an individual plaintiff's case in these Actions where the physician-expert is not that plaintiff's prescribing or treating physician; in such circumstances, Defendants may continue to have ex parte communications with that physician-expert notwithstanding the other provisions of this paragraph. However, Defendants shall not use a physician as a consulting or testifying expert in an individual case in these Actions where that physician's present or former patient is a Plaintiff. Plaintiffs reserve the right to oppose Defendants' selection of any Plaintiff as a Bellwether on the basis that the Plaintiff's physician is a Defendant's expert.
- 17. <u>Modification or Action by the Court</u>. The Court retains the right to allow, *sua sponte* or upon motion, Disclosure of any subject covered by this Protective Order or to modify this Protective Order at any time in the interest of justice.

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: GLUCAGON-LIKE

PEPTIDE-1 RECEPTOR AGONISTS

(GLP-1 RAS) PRODUCTS

LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

MDL No. 3094
24-md-3094

ALL ACTIONS/ALL CASES

QUALIFIED PROTECTIVE ORDER: EXHIBIT A

ENDORSEMENT OF PROTECTIVE ORDER

I,	, hereby attest to my understanding that
information or documents designa	ted as Protected Material are provided to me subject to the
Protective Order dated	, 2024 (the "Order"), in the above-captioned
litigation ("Litigation"); that I hav	e been given a copy of and have read the Order; and, that I
agree to be bound by its terms.	I also understand that my execution of this Endorsement of
Protective Order, indicating my as	greement to be bound by the Order, is a pre-requisite to
my review of any information or	r documents designated as Protected Material pursuant to the
Order.	

I further agree that I shall not disclose to others, except in accord with the Order, any Protected Material, in any form whatsoever, and that such Protected Material may be used only for the purposes authorized by the Order.

I further agree to return all copies of any Protected Material or any document or thing containing Protected Material I have received to counsel who provided them to me, or to destroy

such materials, upon completion of the purpose for which they were provided and no later than the conclusion of this Litigation.

I further agree and attest to my understanding that my obligation to honor the confidentiality of such Protected Material will continue even after this Litigation concludes.

I further agree and attest to my understanding that, if I fail to abide by the terms of the Order, I may be subject to sanctions, including contempt of court, for such failure. I agree to be subject to the jurisdiction of the Eastern District of Pennsylvania for the purposes of any proceedings relating to enforcement of this Order. I further agree to be bound by and to comply with the terms of the order as soon as I sign this Agreement, regardless of whether the Order has been entered by the Court.

Date: _	 		
By:			

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: GLUCAGON-LIKE

PEPTIDE-1 RECEPTOR AGONISTS

(GLP-1 RAS) PRODUCTS LIABILITY LITIGATION **CIVIL ACTION**

MDL No. 3094

THIS DOCUMENT RELATES TO: 24-md-3094

ALL ACTIONS/ALL CASES

HON. KAREN SPENCER MARSTON

:

SEALING PROCESS ORDER

Counsel for Plaintiffs and Defendants Novo Nordisk A/S, Novo Nordisk North America Operations A/S, Novo Nordisk US Holdings Inc., Novo Nordisk US Commercial Holdings Inc., Novo Nordisk Inc., Novo Nordisk Research Center Seattle, Inc., Novo Nordisk Pharmaceutical Industries LP, and Eli Lilly and Company (collectively "Defendants"), hereinafter referred to collectively as the "Parties," and individually as a "Party," in the above-captioned action, have agreed that the Court may enter the following Order regarding filing documents under seal.

1. The Parties seek a process for filing documents under seal in this MDL litigation due to the anticipated disclosure of protected health information and other protected personal identifiable information, and Defendants' trade secrets regarding pharmaceutical products and products under development, as well as highly confidential and competitively sensitive business information. Public disclosure of this information can result in substantial harm to the individual plaintiffs, other persons, to the defendants, and to the defendants' shareholders. Recognizing that the public generally has a right of access to the Court's files, however, Parties seeking to seal any documents or portions of documents in the Court's public records from disclosure must satisfy the

requirements of this stipulated Order and must explore all reasonable alternatives to filing documents under seal, minimize the number of documents filed under seal, and avoid wherever possible sealing entire documents (and instead must redact the truly sensitive information in a document).

- 2. Because documents designated as "Confidential Discovery Material," "Highly Confidential - Attorneys' Eyes Only Discovery Material," or "Highly Confidential - Attorneys' Eyes Only – Outside Counsel Only Discovery Material" pursuant to the Protective Order regarding confidentiality entered in this case (hereafter "Protected Material") may be submitted to the Court, and the filing Party (which may not be the Party that designated the documents as Protected Material (hereafter "Designating Party")) or any other Party may disagree with respect to whether sealing the document (or portions of the document) is appropriate, the filing Party shall initially file all Protected Material conditionally under seal and shall indicate to the Court that the conditionally under-seal filing is made pursuant to the determination that the filing contains Protected Material pursuant to the Protective Order or excerpts therefrom. The caption of documents thus filed conditionally under seal shall include the following language: "Filed Conditionally Under Seal Pursuant to Order Re: Filing Documents Under Seal [ECF]." If, however, the filing Party is the Designating Party, and it determines that material or documents that it previously designated as Protected Material do not require or qualify for sealing, it may file the documents without doing so conditionally under seal.
- 3. Within seven days of the conditional filing under seal, the Designating Party and any Parties opposing sealing of the documents shall meet and confer (including by writing where appropriate) in a good faith effort to narrow or eliminate the materials or information subject to the conditional sealing. Within 14 days of the conditional filing, the Designating Party may file a

motion to seal not to exceed 10 pages of double-spaced 12 point font, identifying the specific materials that should remain under seal, and the basis for the request to seal the materials, and stating whether the motion is opposed. Reference to the Protective Order allowing a Party to designate certain documents as Protected Material is not sufficient to establish that a document, or portions thereof, are sealable. The motion must include a specific statement of the applicable legal standard and the reasons for keeping a document under seal, including an explanation of: (i) the legitimate private or public interests that warrant sealing; (ii) the injury that will result if sealing is denied; and (iii) why a less restrictive alternative to sealing is not sufficient. Additionally, the motion must include evidentiary support from declarations where necessary, and a proposed order that is narrowly tailored to seal only the appropriately sealable material and which lists in table format each document or portion thereof that is sought to be sealed. A party need not file a motion to seal if a federal statute or a prior court order in this litigation, which includes any related actions that have been or will be originally filed in this Court, transferred to this Court, or removed to this Court and assigned to this Court (collectively, "the MDL Proceedings") expressly authorizes the party to file certain documents (or portions of documents) under seal.

- 4. Any Party opposing the sealing may file a response within five days, also limited to 10 pages of double-spaced 12 point font. The documents that are the subject of the motion to seal shall be treated as Protected Material until the Court rules on said motion. If no motion to seal is timely filed, the Court shall direct that the filings be made publicly available.
- 5. Other than filing documents conditionally under seal pursuant to the process set forth above, Parties may file documents under seal only if and to the extent that the Court orders that the documents may be filed under seal. For filing pleadings and briefs under seal pursuant to a prior Court order authorizing the sealing of the filing, the following procedure applies: (1) the

Party shall redact the confidential information from the pleading or brief filed on the public docket; and (2) the Party shall file the unredacted pleading or brief under seal. The unredacted version must include the phrase "FILED UNDER SEAL PURSUANT TO COURT ORDER [ECF #__]" prominently marked on the first page and must highlight the portions that are redacted in the public version of the document (unless the court has granted sealing of the entire document). Where a document filed under seal is a declaration or an exhibit to a document filed electronically, an otherwise blank page reading "EXHIBIT FILED UNDER SEAL" shall replace the exhibit in the document filed on the public docket.

- 6. When the Court grants a motion to seal or otherwise permits a document to remain under seal, the document will remain under seal until further order of the Court. Parties or non-parties may, at any time, file a motion requesting that the Court unseal a document.
- 7. The Court retains the right to allow, *sua sponte* or upon motion, disclosure of any material or subject covered by this stipulated Order or to modify this stipulated Order at any time in the interests of justice.