UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

IN RE: INCRETIN-BASED THERAPIES PRODUCTS LIABILITY LITIGATION	Case No.: 13md2452 AJB (MDD) **ORDER:** **(1) DENYING PLAINTIFFS' OPPOSITION TO NOVO NORDISK INC.'S CLAIM OF ABSOLUTE PRIVILEGE AND REQUEST FOR CLAWBACK;** **(2) DENYING NOVO NORDISK INC.'S CLAIM OF ABSOLUTE PRIVILEGE; AND** **(3) GRANTING REQUEST FOR CLAWBACK** (Doc. No. 1316)

On August 17, 2015, Plaintiffs filed an opposition to Novo Nordisk Inc.'s ("Novo") claim of privilege and request for clawback. (Doc. No. 1316.) The dispute was briefed and a joint hearing was held in Department 322 of the Los Angeles County Superior Court on September 9, 2015, with the parties to the Judicial Council Coordinated Proceedings ("JCCP"). Pursuant to the parties' request, this Court participated in the

hearing telephonically and following a thorough discussion on the record, this Court issued its ruling on Plaintiffs' opposition. For the reasons set forth on the record and herein, the Court finds as follows.

During the course of general causation discovery, Novo inadvertently disclosed a portion of unblinded data from Novo's pending and incomplete "LEADER" cardiovascular clinical trial. Though the parties have characterized the inadvertent disclosure and Novo's request for clawback as a discovery dispute, the more pressing issue becomes the use of the disclosed data in potentially dispositive motions. The relevance and admissibility of the data thus becomes a large factor in the Court's resolution of this dispute.

Upon evaluation of the information at issue, the Court concludes the LEADER data warrants protection under the parties' protective order and pursuant to Federal Rule of Civil Procedure 26(c). While not subject to any particular privilege, the data is proprietary and sensitive. Disclosure of the limited data set at this time would subject Novo and the LEADER study to adverse consequences, and would be inconsistent with FDA guidelines. The relevance of the data is marginal at best as it represents only a portion of a larger and presently unknown data set. Use of the data in isolation and out of context will have minimal evidentiary value which is far outweighed by the prejudice to Novo, the interest of maintaining the integrity of the LEADER study, and the orderly and efficient disposition of the pending issues. Though the data has not been disclosed outside of this litigation to date, the potential for inadvertent disclosure and significant collateral consequences remains.

The LEADER data is therefore excluded from use in the case until further order of the Court upon the completion of the clinical trial and public release of all related data. All parties are ordered to **STRIKE** any reference to the LEADER data in expert reports. Plaintiffs are directed to destroy or return all copies of the LEADER data in their possession or contained in their expert files and submit a declaration verifying such action by October 30, 2015. In reaching this conclusion, the Court aims to reconcile its

duty to adjudicate the parties' claims expeditiously and efficiently with the continually evolving nature of pharmaceutical drug research. Declining to delay discovery and removing the LEADER data from contention of all parties resolves the instant dispute efficiently and protects Novo and the LEADER study from prejudice due to the inadvertent disclosure.

Accordingly, Plaintiffs' opposition to Novo's claim of absolute privilege and request for clawback of the LEADER data is **DENIED**. Novo's claim of absolute privilege is similarly **DENIED**, but finding the LEADER data otherwise protectable under the Court's inherent power to govern discovery and the parties' protective order, Novo's clawback request is **GRANTED**. This order does not limit the use of completed, peer-reviewed and publicly available clinical trial data, such as the "TECOS" study, which does not implicate the concerns addressed above.

IT IS SO ORDERED.

Dated: September 11, 2015

Hon. Anthony J. Battaglia
United States District Judge