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	)	

DEFENDANTS ELI LILLY AND COMPANY AND LILLY USA, LLC'S INTRODUCTORY ROADMAP BRIEF TO ISSUE 2 AND 3 MOTIONS (1) TO EXCLUDE EXPERT OPINIONS AND (2) FOR SUMMARY JUDGMENT

Lilly submits this roadmap to facilitate the Court's review of its Rule 702 and summary judgment motions on Issue 2 (warning adequacy and federal preemption) and Issue 3 (general causation). Part I summarizes the medicines at issue, alleged injuries, experts, and legal issues. Part II identifies and respectfully suggests a proposed sequence to review Lilly's motions.

I. OVERVIEW OF ISSUE 2 AND ISSUE 3.

Lilly's GLP-1 RA medicines at issue in this MDL are (1) Trulicity (dulaglutide), approved in September 2014 to treat type 2 diabetes; (2) Mounjaro (tirzepatide), approved in May 2022 to treat type 2 diabetes; and (3) Zepbound (tirzepatide), approved in November 2023 for chronic weight management.[1] Plaintiffs claim Lilly failed to adequately warn about alleged side effects of these medicines, including gastroparesis, gallbladder disease (gallstones and inflammation), ileus (stopped bowel motility), intestinal obstruction (bowel blockage), and others.[2]

The **Issue 2** questions are whether (1) Plaintiffs can show that Lilly's FDA-approved labels failed to adequately warn prescribing physicians about these risks and/or (2) any claims are preempted. CMO 18, Dkt. No. 235 at ¶¶ 5, 12-14. Expert testimony generally is required to show that a warning is inadequate in pharmaceutical cases. *E.g.*, *LaBarre v. Bristol-Myers Squibb Co.*, 544 F. App'x 120, 125 (3d Cir. 2013).[3] Claims are preempted if there is either (1) insufficient "newly acquired information" that would have allowed a company to use the "changes being

[1] In 2020, Trulicity was approved to reduce risks of major adverse cardiovascular events in type 2 diabetes patients; In 2024, Zepbound was approved to treat obstructive sleep apnea in certain patients. Mounjaro and Zepbound are dual agonists; they activate the GLP-1 and the glucose-dependent insulinotropic polypeptide (GIP) hormone receptors.

[2] General causation (Issue 3) is limited to four alleged injuries: gastroparesis, ileus, small bowel obstruction, and gallbladder injuries. CMO 20 n.1; Dkt. No. 282. There is no injury limit for Issue 2. *See* CMO 18, Dkt. No. 235; Dkt. No. 674. Other alleged injuries include pancreatitis, malnutrition, micronutrient deficiencies, Wernicke's Encephalopathy, muscle wasting, dehydration, acute kidney injury, and aspiration.

[3] This Court recognized that "it is not clear that expert testimony is required to prove a failure-to-warn claim" (at least under Pennsylvania law) "[w]here any layperson can understand the insufficiency of a warning." *See Bloom v. Med. Depot, Inc.*, 2025 WL 2803913, at *20 n.17 (E.D. Pa. Sept. 30, 2025) (Marston, J.). But courts have required expert testimony in cases involving more complicated warnings, such as "where the allegedly defective product is a prescription medical device." *See Id.* (citing *Soufflas v. Zimmer, Inc.*, 474 F. Supp. 2d 737, 751 (E.D. Pa. 2007).

effected" regulation to unilaterally change an FDA-approved label; or (2) "clear evidence" FDA would have rejected a different warning. *In re Fosamax*, 118 F. 4th 322, 330-31 (3d Cir. 2024); *Wyeth v. Levine*, 555 U.S. 555 (2009). Preemption is a legal issue for the Court to decide. *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 317-18 (2019).

Plaintiffs offer no expert opinions at all about warning inadequacy for a number of alleged injuries (*e.g.* malnutrition, pancreatitis). And the opinions they do offer are limited by condition, medicine, and/or time (*e.g.* gallbladder disease opinions apply only to Trulicity labels from December 2017 to June 2022). In particular, Plaintiffs offer opinions from:

- Dr. David Metz—a retired gastroenterologist who opines Lilly did not adequately warn of risks of *gastroparesis and impaired gastric emptying*;
- Dr. David Kessler—a former FDA Commissioner who opines that by 2017, Lilly should have added *ileus, severe constipation including fecal impaction, and intestinal obstruction* to Trulicity label Section 6.2 (Adverse Reactions – Postmarketing Experience);[4] and
- Dr. David Ross—a former FDA medical reviewer who opines that by December 2017, Lilly should have added *gallbladder disease (cholelithiasis (gallstones) and cholecystitis (gallbladder inflammation*)) to Trulicity label Section 5 (Warnings & Precautions).

Drs. Kessler and Ross offer no opinions related to tirzepatide (Mounjaro or Zepbound). Dr. Kessler's Trulicity opinions address only ileus (2017/2018-Nov. 2022) and intestinal obstruction and constipation including fecal impaction (2017/2018-Mar. 2026). Dr. Ross's Trulicity opinions address only gallbladder disease (and only for the period December 2017 through June 10, 2022).

The **Issue 3** question is whether there is sufficient admissible expert testimony on general causation—i.e. whether Plaintiffs have come forward with evidence creating a genuine issue of material fact that Lilly's medicines can cause the alleged side effects. *Zoloft (Sertraline*

[4] Plaintiffs confirmed that Dr. Kessler will not opine on label adequacy for Mounjaro or Zepbound, and he "is not offering an opinion about Lilly['s] Section 5 warnings" at summary judgment. Dkt. No. 655 at 6; *see also id.* at 6-7 (stating "any argument by Plaintiffs in summary judgment briefing under CMO 29 that the Section 5 Warning in the dulaglutide label was inadequate would rely on [ ] factual background and/or other evidence, and not upon expert opinion proffered by Dr. Kessler").

Hydrochloride) Prods. Liab. Litig., 176 F. Supp. 3d 483, 491 (E.D. Pa. 2016); *aff'd* 858 F.3d 787 (3d Cir. 2017). Expert testimony is required to show general causation. *Id.*

Plaintiffs disclosed eight experts who purport to offer opinions related to general causation:

- *Gastroparesis/impaired gastric emptying*: Dr. Metz opines GLP-1 RA medicines can cause "drug-induced gastroparesis" (which he defines as symptoms lasting up to six months after cessation of the medicine); he also opines that the "causality of prolonged symptoms of gastroparesis after cessation of a GLP-1 drug cannot be supported." Dr. Ma Somsouk, a gastroenterologist, opines that there is an association between gastroparesis and GLP-1 RA medicines; he was not asked to evaluate causation. Dr. Joseph Pisegna is a gastroenterologist who opines that it is biologically plausible that GLP-1 RA medicines can cause gastroparesis.

- *Ileus and intestinal obstruction*: Dr. Nilesh Lodhia and Dr. Binu John are gastroenterologists who opine that GLP-1 RA medicines can cause ileus and intestinal obstruction; they do not offer opinions for any individual Lilly medicine. Dr. Pisegna opines that it is biologically plausible that tirzepatide can cause ileus.

- *Gallbladder disease*: Dr. Gabriel Lang is a gastroenterologist who opines that GLP-1 RA medicines as class can cause gallbladder disease; he could not reliably conclude that a cause-and-effect relationship exists between individual Lilly medicines and gallbladder disease.

- *Mechanism of action*: Dr. Jeffery Lansman is a pharmacologist who opines that, because GLP-1 RAs have a "common cellular mechanism," risk profiles may be similar across the class.

- *Animal study data*: Dr. Kevin O'Brien is a veterinarian pathologist who opines on nonclinical animal studies.

In total, Plaintiffs disclosed ten experts with Lilly-related opinions.[5] Rule 702 requires Plaintiffs (as proponents of the testimony) to "demonstrate[] to the court that it is more likely than not" that the opinions satisfy the rule's requirements. Fed. R. Evid. 702; *see also* Adv. Comm. Note, 2023 Amendment. The Advisory Committee "emphasize[d]" that "[j]udicial gatekeeping is essential," as jurors may be unable to assess whether an expert's conclusions "go beyond" what the "basis and methodology may reliably support." *Id.*

[5] Dr. Metz purports to offer both warning adequacy and general causation opinions, so he is listed under both Issue 2 and Issue 3 experts. Plaintiffs withdrew Dr. David Madigan's expert report and opinions as to Lilly after his deposition.

II. PROPOSED ORDER OF REVIEW.

Lilly respectfully suggests the Court review the motions in the order set forth below.

● **Motion #1 to Exclude Gastroparesis General Causation Opinions** moves to exclude the opinions of (1) Dr. Metz that GLP-1 RAs can cause "drug-induced gastroparesis" (which he defines as symptoms lasting up to six months after cessation); (2) Dr. Somsouk that there is an association between GLP-1 RAs and gastroparesis; and (3) Dr. Pisegna that it is biologically plausible GLP-1 RAs could cause gastroparesis. Lilly suggests the Court review this motion first because it introduces Rule 702 and causation concepts relevant to gastroparesis claims (which still comprise more than 60% of the MDL cases against Lilly) and other alleged injuries.

● **Motion #2 for Summary Judgment on Gastroparesis Claims** illustrates the interplay between Rule 702 and Rule 56, and provides independent bases for summary judgment that apply across multiple injuries, including insufficient admissible expert evidence on causation (Mot. #1) and/or warning adequacy (Mot. #3) and failure to show any disputed material fact on general causation or warning adequacy (even if the Court considered the expert opinions). It also shows that claims are preempted where FDA considered and rejected additional gastroparesis warnings.

● **Motion #3 to Exclude Warning Adequacy and/or Preemption Opinions (David Metz, M.D. and David Ross, M.D.)** examines Rule 702 principles as relevant to labeling experts and moves to exclude the warning adequacy and/or preemption-related opinions of Dr. Metz (gastroparesis and impaired gastric emptying) and Dr. Ross (Trulicity gallbladder warnings).

● **Motion #4 to Exclude Warning Adequacy and/or Preemption Opinions (David Kessler, M.D.)** moves to exclude Dr. Kessler's warning adequacy and/or preemption-related opinions, including those related to ileus and intestinal obstruction.[6]

[6] As permitted by the Court, Lilly will file its Motion #4 brief addressing Dr. Kessler's opinions by May 27, 2026.

● **Motion #5 to Exclude Ileus and Obstruction General Causation Opinions** moves to exclude (1) the opinions of Drs. John and Lodhia that GLP-1 RA medicines can cause ileus and intestinal obstruction, and (2) Dr. Pisegna's biological plausibility opinion for ileus.

● **Motion #6 for Summary Judgment on Ileus and Obstruction Claims** seeks summary judgment on all ileus and obstruction claims based on lack of required admissible expert evidence on general causation (Mot. #5) and warning adequacy (Motion #4), and independently dispositive lack of triable fact issues on causation, warning adequacy, and preemption.

● **Joint Motion #7 to Exclude Dr. Lang, M.D.s Gallbladder Causation Opinions** moves to exclude opinions that GLP-1 RA medicines as a class (or any individual GLP-1 RA medicine, including Lilly's Trulicity, Mounjaro, and Zepbound) can cause gallbladder disease.

● **Motion #8 for Summary Judgment on Gallbladder Claims** seeks summary judgment on all gallbladder claims because expert opinions on general causation and warning adequacy opinions are inadmissible (Mot. ##7, 3) and there is no triable issue on causation, warning adequacy, or preemption.

● **Motion #9 for Summary Judgment on Non-Gastroparesis Gastrointestinal and Miscellaneous Claims** seeks summary judgment on other alleged injuries because the warnings are adequate as a matter of law, and no expert opines they are not. The claims also are preempted because there is clear evidence FDA would have rejected (and did reject) additional warnings (malnutrition, micronutrient deficiency, Wernicke's Encephalopathy, and muscle wasting) and because there is no newly acquired information to allow a unilateral label change (all claims).

● **Joint Motions ## 10 & 11 to Exclude the Opinions of Jeffry Lansman, Ph.D and Kevin O'Brien, V.M.D** move to exclude mechanism of action and animal studies opinions.[7]

[7] Motions #7, #10, and #11 are Joint motions submitted by both Novo Nordisk and Lilly.

Dated: May 19, 2026

Respectfully submitted,

/s/ Diana M. Watral

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CERTIFICATE OF SERVICE

I hereby certify that on May 19, 2026, a true and correct copy of the foregoing DEFENDANTS ELI LILLY AND COMPANY AND LILLY USA, LLC'S INTRODUCTORY ROADMAP BRIEF TO ISSUE 2 AND 3 MOTIONS (1) TO EXCLUDE EXPERT OPINIONS AND (2) 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.

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