

**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
2:24-md-03094-KSM**

THIS DOCUMENT RELATES TO:

HON. KAREN SPENCER MARSTON

ALL ACTIONS / ALL CASES

**NOVO NORDISK'S ROADMAP BRIEF IN SUPPORT OF ITS MOTIONS TO
EXCLUDE PLAINTIFFS' GENERAL CAUSATION EXPERTS
AND FOR SUMMARY JUDGMENT**

INTRODUCTION

This brief provides Novo Nordisk’s “roadmap” to its motions to exclude Plaintiffs’ general causation experts under Rule 702 and for summary judgment. Part I provides an overview of Novo Nordisk’s five exclusion motions, while Part II sets forth Novo Nordisk’s motion for summary judgment based on the adequacy of the FDA-approved product labeling and the lack of admissible expert testimony on general causation.

I. NOVO NORDISK’S MOTIONS TO EXCLUDE

Novo Nordisk is filing five motions to exclude Plaintiffs’ proposed expert testimony relating to general causation. The Court is invited to review the motions in the following order, reflecting their relative impact on the overall litigation:

1. Novo Nordisk’s Motion to Exclude Opinions and Testimony of Dr. Binu John and Dr. Nilesh Lodhia (“Ileus & Intestinal Obstruction Motion”);¹
2. Novo Nordisk’s Motion to Exclude Certain Opinions and Testimony of Dr. David Metz (“Persistent Gastroparesis Motion”);²
3. Novo Nordisk’s & Eli Lilly’s Joint Motion to Exclude Opinions and Testimony of Dr. Gabriel Lang (“Gallbladder Disorders Motion”);³
4. Novo Nordisk’s & Eli Lilly’s Joint Motion to Exclude Opinions and Testimony of Dr. Jeffrey Lansman (“Class Effect Motion”);⁴ and,
5. Novo Nordisk’s & Eli Lilly’s Joint Motion to Exclude Opinions and Testimony of Kevin O’Brien, DVM (“Animal Studies Motion”).⁵

The first three motions seek to exclude Plaintiffs’ core causation opinions—specifically, that GLP-1 RAs generally, and Novo Nordisk’s GLP-1 RAs specifically, are capable of causing (1) ileus or intestinal obstruction; (2) gastroparesis persisting after

¹ Referred to as “Novo-Ileus & IO 702” in the accompany May 19, 2026, Declaration of Lucas Przymusinski (“L.P. Decl.”).

² Referred to as “Novo-Metz 702” in the accompanying L.P. Decl.

³ Referred to as “Novo-Lang 702” in the accompanying L.P. Decl.

⁴ Referred to as “Joint-Lansman 702” in the accompanying L.P. Decl.

⁵ Referred to as “Joint-O’Brien 702” in the accompanying L.P. Decl.

medication washout; and (3) gallbladder disorders, including cholelithiasis and cholecystitis. The latter two motions seek to exclude experts who, although not offering causation opinions, claim without reliable foundation that (1) data regarding one GLP-1 RA can be imputed onto another (Dr. Lansman) and (2) Novo missed “signals” for adverse GI effects in pre-approval animal studies (Dr. O’Brien). Each motion rests on independent, dispositive grounds for exclusion under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and its progeny. A brief summary of the three primary motion is included below:

Ileus & Intestinal Obstruction (Drs. John and Lodhia). Plaintiffs’ general causation case for ileus and intestinal obstruction rests on two gastroenterologists whose opinions reflect a standardless, result-oriented methodology. The scientific evidence is overwhelming: none of the five published meta-analyses of randomized controlled trials has reported an increased risk, and fourteen of sixteen published, peer-reviewed observational studies found no increased risk. Rather than engage with this contrary evidence, both experts cherry-picked around it, discarding consistent clinical trial data in favor of a handful of outliers. *See In re Zolof Prods. Liab. Litig.*, 858 F.3d 787, 796 (3d Cir. 2017). Their opinions should also be excluded because neither expert performed any medication-specific analysis for semaglutide or liraglutide, despite acknowledging that each GLP-1 RA has different pharmacokinetics, pharmacodynamics, and clinical data. *See In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (No. II)*, 341 F. Supp. 3d 213, 288–89 (S.D.N.Y. 2018).

Persistent Gastroparesis (Dr. Metz). Dr. Metz, a retired gastroenterologist and Plaintiffs’ only causation expert on gastroparesis, concedes that “there simply is no reported literature of any kind” investigating “prolonged or permanent gastroparesis injury with these

medications” and “no literature that reports on a potential mechanism for prolonged injury.”⁶ Despite these admissions, he opines that GLP-1 RAs can cause gastroparesis persisting for up to six months after washout—a timeframe he admitted he “arbitrarily came up with”—and that a differential diagnosis could establish causation beyond six months. Both opinions are “connected to existing data only by the *ipse dixit* of the expert,” which Rule 702 does not permit. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997); *see also In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994).

Gallbladder Disorders (Dr. Lang). Plaintiffs’ sole gallbladder causation expert, Dr. Lang, lacks the qualifications to opine on epidemiological causation—he is “not familiar enough” with “risk ratio” and “hazard ratio” “to have an intelligent discussion” about them, and treats association and causation as synonymous. His “weight-of-the-evidence” methodology is an unreproducible black box that exists only “in [his] brain,” with no scoring or systematic weighting. *See In re Zolofit*, 858 F.3d at 796. He ignored the highest-quality evidence—including randomized controlled trials and meta-analyses finding no statistically significant association—while selectively citing favorable data. Dr. Lang admitted he is “not here to discuss individual medicines” and conceded that, limited to medicine-specific data, he could not “reliably conclude that a cause and effect relationship exists” between any individual GLP-1RA and gallbladder disease. *See Joiner*, 522 U.S. at 146.

Novo is not moving to exclude the testimony of Plaintiffs’ regulatory and pharmacovigilance experts (Drs. Eisner, Madigan, Kessler, Keller, and Ross), as those opinions are not directly relevant to general causation or Novo’s adequacy defenses. Nor is

⁶ Novo is not moving to exclude Dr. Metz’s testimony that GLP-1 RAs are capable of causing transient “drug-induced gastroparesis” (also referred to as “drug-induced delayed gastric emptying”) in some patients, as the medicines’ intended mechanism of action includes a well-known and labeled effect on gastric emptying.

Novo moving to exclude Dr. Ma Somsouk, who “was not asked to evaluate causation through a review of all available relevant evidence, but only whether there is an association.” Novo reserves the right to move to exclude these experts at an appropriate time.

II. NOVO’S MOTION FOR SUMMARY JUDGMENT

Novo’s summary judgment motion follows the Rule 702 motions and outlines several independent bases for judgment as a matter of law. Fed. R. Civ. P. 56(a); *see Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986).

First, Novo’s FDA-approved labels have always adequately warned about the risks associated with its GLP-1RA medicines. Under the learned intermediary doctrine, adequacy turns on whether a prescribing physician would “reasonably understand the risks.” *Meridia Prods. Liab. Litig. v. Abbott Lab’ys*, 447 F.3d 861, 867 (6th Cir. 2006). Novo’s labels have always disclosed the risk of delayed gastric emptying and gastrointestinal adverse events that can be severe—the original Ozempic label referenced gastrointestinal adverse events over forty times. The only prescribing physician testifying in this matter, Dr. Suneil Koliwad, opines the labels were always adequate. Plaintiffs offer only Dr. David Kessler, a regulatory expert who disclaimed testifying as a prescribing physician and acknowledged the current labels are “improved” such that “we probably wouldn’t be sitting here.” Plaintiffs’ sole gallbladder labeling expert, Dr. Ross, conceded the Saxenda and Wegovy labels were never inadequate, and that the Ozempic and Rybelsus labels were adequate after March 2022 and June 2022, respectively.

Second, pursuant to the Court’s Issue #1 Order, summary judgment is appropriate in any case where a Plaintiff alleges gastroparesis—whether characterized as drug-induced gastroparesis, delayed gastric emptying, or any other label—without objective evidence of

delayed gastric emptying through a properly performed gastric emptying study. The Court held that “[a]ny Plaintiff claiming to suffer (or have suffered) from gastroparesis[] must show that their diagnosis is based on a properly performed gastric emptying study (scintigraphy, breath test, or WMC).” Dkt. 468 at 2. Plaintiffs’ own experts treat these terms as interchangeable, confirming the underlying condition—and the need for objective verification—is the same regardless of nomenclature.

Third, Plaintiffs lack admissible evidence establishing general causation for virtually all of their injury claims. General causation is a threshold requirement in every jurisdiction, and “without general causation, there can be no specific causation.” *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 881 (10th Cir. 2005). This includes claims alleging ileus or intestinal obstruction, persistent gastroparesis, and gallbladder disorders. *See In re Zolof Prods. Liab. Litig.*, 176 F. Supp. 3d 484, 491 (E.D. Pa. 2016).

CONCLUSION

For the foregoing reasons, and the reasons explained in further detail in each of Novo’s Motions, this Court should exclude Plaintiffs’ experts’ opinions related to general causation and grant Defendants’ Motion for Summary Judgment.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 19, 2026, a true and correct copy of the foregoing Novo Nordisk's Roadmap Brief In Support Of Its Motions To Exclude Plaintiffs' General Causation Experts And For Summary Judgment was electronically filed using the Court's CM/ECF System, which will send notification of such filing to all counsel of record.

/s/ Loren H. Brown _____

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