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

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| **IN RE: GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS (GLP-1 RAs) PRODUCTS LIABILITY LITIGATION** | **CIVIL ACTION**<br><br>**MDL No. 3094**<br>**2:24-md-03094-KSM** |
| **THIS DOCUMENT RELATES TO:**<br><br>***ALL ACTIONS / ALL CASES*** | **HON. KAREN SPENCER MARSTON** |

**NOVO NORDISK'S MOTION FOR SUMMARY JUDGMENT AS TO GENERAL CAUSATION AND ADEQUACY OF LABELING**

For the reasons set forth in the accompanying memorandum of law, Novo Nordisk hereby moves the Court for an order for Motion For Summary Judgment as to General Causation and Adequacy of Labeling.

Dated: May 19, 2026

By: */s/ Loren H. Brown*

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**CERTIFICATE OF SERVICE**

I hereby certify that on May 19, 2026, a true copy of the foregoing Novo Nordisk's Motion for Summary Judgment as to General Causation and Adequacy of Labeling 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*
Loren H. Brown

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**MEMORANDUM OF LAW IN SUPPORT OF NOVO NORDISK'S MOTION FOR SUMMARY JUDGMENT AS TO GENERAL CAUSATION AND ADEQUACY OF LABELING**

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## PRELIMINARY STATEMENT

GLP-1 receptor agonist ("GLP-1 RA") medications mimic naturally occurring GLP-1 hormones to treat diabetes and obesity. They work, in part, by stimulating insulin secretion, inhibiting glucagon release, and delaying gastric emptying. From the day these products went to market over fifteen years ago, it has been well-known that GLP-1 RA use can cause gastrointestinal adverse reactions—sometimes severe—due at least in part to the medication's effect on gastric emptying.[1]

Novo's labels have always been replete with warnings about severe gastrointestinal side effects and the gastric emptying mechanism of action, with these disclosures appearing in at least seven separate sections of each Novo label, including: "Highlights of Prescribing Information," Section 5 "Warnings and Precautions," Section 6 "Adverse Reactions," Section 7 "Drug Interactions," Section 12 "Clinical Pharmacology," Section 17 "Patient Counseling Information," and the "Medication User Guide." Yet Plaintiffs have built an inventory of cases resting on an obviously tortured parsing of these labels, basing their failure-to-warn claims on the absence of specific words (e.g., that an adverse event "can lead to hospitalization") even though any reasonable physician knows that gastrointestinal symptoms like vomiting might result in a trip to the hospital. As Dr. Suneil Koliwad—the only prescribing physician offering an opinion in this matter—testified: there is "widespread understanding that GLP-1 receptor agonists can lead to nausea, vomiting, and that that can be severe enough that it might need management acutely," i.e., in an "emergency room."[2] Labels do not need to use the magic word "severe" or "hospitalization"

[1] Novo's Statement of Undisputed Facts in Support of Motion for Summary Judgment as to General Causation and Adequacy of Labeling ("Statement of Undisputed Facts") at ¶ 2.
[2] Transcript of the April 24, 2026, Deposition of Suneil Koliwad, MD, PhD ("Koliwad Tr.") (L.P. Ex. 41D) at 74:14-18.

for a prescribing physician to understand that nausea, vomiting, and constipation can range from mild to severe—that is foundational medical knowledge.

And Novo's labels *did* warn of severe gastrointestinal reactions and delayed gastric emptying[3]—Plaintiffs simply complain these disclosures were not in the *right* part of the label. Courts routinely reject this type of wordplay. As a result, Plaintiffs' warning-based claims fail. Even if Plaintiffs' failure-to-warn claims could survive the plain language of the labels, certain claims fail for additional reasons—including the absence of reliable expert evidence demonstrating that GLP-1 RA use can cause the specific injury, or the lack of requisite diagnostic testing required by the law of this case.

*First*, Novo's labels have always adequately warned of severe adverse gastrointestinal reactions, delayed gastric emptying, and pancreatitis.[4] The adequacy of a pharmaceutical label "become[s] a question of law where the warning is accurate, clear and unambiguous." *Meridia Prods. Liab. Litig. v. Abbott Labs*, 447 F.3d 861, 867 (6th Cir. 2006) (internal quotation omitted). Under the learned intermediary doctrine, adequacy turns on whether a prescribing physician would "reasonably understand the risks." *Id.* The doctrine exists for a reason: the "intermediary" is already learned. Prescribing physicians do not cast aside their education, training, and clinical experience when they read drug labels—they bring all of that knowledge to bear. Rather than proffer an expert prescriber to explain how these warnings failed, Plaintiffs proffer Dr. David Kessler—a regulatory expert who expressly disclaimed testifying as a prescribing physician.[5] But Dr. Kessler's retrospective legal parsing of the label cannot overcome the clear communication of risks to prescribers, as confirmed by Dr. Koliwad. Plaintiffs will no doubt point to the 2025 FDA

[3] Statement of Undisputed Facts at ¶¶ 4-9.
[4] *Id.*
[5] *Id.* at ¶ 3.

request to add an additional severe GI warning to Novo's labeling as evidence that their claims have merit. But this ignores a critical fact: FDA requested the change to harmonize labeling across the GLP-1 RA class—not because any new data suggested the prior labels were inadequate. Read as a whole, Novo's labels have always accurately, clearly, and unambiguously warned of severe gastrointestinal adverse reactions, delays in gastric emptying, and pancreatitis.[6] Accordingly, claims alleging failure to warn of these risks fail.

*Second*, Plaintiffs do not dispute the adequacy of Novo's labeling for gallbladder disease across multiple medications and time periods. Dr. David Ross, Plaintiffs' sole gallbladder labeling expert, limited his opinions at deposition: he has no opinion that the Saxenda or Wegovy labels were ever inadequate; no opinion that the Ozempic label was inadequate after March 2022; no opinion that the Rybelsus label was inadequate after June 2022; and no opinion that the Victoza label was inadequate after December 2017.[7] Without expert testimony challenging labeling adequacy for these medications and timeframes, Plaintiffs cannot proceed.

*Third*, Plaintiffs do not dispute the adequacy of Novo's labeling after October 2025.[8] Dr. Kessler testified that the labels are "improved" and that had they always been written as they are today, "we probably wouldn't be sitting here."[9] Dr. Ross likewise offers no opinion on labeling inadequacy for any GLP-1 RA as to gallbladder disease after 2022.[10] Where Plaintiffs' own experts decline to challenge the current labels, no failure-to-warn claim based on current labeling can survive. Nor can any Plaintiff recover for failure to warn of an injury already identified in the FDA-approved labeling at the time of prescription. Claims predicated on the inadequacy of Novo's

[6] *Id.* at ¶¶ 4-9.
[7] *Id.* at ¶¶ 15-18.
[8] *Id.* at ¶ 14.
[9] Transcript of the March 31, 2026, Deposition of David A. Kessler ("Kessler Dep. I Tr.") (L.P. Ex. 26D) at 127:11–128:15.
[10] Transcript of the March 9, 2026, Deposition of David B. Ross ("Ross Tr.") (L.P. Ex. 37D) at 211:10-15; 218:12-25; 251:9-15; 259:20-260:6; Statement of Undisputed Facts at ¶¶ 15-18.

current labels, or on an injury that post-dates inclusion of that injury on the label, fail as a matter of law.

*Fourth*, any claim for gastroparesis—whether characterized as drug-induced gastroparesis, delayed gastric emptying, impaired gastric emptying, gastric hypomotility, or any other label Plaintiffs invoke to circumvent the law of the case—cannot proceed absent objective evidence of delayed emptying through a gastric emptying study. This Court's Issue #1 Order *requires* any Plaintiff claiming gastroparesis to have a properly performed gastric emptying study confirming delayed emptying.[11] Claims predicated on delayed gastric emptying require this objective verification regardless of nomenclature.[12] Without it, they fail.

*Fifth*, Plaintiffs lack admissible evidence of general causation for many alleged injuries. General causation—proof that a product is capable of causing a particular injury—is a threshold requirement in every jurisdiction. Plaintiffs have failed to proffer admissible evidence that GLP-1 RAs can cause gastroparesis that persists after the medication has left the body, or that they can cause ileus, intestinal obstruction, or gallbladder disease.[13] Without admissible expert evidence of general causation, these claims fail as a matter of law. Specific-causation experts cannot fill this gap: "without general causation, there can be no specific causation." *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 881 (10th Cir. 2005).

For these reasons, and those set forth in the Motions to Exclude Dr. Metz, Drs. John and Lodhia, and Dr. Lang, Novo is entitled to summary judgment.[14]

[11] Statement of Undisputed Facts at ¶ 22.
[12] *Id.* at ¶ 23.
[13] *Id.* at ¶¶ 19-21.
[14] Depending on the Court's ruling and its practical implications for different categories of individual cases and specific claims, the Court may consider a show-cause process or implement a process via a *Lone Pine* order to identify which cases should proceed and which should be dismissed.

## BACKGROUND

### I. Plaintiffs file suit alleging that Novo's GLP-1 RA medications cause gastrointestinal-related adverse events.

Plaintiffs assert claims against Novo for the marketing and sale of five GLP-1 RA medications: Ozempic, Wegovy, Rybelsus, Saxenda, and Victoza. They allege that Novo failed to provide adequate warnings that these medications can cause gastrointestinal adverse events that can be severe. *See, e.g.*, Dkt. 481, Amended Complaint ("Am. Comp.") at ¶¶ 1, 4. Plaintiffs concede, as they must, that "[g]astrointestinal adverse events are well known side effects of the GLP-1 RA class of drugs." *Id.* at ¶ 43.[15] By way of example, the initial FDA-approved label for Ozempic (December 2017) referenced gastrointestinal adverse events over sixty times, including five references to delayed gastric emptying, seven references to gastrointestinal adverse reactions, eight references to nausea, eleven references to vomiting, four references to constipation, eight references to diarrhea, nineteen references to pancreatitis, and five references to abdominal pain.[16] Similar information is included in the product labeling for Novo's other GLP-1 RAs.[17] Attached as Appendix A to this motion is a chart that details all relevant disclosures about gastrointestinal adverse reactions, delayed gastric emptying, and pancreatitis for the initial FDA-approved labels for Ozempic, Victoza, Saxenda, Rybelsus, and Wegovy.

The original FDA-approved Ozempic label also prominently disclosed the possibility of "severe adverse gastrointestinal reactions" or "severe abdominal pain" in four different places, including under the header "warnings and precautions" in the front "highlights of prescribing information" section.[18] Every FDA-approved label for Novo's GLP-1 RAs also includes a table similar to the one below excerpted from the original Ozempic label with each table detailing the

[15] Statement of Undisputed Facts at ¶ 1.
[16] *See* Novo_GLP_MDL_003521535 ("Dec. 2017 Ozempic Label") (L.P. Ex. 134D).
[17] Statement of Undisputed Facts at ¶ 4.
[18] Dec. 2017 Ozempic Label (L.P. Ex. 134D) at 542, 546, & 563; Statement of Undisputed Facts at ¶ 7.

percentages of patients in clinical trials who experienced adverse gastrointestinal symptoms:[19]

**Table 1. Adverse Reactions in Placebo-Controlled Trials Reported in ≥5% of OZEMPIC-Treated Patients with Type 2 Diabetes Mellitus**

| Adverse Reaction | Placebo (N=262) % | OZEMPIC 0.5 mg (N=260) % | OZEMPIC 1 mg (N=261) % |
|---|---|---|---|
| Nausea | 6.1 | 15.8 | 20.3 |
| Vomiting | 2.3 | 5.0 | 9.2 |
| Diarrhea | 1.9 | 8.5 | 8.8 |
| Abdominal pain | 4.6 | 7.3 | 5.7 |
| Constipation | 1.5 | 5.0 | 3.1 |

The label also explains that the rate of adverse events in the above table was similar in the cardiovascular clinical trials,[20] and that "[m]ore patients receiving OZEMPIC 0.5 mg (3.1%) and OZEMPIC 1 mg (3.8%) discontinued treatment due to gastrointestinal adverse reactions than patients receiving placebo (0.4%)."[21]

Plaintiffs allege that these disclosures were insufficient because they "downplayed the chronic nature, duration and severity of gastrointestinal injuries caused by their GLP-1 RAs." Am. Comp. at ¶ 43. Specifically, Plaintiffs contend that Novo failed to warn about the risk of gastroparesis, a gastrointestinal injury "characterized by upper GI symptoms, such as nausea, vomiting, early satiety, and abdominal pain, and delayed gastric emptying in the absence of a mechanical obstruction." Dkt. 467, August 15, 2025 Memorandum ("Mem. Op.") at 4. Plaintiffs further allege that Novo failed to warn about the risk that GLP-1 RA can cause ileus, intestinal obstruction, gallbladder disease, Wernicke's encephalopathy, pancreatitis, gastroenteritis, severe gastrointestinal adverse events (e.g., cyclical vomiting, esophageal injury, and bowel injury), muscle wasting, aspiration, and vitamin deficiency. *See, e.g.*, Am. Comp. at ¶ 41.

[19] Statement of Undisputed Facts at ¶¶ 8; *see also* Appendix A.
[20] L.P. Ex. 134D, Dec. 2017 Ozempic Label at 548.
[21] *Id.*

## II. The Court requires that plaintiffs claiming gastroparesis must have objective evidence of delayed gastric emptying.

While this case involves multiple drugs and injuries, the Court found "many commonalities," including that "each Plaintiff claims they were prescribed one or more" GLP-1 RA medications "for the treatment of type 2 diabetes and/or chronic weight management and that as a result, they suffered gastrointestinal symptoms and/or injuries." Mem. Op. at 3. And despite the litany of injuries listed, Plaintiffs' counsel "represented that they anticipate the 'vast majority, over 95%' of the cases eventually filed as part of this MDL will allege that the Plaintiff suffered or continues to suffer from gastroparesis." *Id*. at 3, 7.

Accordingly, "the Court found it pertinent to frontload resolution of the parties' debate about when a diagnosis of gastroparesis will be considered reliable, and in particular, whether a diagnosing physician can reliably make such a diagnosis without performing a gastric emptying study." *Id*. at 3. After full briefing and an evidentiary hearing, 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, Aug. 15. 2025 Order at 2.

## III. Defendants file motions to exclude Plaintiffs' proffered expert opinions as to persistent gastroparesis, ileus, intestinal obstruction, and gallbladder disease.

The Court identified two additional cross-cutting issues to be resolved at the preliminary stages of litigation: whether Defendants' warnings are adequate as a matter of law ("Issue #2") and/or whether Defendants' GLP-1 RA medications are capable of causing the alleged gastrointestinal injuries ("Issue #3"). Dkt. 235, Aug. 23, 2024, Case Management Order 18. The parties subsequently agreed, and the Court so ordered, that early discovery and motion practice would proceed simultaneously on label adequacy and general causation. Dkt. 282, Oct. 25, 2024,

Case Management Order 20.[22]

Discovery and expert work on Issues #2 and #3 have proceeded under the Court's amended scheduling orders. *See, e.g.*, Dkt. 610, Feb. 23, 2026 Case Management Order 31. On January 3, 2026, Plaintiffs produced expert reports on general causation: Dr. David Metz opined on gastroparesis, Drs. Binu John and Nilesh Lodhia opined on ileus and intestinal obstruction, and Dr. Gabriel Lang opined on gallbladder disease. Plaintiffs have not yet offered expert testimony as to whether GLP-1 RA can cause Wernicke's encephalopathy, pancreatitis, gastroenteritis, muscle wasting, aspiration, or vitamin deficiency. Relevant to this Motion, that same day, Plaintiffs also produced a report from Dr. David Kessler, a regulatory expert, opining on whether Novo's labels complied with regulatory requirements. On January 8, 2026, Plaintiffs produced a report from Dr. David Ross, addressing the adequacy of gallbladder labeling. Novo concurrently submitted Rule 702 motions to exclude the general causation opinions of Drs. Metz, John, Lodhia, and Lang.[23]

## LEGAL STANDARD

Summary judgment is warranted where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party bears the initial burden of demonstrating the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Once the movant satisfies this burden, the nonmoving party must go beyond the pleadings and "designate specific facts showing that there is a genuine issue for trial." *Id.* at 324 (internal quotation marks omitted). A genuine dispute of fact exists only

[22] Novo explicitly reserves the right to move for summary judgment on case dispositive issues in any individual case that proceeds past this motion for summary judgment.

[23] At this time, Novo is not moving to exclude the expert opinions offered by Plaintiffs' regulatory experts (Dr. Kessler and Dr. Ross) or pharmacovigilance experts (Dr. Keller, Dr. Madigan, Dr. Eisner) because these opinions are not relevant to the central issues on causation and adequacy in Novo's briefing. Novo reserves the right to move to exclude these experts at the appropriate time.

if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Id.* at 249–50 (internal citations omitted); *see also Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986) (the nonmoving party "must do more than simply show that there is some metaphysical doubt as to the material facts"); *Anderson*, 477 U.S. at 247–48 ("the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact") (emphasis in original).

## ARGUMENT

### I. The FDA-approved product labeling for Novo's GLP-1 RA medicines provide adequate warning that users can experience severe adverse gastrointestinal reactions, delayed gastric emptying, and pancreatitis.

Adequacy is an essential element of any failure-to-warn claim. *See, e.g.*, *In re Fosamax (Alendronate Sodium) Prod. Liab. Litig.*, 2014 WL 2738224, at *8 (D. N.J. 2014); *Salvio v. Amgen Inc.*, 2012 WL 517446, at *4–6 (W.D. Pa. 2012).[24] Adequacy may be determined as a matter of law, including by a court overseeing an MDL. *See, e.g.*, *Meridia Prods. Liab. Litig.*, 447 F.3d at 867 (affirming district court's order in MDL that found drug adequately warned of risk of high blood pressure as a matter of law); *In re Chantix (Varenicline) Prods. Liab. Litig.*, 881 F. Supp. 2d 1333, 1343 (N.D. Ala. 2012) (holding in an MDL that a drug label adequately warned of risk of neuropsychiatric injuries as a matter of law).

As set forth above, label adequacy "become[s] a question of law where the warning is

[24] Novo moves for a finding of adequacy as a matter of law on severe adverse gastrointestinal reactions, delayed gastric emptying, and pancreatitis across all FDA-approved labeling. Novo reserves the right to challenge individual Plaintiffs' failure to warn claims—regardless of the injury alleged—based on later produced expert testimony, the testimony of the Plaintiffs' prescribing physician and particulars of state law that applies to those claims at the appropriate time (if necessary).

accurate, clear and unambiguous," and under the learned intermediary doctrine, adequacy turns on whether a prescribing physician would "***reasonably understand the risks***." *Meridia*, 447 F.3d at 867 (emphasis added) (internal quotation omitted); *see also id.* (noting that at least 45 of the 50 states apply the learned intermediary doctrine). Although "a meticulous examination and parsing of individual sentences in the insert may arguably reveal differing nuances in meaning or variations in emphasis as to the seriousness of a side effect, any resulting vagueness may be overcome if, when read as a whole, the warning conveys a meaning as to the consequences that is unmistakable." *McDowell v. Eli Lilly and Co.*, 58 F. Supp. 3d 391, 403 (S.D.N.Y. 2014) (internal quotation omitted).

For example, in *Ideus v. Teva Pharms. USA, Inc.*, the plaintiff alleged that the manufacturer failed to adequately warn of the risk that small pieces, as opposed to the whole, of the product at issue, an IUD, could separate and embed in the uterus, and break when removed. 361 F. Supp. 3d 938, 941 (D. Neb. 2019). Applying the learned intermediary doctrine, the question for the Court was whether the warning was adequate to the medical community, such that no reasonable prescriber would fail to appreciate the risks conveyed. *See id.* at 946. The Court analyzed the FDA-approved package insert, finding that it expressly warned about the possibility of breakage, embedment, and removal difficulty, and that a prescribing physician would be aware that the separated pieces could embed in the uterus. *Id.* The Court also considered testimony from the manufacturer's experts that "in the medical community, that warning is clearly adequate." *Id.* at 946-47; *see also Scelta v. Boehringer Ingelheim Pharms., Inc.*, 404 Fed. App'x. 92, 94 (8th Cir. 2010) (in the prescription drug arena, expert medical testimony is needed to determine whether the drug manufacturer's warning to the medical community is adequate). Based on this evidence, the Court held that there could be no genuine dispute as to the adequacy of the warning. *Ideus*, 361 F. Supp. 3d at 947.

Here, there is no dispute that the FDA-approved product labeling for Novo's GLP-1 RA medications has always included language about severe adverse gastrointestinal reactions, delayed gastric emptying, and pancreatitis.[25] The only question is whether these warnings adequately conveyed to prescribing physicians that users of GLP-1 RAs were at risk for severe gastrointestinal adverse reactions, the possibility of delayed gastric emptying, and pancreatitis. As demonstrated below, Novo's labeling has always conveyed these risks clearly and unambiguously.

**A. Severe adverse gastrointestinal reactions.**

**1. Novo's labeling always disclosed the risk of severe adverse gastrointestinal reactions.**

The FDA-approved product labeling for Novo's GLP-1 RA medicines has always warned that these medicines can cause severe adverse gastrointestinal reactions.[26] A warning is "adequate as a matter of law" where it describes "the risk of the exact injury of which the [plaintiffs] now complain." *Rounds v. Genzyme Corp.*, 440 F. App'x 753, 755 (11th Cir. 2011); *see also id.* at 756 (dismissing claim because packaging insert "provid[ed] clear, unambiguous information about [] risks"); *see also Nelson v. Bard. Inc.*, 44 F. 4th 277, 284 (5th Cir. 2022) (affirming summary judgment because Plaintiffs failed to raise a genuine issue of material fact as to "insufficient warning of incidence and seriousness" of fracture and migration where label warned of those complications in two different locations); *Ralston v. Smith & Nephew Richards, Inc.*, 275 F.3d 965, 976 (10th Cir. 2001); *Gerber v. Hoffmann-La Roche Inc.*, 392 F. Supp. 2d 907, 916 (S.D. Tex. 2005).

For example, Ozempic's original label (December 2017) warned physicians about the risk of gastrointestinal adverse reactions over sixty times and included language notifying that these

[25] Statement of Undisputed Facts at ¶¶ 4.
[26] *Id.* at ¶¶ 4-9.

events could be severe. Notably the "Warnings and Precautions" section—included in the front "Highlights of Prescribing Information"—instructed physicians to "[m]onitor renal function in patients with renal impairment reporting ***severe adverse gastrointestinal reactions***."[27]

In Section 5 "Warnings and Precautions," Novo reiterated this warning under a heading "Acute Kidney Injury," noting that:

> [S]ome of these [renal] events ***have been reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration***. Monitor renal function when initiating or escalating doses of OZEMPIC in ***patients reporting severe adverse gastrointestinal reactions***."[28]

The label goes on in Section 6 "Adverse Reactions," under a subheader called "Common Adverse Reactions," to include, a table detailing the precise percentages of patients in clinical trials who experienced adverse gastrointestinal symptoms at rates >5%, which list included nausea, vomiting, constipation, and abdominal pain.[29] *See In re Rezulin Prods. Litig.*, 331 F. Supp. 2d 196, 200 (S.D.N.Y. 2004) (finding reference to a "clear and conspicuous table" in the "adverse reactions section" of the label was, for "the maladies complained of . . . adequate as a matter of law"). Underneath the subheader, "Gastrointestinal Adverse Reactions," the label provided discontinuation rates attributable to these adverse reactions.[30] The FDA-approved Ozempic label also lists "gastrointestinal adverse reactions with a frequency of <5% [that] were associated with OZEMPIC (frequencies listed, respectively, as: placebo; 0.5 mg; 1 mg): dyspepsia (1.9%, 3.5%, 2.7%), eructation (0%, 2.7%, 1.1%), flatulence (0.8%, 0.4%, 1.5%), gastroesophageal reflux

[27] L.P. Ex. 134D, Dec. 2017 Ozempic Label at 542; *see also* Novo_GLP_MDL_RYB_NDA_000034151 ("Sep. 2019 Rybelsus label") (L.P. Ex. 140D); Novo_GLP_MDL_006195623 ("June 2021 Wegovy label")(L.P. Ex. 175D); Statement of Undisputed Facts at ¶ 5.
[28] L.P. Ex. 134D, Dec. 2017 Ozempic Label at 546 (emphasis added); *see also* L.P. Ex. 140D, Sep. 2019 Rybelsus label; L.P. Ex. 175D, June 2021 Wegovy label.
[29] Statement of Undisputed Facts at ¶¶ 8.
[30] L.P. Ex. 134D, Dec. 2017 Ozempic Label at 548.

disease (0%, 1.9%, 1.5%), and gastritis (0.8%, 0.8%, 0.4%)."[31]

Notably, nowhere in the Ozempic, Rybelsus, Wegovy or Victoza FDA-approved labeling are these symptoms described as "mild" or "moderate."[32] All of Novo's labels, dating back to the original Victoza label, contained similar tables, charts, and discontinuation rates.[33]

The "Patient Counseling Section" of the Ozempic 2017 product labeling directs physicians to: (1) "[i]nstruct patients to discontinue OZEMPIC promptly and contact their physician if pancreatitis is suspected (severe abdominal pain that may radiate to the back, and which may or may not be accompanied by vomiting)"; (2) "[a]dvise patients treated with OZEMPIC of the potential risk of dehydration due to gastrointestinal adverse reactions and take precautions to avoid fluid depletion"; and (3) "[a]dvise patients that the most common side effects of OZEMPIC are nausea, vomiting, diarrhea, abdominal pain and constipation." The FDA-approved medication guide similarly instructs users to: (1) "Stop using OZEMPIC and call your healthcare provider right away if you have severe pain in your stomach area (abdomen) that will not go away, with or without vomiting"; (2) understand that "diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration)"; and (3) be aware that "[t]he most common side effects of OZEMPIC may include nausea, vomiting, diarrhea, stomach (abdominal) pain and constipation."[34] Similar instructions are included in Novo's other GLP-1 RA medicines.[35]

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[31] *Id*.

[32] Saxenda's initial label states: "Most episodes of gastrointestinal events were mild or moderate and did not lead to discontinuation of therapy," but also disclosed that "6.2% with Saxenda versus 0.8% with placebo discontinued treatment as a result of gastrointestinal adverse reactions" and that "[t]here have been reports of gastrointestinal adverse reactions, such as nausea, vomiting, and diarrhea, associated with volume depletion and renal impairment [*see Warnings and Precautions (5.6)*]." Novo_GLP_MDL_001247737 ("Dec. 2014 Saxenda Label") (L.P. Ex. 147D) at 755-56.

[33] Victoza's first FDA-approved label identifies that the incidence of withdrawal due to adverse events was 7.8% for Victoza-treated patients and 3.4% for comparator-treated patients, and explicitly states "[t]his difference was driven by withdrawals due to gastrointestinal adverse reactions" (the most common of which was nausea). *See* Novo_GLP_MDL_003858960 ("Jan. 2010 Victoza label")(L.P. Ex. 167D) at 975; *see also* Appendix A.

[34] L.P. Ex. 134D, Dec. 2017 Ozempic Label at 566.

[35] *See* Appendix A (detailing all relevant disclosures for gastrointestinal adverse reactions listed in the first FDA-approved labels for Ozempic, Victoza, Saxenda, Rybelsus, and Wegovy).

These warnings—disclosed across every section of the label addressing adverse reactions—reasonably conveyed the risk of severe gastrointestinal reactions, including through instructions to monitor patients experiencing these reactions and disclosure of discontinuation rates attributable to gastrointestinal events.

**2. The expert testimony offered by the parties confirms the adequacy of Novo's FDA-approved labels.**

The testimony of the parties' respective experts confirms the adequacy of the label. Dr. Suneil Koliwad, a board-certified endocrinologist and Professor of Medicine at the University of California San Francisco, where he serves as Chief of the Division of Endocrinology and Metabolism and is a member of the UCSF Diabetes Center, opines that Novo's labeling was always adequate.[36] Dr. Koliwad is the only prescribing physician testifying in this matter—and thus the only expert who can offer the perspective relevant under the learned intermediary doctrine. *See Meridia Prods. Liab. Litig.*, 447 F.3d at 867. He has prescribed GLP-1 RA medications "since the class was initially developed" in the mid-2000s.[37] In his opinion, "Novo's GLP-1 RA product labels have always informed prescribers of the risk of GI-related adverse reactions, including GI adverse reactions that can be severe."[38] In his practice, Dr. Koliwad advises his patients about the "warning signs of delayed gastric emptying, nausea, the potential for vomiting, diarrhea, injection site reactions, abdominal pain, potential signs of pancreatitis, and gallstones," along with "thresholds at which the severity and duration of gastrointestinal effects should prompt dose reduction and continuation."[39]

Dr. Koliwad explained that there is "widespread understanding that GLP-1 receptor agonists can lead to nausea, vomiting, and that that can be severe enough that it might need

[36] February 13, 2026, Expert Report of Suneil Koliwad, MD, PhD ("Koliwad Rep.") (L.P. Ex. 23D) at 1, 4.
[37] *Id*. at 29.
[38] *Id*. at 31.
[39] *Id*. at 29.

management acutely," i.e., in an "emergency room."[40] Physicians also are trained in medical school, residency, and fellowship to assess the benefit-risk profile of medications on a patient-by-patient basis, understanding that each patient is unique, may react differently to the medication, and may experience side effects across a range of severity. In his practice, Dr. Koliwad tells his patients "that they might end up having nausea severe enough to cause vomiting and that they should let [him] know if that's the case."[41] He also tells them "to seek care" if they are unable to get ahold of him and the "vomiting is intense."[42] He further testified that he tries to ensure his patients "understand that symptom really well, because it affords [him] the chance to discontinue the medicine or reduce the dose and, therefore, quell the symptom, or get care acutely so that [he] or the treating provider in an emergency room, for example, can determine what actually is going on."[43]

Dr. Koliwad further opines that "[i]n multiple sections, the labeling of Novo's GLP-1 RAs always have conveyed that GI adverse reactions can be severe."[44] For example, the original Ozempic label explicitly warned that in clinical trials, a higher percentage of patients on the medication discontinued treatment due to gastrointestinal adverse reactions compared to placebo.[45] Dr. Koliwad explains: "As a prescriber, my understanding of patients needing to discontinue treatment because of GI-related adverse reactions is that those adverse events were severe enough that the patient could no longer tolerate the treatment."[46] The labeling for Saxenda, Ozempic, Rybelsus, and Wegovy has always instructed prescribers to monitor renal function in patients reporting adverse gastrointestinal reactions and warns physicians that reports of acute kidney

[40] L.P. Ex. 41D, Koliwad Tr. 74:14-18.
[41] *Id*. at 72:3-11.
[42] *Id.*
[43] *Id*. at 72:17-23.
[44] L.P. Ex. 23D, Koliwad Rep. at 32.
[45] Statement of Undisputed Facts at ¶ 9.
[46] *Id*.

injuries were not limited to those with underlying renal disease.[47] A similar disclosure was added to the Victoza label in 2011.[48] The presence of such warning indicates to prescribers that gastrointestinal adverse reactions can be severe for some patients—a point Dr. Koliwad states is "broadly recognized in clinical practice, literature, and guidelines for nearly two decades."[49]

Against this backdrop, Plaintiffs offer only the opinion of Dr. David Kessler, a regulatory expert who emphatically testified: "I'm **not** here as a prescribing doc. Right. So I just want to make that clear for the record."[50] Dr. Kessler further stated that "what doctors know is maybe interesting to certain people, and I don't want to minimize that. But that's not the regulatory standard [] by which I issued my opinions."[51] These concessions limit the import and relevancy of Dr. Kessler's adequacy opinions. *See LaBarre v. Bristol-Myers Squibb Co.*, 544 F. App'x 120, 125 (3d Cir. 2013) ("[t]o demonstrate inadequate warnings, a plaintiff must generally show through expert testimony that the warnings were not 'adequate to warn a physician of the possibility that [the drug] might be causing the condition experienced'"); *see also D.W.K. v. Abbott Labs. (In re Depakote)*, 2015 U.S. Dist. LEXIS 108400, at *11, *25 (S.D. Ill. 2015) (finding that qualified regulatory expert could testify about "the inadequacy of the Depakote label," but would "not be allowed to substitute her judgment for a physician interpreting the Depakote label"); *Begley v. Bristol-Myers Squibb Co.*, 2013 U.S. Dist. LEXIS 4849, at *25-26 (D.N.J. 2013) (granting summary judgment where plaintiff's expert failed to address "how a prescribing physician at the time of Plaintiff's injury would have interpreted the warning label or any other medical information available at that time"); *Calisi v. Abbott Labs.*, 2013 U.S. Dist. LEXIS 139257, at *17,

[47] *See* Appendix A; Statement of Undisputed Facts at ¶ 5.
[48] *See* Appendix A; Statement of Undisputed Facts at ¶ 6.
[49] L.P. Ex. 23D, Koliwad Rep. at 32.
[50] Transcript of the April 27, 2026, Deposition of David A. Kessler ("Kessler Dep. III Tr.") (L.P. Ex. 28D) at 579:14-16 (emphasis added).
[51] L.P. Ex. 26D, Kessler Dep. I Tr. at 111:2-6.

*30 (D. Mass. 2013) (granting summary judgment where only labeling expert was "an expert in federal Food and Drug Administration regulations with a specialization in drug labeling," but was "not qualified to opine as to the adequacy for prescribing purposes").

Dr. Kessler is a pediatrician who has spent most of his career at FDA and testifying as a litigation expert, with the latter earning him millions of dollars to opine that product labeling is insufficient.[52] Although he represented himself as "board certified" in obesity medicine, that certification was obtained on December 3, 2025—just one month before he issued his report in this case.[53] When asked if he had "ever prescribed a GLP-1 RA," he responded, "I believe I have," but he could not recall how often, whether he wrote "the script," or other basic details.[54]

To be clear, Dr. Kessler himself recommends that patients use GLP-1 RA medications and believes that the Government's failure to reimburse for these medications constitutes discrimination—he even offered his services to Novo "to sit as an expert and testify" on its behalf to stop the "denial of insurance coverage."[55] Yet he offers criticism of Novo's "severe gastrointestinal adverse reactions" warning that amounts to precisely the sort of after-the-fact legal parsing that courts have consistently rejected in the adequacy analysis. His "major beef with the label is that you have…things like nausea, vomiting, constipation" without saying these injuries "can be severe that can lead you in the hospital."[56]

But the law does not require a reference to hospitalization to convey the possibility that these adverse events could be severe or serious. *Plenger v. Alza Corp.* is analogous. 13 Cal. Rptr. 2d 811, 818-19 (Cal Ct. App. 1992). In *Plenger*, the issue was whether a warning about the risk of pelvic infection was adequate to convey to prescribers the possibility that pelvic infection could

[52] *See generally id*. at 60:7-62:16.
[53] Verification of Certification ("Board Certification")(L.P. Ex. 270D).
[54] L.P. Ex. 26D, Kessler Dep. I Tr. at 44:5-45:6.
[55] *Id*. at 144:11-21.
[56] *Id*. at 125:2-10.

cause death. *Id.* The plaintiffs filed suit after their wife and mother died from a pelvic infection, alleging the manufacturer of an intrauterine device (IUD) failed to warn of the risk of death. *Id.* at 812, 818-19. The trial court held that the warnings were adequate as a matter of law. *Id.* at 812. The summary judgment record included evidence that the label expressly warned of pelvic infection and included expert testimony that the label was adequate to convey the risks. *Id*. The plaintiffs submitted expert testimony that the warnings were inadequate "because they did not specifically advise of the risk of death," but this was not enough to create a genuine factual dispute as to adequacy. *Id.* at 819. The appeals court affirmed despite the plaintiffs' evidence because the risk of death from an untreated infection was a matter of general medical knowledge, and a manufacturer is not required to warn of a risk that is readily known and apparent. *Id.*

Dr. Kessler ignores that a prescribing physician, as Dr. Koliwad testified, would be well aware that conditions like vomiting might be severe enough to result in hospitalization or discontinuation.[57] *See In re Meridia Prod. Liab. Litig.*, 328 F. Supp. 2d 791, 813-14 (N.D. Ohio 2004) (holding label adequate because "[p]hysicians are well aware of the scope of the risks associated with increased blood pressure and do not need specifics regarding the possible consequences of blood pressure increases"), *aff'd*, 447 F.3d 861 (6th Cir. 2006); *Bergstresser v. Bristol-Myers Squibb Co.*, No. 3:12-1464, 2013 WL 6230489, at *7 (M.D. Pa. Dec. 2, 2013) ("The law does not require that the drug manufacturer provide such detailed information or instructions so as to remove the medical judgment of the physicians, who are in the best position to monitor and treat their patients and make medical judgments with respect to their care.")

Further, Dr. Kessler constructs several strawman arguments. First, he asserts that Novo describes these symptoms "are mild to moderate."[58] But nowhere in the Victoza, Ozempic,

[57] Statement of Undisputed Facts at ¶ 3.
[58] L.P. Ex. 26D, Kessler Dep. I Tr. at 125:11-16.

Rybelsus, or Wegovy labels are nausea, vomiting, constipation, or any other gastrointestinal adverse reaction described as "mild to moderate,"[59] and as discussed in footnote 32 the Saxenda label warned that gastrointestinal adverse events may be more intense than mild to moderate. He similarly argues that "GI effects is not the same thing as saying that ileus and intestinal obstruction can occur."[60] This argument improperly conflates the adequacy of Novo's warning with specific conditions like ileus and intestinal obstruction. This argument also fails on the grounds that there is insufficient evidence to demonstrate that GLP-1 RAs cause ileus or intestinal obstruction, as demonstrated in Section V below and in the motions to exclude Drs. John and Lodhia.

**3. The inclusion of an additional Section 5 warning in 2025 to harmonize GLP-1 RA labeling across the class does not change the fact that the initial FDA-approved Novo labels adequately disclosed this risk.**

Plaintiffs will no doubt point to the fact that, in 2025, FDA mandated the addition of a severe gastrointestinal adverse reaction warning to the Warnings and Precautions section of the product labeling for Novo's GLP-1 RA medicines. But subsequent label changes do not render prior labeling inadequate. For example, if additional or different warnings convey risks that doctors should already know as the learned intermediary, those warnings do not render prior labeling inadequate. *See, e.g., Gerber*, 392 F. Supp. 2d at 919-20.

In *Gerber*, the plaintiff claimed that Accutane labeling failed to adequately warn dermatologists in 1983 of the dangers the medication posed to women in childbearing years and failed to instruct such users on how to safely use the drug. *Id*. Faced with labeling that disclosed the risks posed to pregnant women and women who intended on becoming pregnant, the plaintiff argued the label was inadequate pointing to a 2002 label amendment that added a "black box warning" relating to use of Accutane in women of childbearing ages. *Id*. The Court agreed with

[59] *See, e.g.*, L.P. Ex. 134D, Dec. 2017 Ozempic Label; *see also* Appendix A.
[60] L.P. Ex. 26D, Kessler Dep. I Tr. at 125:24-126:11.

the defendant that the additional warnings "concern facts doctors should already know as learned intermediaries," and found that the disclosures from 1983 "collectively constitute a legally adequate warning to dermatologists about the hazards of and precautions necessary for the use of the product." *Id.* at 920.

Further, the decision to update the label had nothing to do with the adequacy of prior labels; FDA requested the update "to harmonize labeling for this risk across the GLP-1 RA class"—not because existing warnings were inadequate.[61] Label harmonization is a routine regulatory process by which FDA aligns the format and placement of information across products within the same drug class to promote consistency for prescribers. Recent examples of FDA mandated class-wide harmonization of labels include changes to labeling for testosterone,[62] opioids,[63] ADHD stimulants,[64] and to remove suicidal ideation from GLP-1 RAs.[65]

Harmonization does not constitute a determination that prior labeling failed to convey the relevant risk information. Here, when read as a whole, Novo's labels thoroughly disclosed the risk of severe gastrointestinal adverse reactions through disclosures in the Warnings and Precautions section (Section 5), Adverse Reactions section (Section 6), the Drug Interactions section (Section 7), the Patient Counseling Information section, and the Medication Guide—the same substantive information was simply consolidated into an additional location in Section 5 to match the format adopted for newer class members like Mounjaro.

Prior to marketing, FDA reviewed the clinical data and approved the product labeling for

[61] Novo_GLP_MDL_OZM_NDA_005135901 ("Labeling Discussion Comments") (L.P. Ex. 197D) at 908.
[62] Food & Drug Admin., FDA issues class-wide labeling changes for testosterone products (Feb. 28, 2025) (L.P. Ex. 118D).
[63] Food & Drug Admin., FDA is requiring opioid pain medicine manufacturers to update prescribing information regarding long-term use (July 31, 2025) (L.P. Ex. 119D).
[64] Food & Drug Admin., FDA requires expanded labeling about weight loss risk in patients younger than 6 years taking extended-release stimulants for ADHD (June 30, 2025) (L.P. Ex. 120D).
[65] Food & Drug Admin., FDA Requests Removal of Suicidal Behavior and Ideation Warning from Glucagon-Like Peptide-1 Receptor Agonist (GLP-1 RA) Medications (Jan. 13, 2026) (L.P. Ex. 121D).

each of Novo's GLP-1 RA medicines, including specifically the content and placement of information regarding potentially serious gastrointestinal side effects. For example, in 2017, FDA's Division of Risk Management reviewed Ozempic data and concluded that: "Higher incidences of serious gastrointestinal adverse events were observed with semaglutide arm than with comparator and placebo arms."[66] The Division subsequently concluded that "[s]imilar to other drugs in this class, the risk of gastrointestinal adverse reactions will be communicated in labeling in the Adverse Reactions section," which is Section 6, "of the label."[67]

In May 2022, the Division conducted a similar pre-approval review for Mounjaro (tirzepatide). The Division concluded that the labeling for Mounjaro would differ from that of other GLP-1 RAs in that it would include a Section 5 warning about the risk of "sometimes-severe gastrointestinal reactions":

> Across all Phase 3 trials, higher proportions of tirzepatide-treated subjects experienced GI AEs compared to each control arm, although GI related AEs were seen in the active comparator arms, dulaglutide (31%) and semaglutide (41%). Unlike other GLP-1 RA products, the labeling for tirzepatide will include these sometimes-severe gastrointestinal reactions in [Section 5] warnings and precautions and include that tirzepatide has not been studied in, nor is recommended for, patients with severe GI disease.[68]

The warning as included in the Mounjaro label reads as follows:

> **5.6 Severe Gastrointestinal Disease**
> Use of MOUNJARO has been associated with gastrointestinal adverse reactions, sometimes severe [see Adverse Reactions 6.1]. MOUNJARO has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis, and is therefore not recommended in these patients.

Notably, FDA did not request a similar warning be added to the labeling for Novo's GLP-1 RA

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[66] FDA's Division of Risk Management, Ozempic Risk Assessment and Risk Mitigation Review(s), Application Number 209637Orig1s000 (November 6, 2017) ("209637Orig1s000 Application") (L.P. Ex. 122D) at 15.
[67] *Id.*
[68] FDA's Division of Risk Management, Mounjaro Risk Assessment and Risk Mitigation Review(s), Application Number 215866Orig1s000 (May 15, 2022) (L.P. Ex. 123D) at 10. FDA also noted that Mounjaro's label included a Section 5 warning to "monitor patients with renal impairment and severe gastrointestinal reactions" consistent with "other GLP-1 RA products [that] contain similar language in warnings and precautions." *Id.*

medicines at that time.

In late 2024, Novo submitted supplemental new drug applications to expand the indication for some of its GLP-1 RAs, including Ozempic, Rybelsus, and Wegovy. During the review, FDA requested that the labeling for these products be updated to include a Section 5 warning regarding "Severe Gastrointestinal Disease"—not because the current information was inadequate—but rather "***to harmonize labeling for this risk across the GLP-1 RA class***."[69] A harmonization request reflects the preference for uniformity across labels, not a conclusion that the label does not adequately describe a risk.

As discussed above, the original FDA-approved labels for Ozempic, Rybelsus, and Wegovy all explicitly reference "severe adverse gastrointestinal adverse reactions" in both the Highlights and Warnings and Precautions section of labels, with similar labeling for Victoza and Saxenda.[70] *See* Appendix A. Further, as the FDA concluded, the risk of serious gastrointestinal adverse reactions would "be communicated in labeling in the Adverse Reactions section"[71] that described the increased risk of adverse gastrointestinal reactions, the discontinuation rate due to these gastrointestinal adverse reactions, and which did not contain language equivocating about the possibility or range of severity associated with medication use.[72]

Because Novo's labels always have provided accurate, clear, and unambiguous warnings regarding severe gastrointestinal adverse reactions, Plaintiffs' failure-to-warn claims based on such events must be dismissed as a matter of law.[73] *See Meridia*, 447 F.3d at 867; *Salvio*, 2012

[69] L.P. Ex. 197D, Labeling Discussion Comments at 908 (emphasis added).
[70] Statement of Undisputed Facts at ¶ 6.
[71] L.P. Ex. 122D, 209637Orig1s000 Application at 1.
[72] *See* Appendix A (listing contents of Adverse Reactions section of original Ozempic, Rybelsus, Wegovy, Victoza).
[73] To the extent Plaintiffs attempt to assert claims under state consumer-protection statutes or other theories that do not require proof of inadequate warnings to prescribing physicians, those claims likewise fail. Regardless of the legal theory, Plaintiffs must establish that the labeling was deficient in some material respect—and the foregoing analysis demonstrates that Novo's labels have always provided accurate, clear, and unambiguous warnings regarding the risks of severe gastrointestinal adverse events and delayed gastric emptying. No repackaging of the claim under a different

WL 517446, at *4-6.

**B. Delayed gastric emptying and drug-induced gastroparesis.**

The parties agree that gastroparesis is a delay in gastric emptying with accompanying adverse gastrointestinal symptoms in the absence of mechanical obstruction.[74] As Plaintiffs' gastroparesis expert Dr. Metz states: "Gastroparesis is a condition in which gastric motility is disordered leading to a delay in emptying of ingested food into the duodenum" and "symptoms of delayed gastric emptying . . . includ[ing] early satiety, abdominal pain, epigastric fullness, bloating, nausea and vomiting, regurgitation and heartburn."[75] Novo's labels have always warned of each of these constituent elements. "If 'a warning specifically mentions the circumstances complained of, the warning is adequate as a matter of law.'" *Gerber*, 392 F. Supp. 2d at 916; *see Cather v. Catheter Tech. Corp.*, 753 F. Supp. 634, 640 (S.D. Miss. 1991).

Since they came to market, the FDA-approved product labeling for Novo's GLP-1 RA medications have warned in the "Highlights of Prescribing Information" under the heading "Drug Interactions" that the medications delay gastric emptying.[76] And, as discussed above, the labeling also prominently has warned about potential symptoms associated with such delay, including nausea, vomiting and abdominal pain. As such, the labeling always has adequately warned physicians that Novo's GLP-1 RA medicines may cause patients to experience delayed gastric

statutory framework can overcome the adequacy of the warnings themselves. *See Meridia*, 447 F.3d at 867 (affirming summary judgment on adequacy as a matter of law); *Felix v. Hoffmann-LaRoche, Inc.*, 540 So. 2d, 102, 105 (Fla. 1989).

[74] Statement of Undisputed Facts at ¶ 24.

[75] January 2, 2026, Expert Report of David C. Metz, M.D. to Novo ("Metz Novo Rep.") (L.P. Ex. 13D) at 11; *see also* Transcript of the March 24, 2026, Deposition of David Metz ("Metz Tr.") (L.P. Ex. 33D) at 15:9-15 ("drug induced gastroparesis" is "essentially" "taking a medication that causes the stomach muscles to weaken and to delay its emptying"); Transcript of the March 12, 2026, Deposition of Ma Somsouk ("Somsouk Tr.") (L.P. Ex. 39D) at 13:7-12 (agreeing that gastroparesis is a "condition characterized by upper GI symptoms such as nausea, vomiting, early satiety, abdominal pain, and delayed gastric emptying in the absence of a mechanical obstruction").

[76] L.P. Ex. 167D, Jan. 2010 Victoza Label; *see also* Appendix A (detailing all relevant disclosures for delayed gastric emptying listed in the first FDA-approved labels for Ozempic, Victoza, Saxenda, Rybelsus, and Wegovy); Statement of Undisputed Facts at ¶ 4.

emptying and that such patients may have related gastrointestinal side effects.

In opposition, Plaintiffs will likely emphasize that the labels do not specifically use the word "gastroparesis." But this argument fails as a matter of law. There is no legal requirement to use a specific term to describe a condition when the label describes the condition's components. *See, e.g.*, *Salvio*, 2012 WL 517446, at *4-6 (finding label adequate as a matter of law where "Warnings" section disclosed "reports" of "serious infections . . . including fatalities," but did not specifically identify the infection type that caused death).

*Meridia* is directly on point. There, the plaintiff alleged Abbott failed to warn that Meridia could cause heart attack, stroke, and death—despite a bold-lettered warning that the drug "SUBSTANTIALLY INCREASES BLOOD PRESSURE IN SOME PATIENTS." 328 F. Supp. 2d at 810. The court held the label adequate because "[p]hysicians are well aware of the scope of the risks associated with increased blood pressure and do not need specifics regarding the possible consequences of blood pressure increases." *Id.* at 813, *aff'd*, 447 F.3d at 867.

*Salvio* is equally instructive. There, the Enbrel label warned in boldface capital letters of "SERIOUS INFECTIONS AND SEPSIS, INCLUDING FATALITIES," yet the plaintiff argued this was insufficient because it did not specifically warn of fungal infections. 2012 WL 517446, at *4. The court dismissed the failure-to-warn claim as a matter of law, holding that "[w]arnings that 'advise[] physicians of the specific risks at issue' are adequate as a matter of law" and that "the Package Insert warning provided by Defendants advised Decedent's prescribing physicians of the very injury that occurred." *Id.* at *5–6.

The same analysis compels the same result here. Like the blood pressure warning in *Meridia* and the infection warning in *Salvio*, Novo's labels have always warned of the mechanism (delayed gastric emptying) and its symptomatic consequences (nausea, vomiting, abdominal pain,

constipation).[77] Prescribing physicians understand that delayed gastric emptying can manifest in the symptoms that characterize gastroparesis. Dr. Metz himself testified that the "manifestations" of impaired gastric emptying and drug-induced gastroparesis "are the same," including nausea, vomiting, and abdominal pain.[78] Even Dr. Kessler concedes that the "drugs work in significant part by delayed gastric emptying, which induces nausea."[79]

Dr. Kessler does not dispute the use of the phrase "delayed gastric emptying"; rather, he takes issue with the fact that "delayed gastric emptying" does not appear in Section 5 of the label.[80] But Dr. Kessler is not testifying to the adequacy of the label from a prescribing physician's perspective—he is testifying as a regulatory expert. "The warning should [] be evaluated as a whole and not through the nitpicking prism of an interested legal advocate after the fact." *McDowell*, 58 F. Supp. 3d at 403. Tellingly, Novo's current labels still state only that use of the medication can "delay gastric emptying"—without reference to "gastroparesis" or "impaired gastric emptying"—yet no one, including Dr. Kessler, alleges the current label is inadequate.[81]

### C. Pancreatitis

Plaintiffs nitpicking of the label is perhaps best exemplified through their allegation that Novo failed to warn about the risk of pancreatitis. Am. Comp. at ¶ 4. Novo's first FDA-approved GLP-1 RA product label (Victoza 2010) has 26 references to pancreatitis.[82] The "Warnings and Precautions" section of the front cover, "Highlights of Prescribing Information," states: "In clinical trials, there were more cases of pancreatitis among Victoza-treated patients than among

[77] Statement of Undisputed Facts at ¶ 4.
[78] L.P. Ex. 33D, Metz Tr. at 18:11-19:17.
[79] L.P. Ex. 26D, Kessler Dep. I Tr. at 73:19-21.
[80] *See* Deposition of David A. Kessler ("Kessler Dep. II Tr.") (L.P. Ex. 27D) at 386:1-4 ("I think delayed gastric emptying or impaired gastric emptying should be in 5 and should have been in the label in 5"); L.P. Ex. 26D, Kessler Dep. I Tr. at 303:23-304:2 ("I mean, there is delayed gastric emptying, I mean, in different sections of the label. That doesn't mean there's a warning").
[81] *See, e.g., id*. at 130:16-20 ("I don't give a specific opinion on the 2025 label. I don't believe I've given – again, I think it's – I think it's much improved.")
[82] Statement of Undisputed Facts at ¶ 4.

comparator-treated patients. If pancreatitis is suspected, Victoza and other potentially suspect drugs should be discontinued. Victoza should not be restarted if pancreatitis is confirmed."[83] The Section 5 "Warnings and Precautions" has a whole subsection devoted to Pancreatitis with a notation about acute and necrotizing pancreatitis: "Five cases with Victoza were reported as acute pancreatitis and two cases with Victoza were reported as chronic pancreatitis" and "In one case in a Victoza-treated patient, pancreatitis, with necrosis, was observed and led to death; however clinical causality could not be established."[84] The Patient Counseling Information further instructs physicians that:

> Patients should be informed that persistent severe abdominal pain, that may radiate to the back and which may (or may not) be accompanied by vomiting, is the hallmark symptom of acute pancreatitis. Patients should be instructed to discontinue Victoza promptly, and to contact their physician, if persistent severe abdominal pain occurs.[85]

Each Novo GLP-1 RA medication has had similar disclosures regarding the risk of pancreatitis since inception.[86]

Plaintiffs may quibble that two of Novo's semaglutide labels (Ozempic and Rybelsus) did not include the specific phrase "necrosis" or "necrotizing" until 2024.[87] But "necrotizing pancreatitis" is simply a complication of acute pancreatitis:[88] a condition that was always warned about in the Ozempic and Rybelsus labels with clear instructions to monitor, discontinue, and seek further medical treatment if suspected.[89] Tellingly, neither Drs. Kessler nor Ross claim that Novo failed to warn of the risk of pancreatitis.

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[83] L.P. Ex. 167D, Jan. 2010 Victoza label at 971.
[84] *Id*. at 974.
[85] *Id*. at 992.
[86] Statement of Undisputed Facts at ¶ 4.
[87] Victoza, Saxenda, and Wegovy labels have always included the words "necrosis" or "necrotizing" in connection with their pancreatitis warnings. *See* Appendix A.
[88] Cleveland Clinical, *Necrotizing Pancreatitis: What it is, Symptoms & Treatment*, available at https://my.clevelandclinic.org/health/diseases/necrotizing-pancreatitis.
[89] *See* Appendix A.

## II. Plaintiffs do not dispute the adequacy of the Saxenda and Wegovy labels as to gallbladder disease, nor do Plaintiffs dispute the adequacy of the Victoza, Ozempic, and Rybelsus labels as to gallbladder disease at certain times.

Plaintiffs have not identified any expert other than Dr. David Ross who will opine that the FDA-approved labeling for Novo's GLP-1 RA medicines was inadequate as to gallbladder disorders.[90] "In the prescription drug arena, expert medical testimony is generally required to determine whether the drug manufacturer's warning to the medical community is adequate because prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect." *Rowland v. Novartis Pharms. Corp.*, 34 F. Supp. 3d 556, 572 (W.D. Pa. 2014) (internal quotation omitted); *see also Keen v. C.R. Bard, Inc.*, 480 F. Supp. 3d 624, 641 (E.D. Pa. 2020) ("Typically, expert testimony is required to determine the adequacy of a warning."). The adequacy of Novo's GLP-1 RA labeling for gallbladder disease is no exception.

Dr. Ross expressly limited his opinions at deposition in four ways that warrant judgment as a matter of law on certain Plaintiffs' failure to warn claims: (1) he has no opinion that the Saxenda or Wegovy labels were ever inadequate; (2) he is only opining that the Ozempic label was inadequate from approval until the label update in March 2022; (3) he is only opining that the Rybelsus label was inadequate from approval in September 2019 until the class-wide label update in June 2022; and (4) he is only opining that the Victoza label was inadequate between 2014 and the labeling update in August 2017.[91] Without expert testimony on adequacy, no plaintiff can proceed on any claim (1) that Novo Nordisk failed to warn of the risk of gallbladder disease in the labeling for Saxenda or Wegovy; (2) that Novo Nordisk failed to warn of the risk of gallbladder disease or injury in the labeling for Ozempic after March 2022; (3) that Novo Nordisk failed to warn of the risk of gallbladder disease or injury in the labeling for Rybelsus after June 2022; or (4)

[90] L.P. Ex. 37D, Ross Tr. at 207:23-208:11; Statement of Undisputed Facts at ¶ 15.
[91] *Id*. at 211:10-15; 218:12-25; 251:9-15; 259:20-260:6; Statement of Undisputed Facts at ¶¶ 16-18.

that Novo Nordisk failed to warn of the risk of gallbladder disease or injury in the labeling for Victoza before 2014 and after August 2017. These claims should be dismissed.

**III. Plaintiffs do not dispute the adequacy of Novo's "current" labels.**

The FDA-approved labeling for Novo's GLP-1 RA medications has been updated over time to reflect new indications, incorporate accruing data, and—particularly relevant here—harmonize labeling across the class. It is undisputed that the current labeling for Novo's GLP-1 RA medicines is adequate.[92] Accordingly, at a minimum, no plaintiff can bring a failure-to-warn claim predicated on an alleged injury for which the operative labeling at the time of prescription is identical in relevant part to the current label.

Dr. Koliwad opines that "Novo's GLP-1 RAs have consistently communicated the risk of GI adverse events…that these medicines delay gastric emptying as part of their mechanism of action, and the potential risk of gallbladder-related adverse events."[93] Specifically, Dr. Koliwad opines that Novo's labels have "long and consistently communicated GI risks, including: (1) disclosing the risk of severe GI adverse reactions; (2) describing the higher frequency of treatment discontinuations. . .; and (3) identifying serious clinical consequences linked to GI symptoms (e.g., dehydration and acute kidney injury)."[94] He similarly opines that "the effect of Novo's GLP-1 RA medicines on gastric emptying—as well as the potential side effects of such delay—always have been featured in the FDA-approved product labeling and are well known to prescribers such as myself."[95]

Dr. Kessler also made clear he is not offering an opinion on the current label, that the labels are "improved," and "had the label[s] [been] as they are written today, we probably wouldn't be

[92] Statement of Undisputed Facts at ¶ 14.
[93] L.P. Ex. 23D, Koliwad Rep. at 31.
[94] *Id*. at 33.
[95] *Id*. at 35.

sitting here."[96] Dr. Kessler found the label to be "much improved" because of the inclusion of "fecal impaction, intestinal obstruction, ileus on the label, and with severe GI disorders."[97] He also credited Novo's inclusion of pulmonary aspiration in Section 5 in connection with GLP-1 RAs effect on gastric emptying.[98] And as explained above, Dr. Ross does not opine on any labeling inadequacy for any GLP-1 RA as to gallbladder disease after June 2022.[99]

The timing of each of the class-wide updates identified by Dr. Kessler as "improvements" are reflected below. These improvements go directly to Plaintiffs' failure to warn of ileus, intestinal obstruction, aspiration, and gallbladder disease. Because the post-update labels address the specific injuries alleged by Plaintiffs, any claim predicated on use that post-dates the relevant label update fail as a matter of law. *Gerber*, 392 F. Supp. 2d at 916; *see Cather*, 753 F. Supp. at 640. Accordingly, summary judgment should be granted in all cases where the plaintiff alleges:

- any "severe" gastrointestinal condition occurring after November 2024 for Wegovy, December 2024 for Rybelsus, January 2025 for Ozempic, and May 2025 for Saxenda/Victoza;[100]
- any injuries connected to delayed gastric emptying occurring after November 2024, regardless of the medication;[101]

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[96] L.P. Ex. 26D, Kessler Dep. I Tr. at 127:11–128:15; *id.* at 129:2–3 (stating "I don't think I give an opinion specifically" on whether the current labels are adequate); *id.* at 129:13–14 (confirming "I've not given an opinion on the 2025 label"); *id.* at 130:16–20 (reiterating "I don't give a specific opinion on the 2025 label" and that the label is "much improved").
[97] *Id*. at 131:5-11.
[98] L.P. Ex. 27D, Kessler Dep. II Tr. at 370:15-371:1. As of November 2024, pulmonary aspiration is listed in Section 5.10 of the warnings and precautions section of Novo's labeling in connection with GLP-1 RA medications' effect on "delay[] gastric emptying *[see Clinical Pharmacology (12.2)]*." Novo_GLP_MDL_011300508 ("Nov. 2024 Ozempic label") (L.P. Ex. 134D). Dr. Kessler was satisfied with the Novo labeling inclusion of pulmonary aspiration on the label because it included a reference to delayed gastric emptying in Section 5 of the label. *See, e.g.*, L.P. Ex. 27D, Kessler Dep. II Tr. at 376:13-16. But as Dr. Koliwad explains, "the update did not add any new information regarding the effect of GLP-1 RAs on gastric emptying, instead referencing to information," i.e., the Clinical Pharmacology 12.2 section, "that has been in the label since initial approval." L.P. Ex. 23D, Koliwad Rep. at 37.
[99] L.P. Ex. 37D, Ross Tr. at 211:10-15; 218:12-25; 251:9-15; 259:20-260:6 (limiting opinions to pre-2022 labels).
[100] Statement of Undisputed Facts at ¶ 10.
[101] *Id.* at ¶ 11.

- ileus occurring after January 2023 for Rybelsus, April 2023 for Saxenda, July 2023 for Victoza, September 2023 for Ozempic, and December 2023 for Wegovy;[102]
- intestinal obstruction occurring after October 2025, regardless of the medication; and, as discussed earlier;[103]
- gallbladder disease occurring after August 2017 for Victoza, after March 2022 for Ozempic, after June 2022 for Rybelsus, and at any time for Saxenda and Wegovy.[104]

| | **Severe GI Reactions (Section 5)** | **Pulm. Aspiration & DGE (Section 5)** | **Ileus (Section 6)** | **Intestinal Obstruction (Section 6)** | **Gallbladder Disease (Section 5)** |
|---|---|---|---|---|---|
| Victoza | May 2025 | November 2024 | July 2023 | October 2025 | August 2017 |
| Saxenda | May 2025 | November 2024 | April 2023 | October 2025 | N/A (at approval) |
| Ozempic | January 2025 | November 2024 | September 2023 | October 2025 | March 2022 |
| Rybelsus | December 2024 | November 2024 | January 2023 | October 2025 | June 2022 |
| Wegovy | November 2024 | November 2024 | December 2023 | October 2025 | N/A (at approval) |

## IV. Plaintiffs cannot recover for claims that GLP-1 RA medicines caused any injury predicated on delayed or abnormal gastric emptying without a confirmatory gastric emptying study.

This Court has already resolved the question of what evidence is required to substantiate a claim alleging that Novo's GLP-1 RAs caused an injury related to a delay in gastric emptying.

[102] *Id.* at ¶ 12.
[103] *Id.* at ¶ 13.
[104] *Id.* at ¶¶ 16-18.

Pursuant to this Court's Issue 1 Order, all claims alleging gastroparesis or delayed gastric emptying may only proceed if a Plaintiff has objective evidence of delayed gastric emptying through a properly performed gastric emptying study at the time of diagnosis. The Court held: "[A]ny plaintiff claiming to have had drug-induced gastroparesis must have had a gastric emptying study (scintigraphy, breath test, or [wireless motility capsule]) properly performed at the time of diagnosis, which confirmed delayed emptying." Mem. Op. at 77.

In response to the Court's ruling, numerous Plaintiffs have attempted to amend or file new complaints reframing allegations of gastroparesis under alternative labels: delayed gastric emptying, gastric dysmotility, gastric emptying impairment, gastric hypomotility, gastrointestinal hypomotility,[105] gastrointestinal hypomotility disorder, hypomotility, impaired gastric emptying, impaired gastric emptying with symptoms, impaired gastric emptying with sequelae, gastroparesis-like sequelae, impaired gastrointestinal motility, impairment of gastric emptying, impairment of gastric motility, severe impairment of gastric emptying, significantly impaired gastric emptying, or suspected gastroparesis. This semantic gamesmanship does not avoid the Court's holding. The question before the Court was whether a physician can reliably diagnose gastroparesis without objectively confirming delayed emptying—and the answer was no. Mem. Op. at 8.

Objective evidence of delayed emptying through a gastric emptying study is required regardless of how a plaintiff characterizes their injury, whether as drug-induced gastroparesis, impaired gastric emptying, delayed gastric emptying, or any of the synonymous conditions identified above. The Court's reasoning in the Issue #1 Order was not limited to the diagnostic

[105] "Gastrointestinal hypomotility" involves slowing of gastric motility and/or intestinal motility. The Court's Issue 1 reasoning clearly applies to slowing of gastric motility, and the spirit of the Court's Issue 1 reasoning applies with equal force to the slowing of intestinal motility because there still needs to be objective evidence that intestinal transit is in fact delayed.

label "gastroparesis"; rather, it rested on the fundamental principle that delayed gastric emptying is a physiological condition that cannot be reliably established without objective testing. That reasoning applies with equal force regardless of how a plaintiff labels the injury, because each of these characterizations is fundamentally predicated on the presence of a delay or other abnormality in gastric emptying. Indeed, Plaintiffs' own experts uniformly treat these terms as interchangeable, which confirms that the underlying physiological condition—and the need for objective verification—is the same regardless of nomenclature. [106]

Accordingly, summary judgment should be granted on any claim predicated on a delay or other abnormality in gastric emptying that is not supported by objective evidence of delayed emptying through a properly performed gastric emptying study. The Court should not permit Plaintiffs' nomenclature games to circumvent the law of the case.

## V. Plaintiffs cannot assert claims for injuries where there is insufficient evidence to establish that Novo's GLP-1 RAs can cause these conditions.

To survive summary judgment, Plaintiffs must present admissible evidence that each GLP-1 RA medication at issue is capable of causing the claimed injuries. They have not done so for the following conditions: gastroparesis that persists after treatment cessation and medication

[106] February 13, 2026, Expert Report of Dr. Linda Nguyen ("Nguyen Rep.") (L.P. Ex. 22D) at 11; L.P. Ex. 33D, Metz Tr. at 58:7–14 (confirming that he uses "drug-induced gastroparesis," "impaired gastric emptying," and "gastric dysmotility" synonymously); *id.* at 88:13–24 (testifying that the distinctions between "gastroparesis," "drug-induced gastroparesis," "gastric atony," and "functional outlet" are "semantics" because "[i]t's all the same problem"); L.P. Ex. 39D, Somsouk Tr. at 15:19–22 (agreeing that impaired gastric emptying and delayed gastric emptying are "broadly . . . the same or very similar"); *id.* at 17:18–22 (testifying that gastroparesis, delayed gastric emptying, and impaired gastric motility are "all in that basket of abnormal gastric motility and delayed gastric emptying"); L.P. Ex. 27D, Kessler Dep. II Tr. at 388:6–11 (stating "[w]e can call it impaired gastric emptying. You want to call it gastroparesis. You want to call it drug-induced gastroparesis that resolved – that likely resolved after the drug, I'm okay with that").

washout,[107] ileus, intestinal obstruction, or gallbladder disease.[108]

General causation is an essential element of Plaintiffs' claims; without admissible expert testimony establishing it, Plaintiffs cannot proceed. MDL courts routinely grant summary judgment on this basis. *See, e.g.*, *In re Onglyza (Saxagliptin) & Kombiglyze XR (Saxagliptin & Metformin) Prods. Liab. Litig.*, 93 F.4th 339 (6th Cir. 2024); *In re Mirena IUS Levonorgestrel-Related Prod. Liab. Litig. (No. II)*, 982 F.3d 113 (2d Cir. 2020); *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prod. Liab. Litig. (No. II)*, 892 F.3d 624 (4th Cir. 2018); *In re Viagra (Sildenafil Citrate) and Cialis (Tadalafil) Prod. Liab. Litig.*, Order Granting Summary Judgment, Dkt. 1021, No. 3:16-md-02691-RS (N.D. Cal. Apr. 8, 2020).

Indeed, every jurisdiction requires general-causation evidence. In the *Mirena* litigation, the district court examined "hundreds of cases from the 53 jurisdictions" and found that "***every jurisdiction requires a showing of general causation.***" *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (Mirena II)*, 387 F. Supp. 3d 323, 337 n.2 (S.D.N.Y. 2019) (emphasis added) (collecting cases), *aff'd*, 982 F.3d 113, 124 (2d Cir. 2020). The Sixth Circuit reached the same conclusion in *Onglyza*, affirming that "***all jurisdictions require expert testimony to show general causation in complex medical cases***" and observing that "the district court does not stand alone." 93 F.4th at 348–49 (emphasis added) (collecting cases).

Moreover, specific-causation experts cannot fill the gap left by the absence of general-

[107] Washout refers to the period of time that it takes for a medication to leave the system. "[A]fter five half-lives, it's accepted that a medication will have left the body and typically effects of that medication will have abated." L.P. Ex. 33D, Metz Tr. at 52:17-21. The half-life of liraglutide is approximately 13 hours, and the half-life of semaglutide is approximately one week; accordingly, the effects of liraglutide on gastric emptying should resolve approximately three days after cessation, while the effects of semaglutide should resolve approximately five weeks after cessation. L.P. Ex. 22D, Nguyen Rep. at 7 (Table 1).

[108] Novo reserves the right to move with respect to causation and adequacy as to the following injuries: "Wernicke's encephalopathy; gastroenteritis; micronutrient deficiencies, including but not limited to deficiencies of vitamin C, D, thiamine or B12; hypovitaminosis; cyclical vomiting; [] esophageal injury; bowel injury; intraoperative aspiration; [] ischemic bowel; muscle wasting; dehydration." Dkt. 481 at ¶ 419. Novo reserves the right to move with respect to causation and pancreatitis.

causation evidence. As the Tenth Circuit explained in *Norris*, causation in complex medical cases divides into two analytically distinct questions: (1) whether the substance *is capable* of causing the injury in the general population ("general causation"); and (2) whether the substance *did in fact* cause the injury in this plaintiff ("specific causation"). 397 F.3d at 881. The court concluded: "without general causation, there can be no specific causation." *Id.; see also Wells v. Smith Kline Beecham Corp.*, 601 F.3d 375, 378 (5th Cir. 2010) (claim cannot survive "without the predicate proof of general causation"); *Raynor v. Merrell Dow Pharms., Inc.*, 104 F.3d 1371, 1376 (D.C. Cir. 1997) ("[S]pecific causation ha[s] legitimacy only as follow-up to admissible evidence that the drug in question *could* in general cause" the injury at issue.).

### A. Plaintiffs have no admissible evidence that Novo's GLP-1 RA medicines cause gastroparesis following washout.

Plaintiffs have offered two witnesses who purport to provide expert opinions on GLP-1 RA use and gastroparesis: Dr. David Metz and Dr. Ma Somsouk. But Dr. Metz—a retired gastroenterologist whose board certification lapsed in 2021—is the only expert who actually opined on causation.[109] Dr. Somsouk stopped at association, never opining that GLP-1 RAs *cause* gastroparesis.

Dr. Metz offers two opinions that GLP-1 RA medications can cause gastroparesis to persist after the medication has been discontinued and washed out. First, he claims—without any supporting data—that GLP-1 RA-related gastroparesis and its symptoms can persist for up to six months following treatment cessation. Second, he claims—again without support—that in individual cases, such gastroparesis can persist even longer. As set forth in Novo's Memorandum of Law in Support of Its Motion to Exclude the General Causation Opinions and Testimony of Dr. David Metz, these opinions are inadmissible because they rest on speculation and an

[109] Statement of Undisputed Facts ¶ 19.

acknowledged evidentiary void. Because Dr. Metz's opinions regarding post-washout gastroparesis are inadmissible, summary judgment must be granted on any claim in which the Plaintiff alleges that they either (1) were diagnosed with gastroparesis after treatment cessation and washout or (2) were diagnosed with gastroparesis while taking a GLP-1 RA medicine and the condition persisted after treatment cessation and washout.

**B. Plaintiffs have submitted no admissible evidence to establish that Novo's GLP-1 RA medicines cause ileus or intestinal obstruction.**

Plaintiffs' general causation case for ileus and intestinal obstruction rests entirely on two gastroenterologists—Drs. Binu John and Nilesh Lodhia—both of whom opine that GLP-1 RAs, *as a class*, are capable of causing these conditions.[110] Neither expert performed any medication-specific analysis for semaglutide or liraglutide, despite acknowledging that each GLP-1 RA is a unique compound with different pharmacokinetics, pharmacodynamics, receptor affinity, and clinical data. Their opinions also fail because they are standardless, subjective, and grounded in a results-oriented methodology that discounts the most reliable scientific evidence while cherry-picking data to support a preordained conclusion.

For these reasons and those set forth in Novo's Memorandum of Law in Support of Its Motion to Exclude the Opinions and Testimony of Dr. Binu John and Dr. Nilesh Lodhia, their opinions do not satisfy Rule 702 and must be excluded. Without admissible expert testimony on the essential element of general causation, no Plaintiff can proceed on any claim alleging a GLP-1 RA caused them to develop ileus or intestinal obstruction.

**C. Plaintiffs have submitted no admissible evidence to establish that Novo's GLP-1 RA medicines cause gallbladder disease.**

[110] Statement of Undisputed Facts ¶ 20.

Plaintiffs identify only one expert, Dr. Lang, to opine on whether GLP-1 RA medications are capable of causing gallbladder disease.[111] Dr. Lang did not conduct any medication-specific analysis, instead evaluating the medications as a class. As set forth in Novo's Memorandum of Law in Support of Its Motion to Exclude the General Causation Opinions and Testimony of Dr. Gabriel Lang, his analysis failed each and every prong of the Rule 702 inquiry, both with respect to his class-wide opinions and specifically with respect to Ozempic and Rybelsus, for which he admitted he had no data at all.

Without admissible expert testimony on the essential element of general causation, no Plaintiff can proceed with any claim alleging Novo's GLP-1 RAs caused their gallbladder disease. If the Court excludes Dr. Lang's opinions only as to Ozempic and Rybelsus, no Plaintiff can proceed with any claim alleging Ozempic or Rybelsus caused their gallbladder disease. Further, even if Dr. Lang's opinions satisfied Rule 702, he does not opine that GLP-1 RA use for less than six months causes gallbladder disease.[112] Accordingly, no Plaintiff who used a Novo GLP-1 RA for less than six months can proceed on any claim alleging gallbladder disease.

## CONCLUSION

For the foregoing reasons, Novo Nordisk respectfully requests that this Court grant summary judgment on Plaintiffs' claims alleging failure to warn where the FDA-approved labeling has always been adequate as a matter of law, claims alleging failure to warn without supporting expert testimony on adequacy, claims predicated on delayed gastric emptying absent a confirmatory gastric emptying study, and claims for which there is no admissible evidence of general causation.

[111] Statement of Undisputed Facts ¶ 21.
[112] L.P. Ex. 29D, Lang Tr. at 115:19-116:4.

Dated: May 19, 2026

By: */s/ Loren H. Brown*

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**CERTIFICATE OF SERVICE**

I hereby certify that on May 19, 2026, a true copy of the foregoing Novo Nordisk's Memorandum of Law in Support of Motion for Summary Judgment as to General Causation and Adequacy of Labeling 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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