

December 16, 2024

The Honorable Karen S. Marston
 United States District Court for the
 Eastern District of Pennsylvania
 601 Market Street
 Philadelphia, PA 19106

Re: *In re GLP-1 RAs Prod. Liab. Litig.*, MDL No. 3094: Defendants' Response to Plaintiffs'
 Dec. 11, 2024 Letter re Scheduling A Hearing on Cross-Cutting Issue No. 1 (ECF No. 303)

Dear Judge Marston:

Recognizing that “early motion practice on how to reliably diagnose gastroparesis will be a pivotal issue in this action,” the Court adopted a schedule that front-loaded expert discovery and Rule 702 motions on Issue 1 (reliable gastroparesis diagnosis). CMO Nos. 18, 19, 21, ECF Nos. 235, 269, 291. Defendants are prepared to proceed with the Issue 1 hearing in May 2025—the timeframe the Court proposed consistent with its cross-cutting-issues orders.

Plaintiffs now propose to defer the Issue 1 hearing for months, so they can (among other things) finish and use non-expert *company* discovery. ECF No. 303. Their request is contrary to the Court's orders prioritizing resolution of—and denying use of non-expert, company discovery for—Issue 1. As the Court explained more than four months ago, Issue 1 “is going to be decided based on [Plaintiffs'] experts and [Defendants'] experts.” 8.8.24 Hrg., ECF No. 227 at 16:8-9.

The Court should not reconsider an issue that was already “fully considered by the Court after it was repeatedly raised and argued by counsel.” *See* ECF No. 276 at 9. Defendants respectfully request the Court set the Issue 1 hearing for May 2025 now, with further guidance on the format at an appropriate time.

1. Delaying Issue 1 Resolution Will Undermine Cross-Cutting Issue Priority And Purpose.

The request to delay the hearing on and resolution of Issue 1 fundamentally is inconsistent with the Court's sequencing of cross-cutting issues. In July 2024 (five months ago), the Court summed up the centrality of gastroparesis diagnoses to this MDL: “[I]t seems like the claims in this case, in particular, the failure to warn claims are going to turn on plaintiffs' diagnosis and whether that diagnosis was one included in the label.” *See* 7.12.24 Hrg., ECF No. 224 at 18:7-11.

In CMO No. 18 (nearly four months ago), the Court underscored “the importance of proving gastroparesis specifically, as opposed to gastrointestinal symptoms generally, in this litigation.” CMO No. 18, ECF No. 235 at 4. The gastroparesis diagnosis is important because (among other things) “to the extent a symptom or illness was adequately warned for on the label, many Plaintiffs may find their failure to warn claims fail under the learned intermediary and similar doctrines.” *Id.* “[G]iven the proportion of Plaintiffs alleging gastroparesis and the potential importance of that diagnosis to Plaintiffs' failure to warn claims” the Court appropriately held that “an early decision on how to reliably diagnose that condition is appropriate.” *Id.*

Plaintiffs primarily argue the Court should delay the hearing on and resolution of Issue 1 because it “would be best to defer the hearing until the end of discovery” in light of “ongoing ... discovery that could possibly impact the Court's consideration of Issue No. 1.” ECF No. 303 at 2. They say they “continue to believe that discovery will uncover evidence relevant to Issue No. 1.” *Id.* But the Court already “decided this issue after fulsome discussion,” and “full[]

consideration by the Court after it was repeatedly raised and argued by counsel.” *See* ECF No. 276 at 9 (denying Plaintiffs’ motion to reconsider marketing discovery). The Court stated, “as to this issue now, I don’t think it’s the time;” Issue 1 “is going to be decided on your experts and their experts.” 8.8.24 Hrg., ECF No. 227 at 15:25-16:1, 16:8-9.¹ And Plaintiffs have already served Issue 1 expert reports, none of which relies on company-specific information or documents. The depositions of those experts will take place in late January or early February. The Court should not revisit the sequence and scope of Issue 1 discovery now.

In short, gastroparesis diagnosis requirements are a gating issue that will impact subsequent cross-cutting issues; shape fact discovery, expert reports, and Rule 702 briefing; and inform the scope of summary judgment briefing on cross-cutting Issue 2 (warning adequacy, preemption) and Issue 3 (general causation). Given the prevalence of pending and anticipated gastroparesis claims (which still make up over 80% of pending claims), resolving Issue 1 will help efficiently steer the course of this MDL.

2. No Good Cause Exists To Modify The Court’s Scheduling Orders.

The Court’s cross-cutting motion and scheduling orders contemplate that the parties would exchange Issue 1 expert reports, complete expert discovery, brief Rule 702 motions, and submit them for the Court’s consideration before fact discovery is completed on Issues 2 (warning adequacy/preemption) and 3 (general causation). Pursuant to CMO No. 18, the parties met and conferred and “jointly propose[d] deadlines for the exchange of expert reports, the taking of expert depositions, and the filing of Rule 702 motions” for Issue 1. CMO 18, ECF No. 235 at 4-5. At no point did the parties or the Court suggest that the resolution of Issue 1 would be delayed until after the close of discovery for Issues 2 and 3. Just the opposite. No good cause exists to change this sequencing or schedule now.

First, neither the format nor timing of the hearing is a surprise. More than four months ago, the Court said (in response to Plaintiffs’ attorney’s comment) that there “most likely” would be an evidentiary hearing on Issue 1. *See* 8.8.24 Hrg., ECF No. 227 at 14:1-4. Months ago, the Court adopted the parties’ jointly proposed schedule setting Issue 1 briefing for completion in April 2025. CMO Nos. 20, 21, ECF Nos. 282, 291. The Court scheduled Issues 2 and 3 to lag Issue 1, with discovery (including certain company discovery) extending through July 2, 2025. *Id.*

Second, Defendants do not oppose reasonable schedule adjustments (and both Defendants and Plaintiffs have already consented to such requests in this MDL). The Court also has been flexible and accommodating. As to the Issue 1 hearing in particular, the Court noted that, while it “prefer[s] live witnesses. ... we can certainly do them by Zoom or Teams or whatever the video conferencing is, if that becomes necessary.” 12.6.24 Hrg.at 6:4-7. But the instant request is not

¹ In July 2024, Plaintiffs argued that, to respond to “a proposed ‘cross-cutting motion’ by Defendants on the topic of a gastroparesis diagnosis ... Discovery would also be required of Defendants in order to determine the corporate conduct and methods by which gastroparesis was (or was not) considered and diagnosed in clinical studies and was (or was not) addressed and reported to the FDA.” ECF No. 175 at 3. In August 2024, Plaintiffs’ counsel advocated for discovery “on gastroparesis diagnosis within the company,” but ultimately *conceded* that company discovery “is not something that we feel our experts must have for presenting to the court their opinions on this issue” and that their “experts don’t need that to proceed to offer their opinions and the methodologies that they think can lead to a diagnosis of this ailment.” 8.8.24 Hrg., ECF No. 227 at 9:3-10:1, 11:16-18, 15:7-9.

reasonable. Plaintiffs ask to postpone the hearing until their work on Issue 2 and 3 discovery and experts is done. ECF No. 303 at 2. This is problematic because Issue 1 will inform the scope of Issue 2 and 3 discovery and expert opinions. Delaying Issue 1 could result in amended Issue 2 and 3 expert reports and jeopardize the cross-cutting issue schedule. Further, if the Court were to postpone the hearing until after Plaintiffs' Issue 2 and 3 expert reports, then the hearing would instead overlap with other workstreams—including Defendants' preparation of their experts and discovery of Plaintiffs' experts. In other words, there will likely be multiple projects ongoing at the same time no matter when the hearing occurs.

Plaintiffs have disclosed only three experts. Defendants are confident that the experienced and well-resourced Plaintiffs Lead Counsel and other law firms are fully capable of handling overlapping work needed to resolve the cases they chose to file, as is common in MDLs.

* * *

The Court should reject Plaintiffs' request to delay the Issue 1 hearing or otherwise expand the scope of Issue 1 beyond the scientific, expert-driven gastroparesis-diagnosis question before the Court. Defendants look forward to addressing these issues at the December 17, 2024 hearing.

Respectfully Submitted,

/s/ Samuel W. Silver

Samuel W. Silver (PA Bar No. 56596)
Catherine M. Recker (PA Bar No. 56813)
Bruce P. Merenstein (PA Bar No. 82609)
Abigail T. Burton (PA Bar No. 334450)
WELSH & RECKER, P.C.
306 Walnut Street
Philadelphia, PA 19106
Telephone: (215) 972-6430
Facsimile: (985) 617-1021
ssilver@welshrecker.com
cmrecker@welshrecker.com
bmerenstein@welshrecker.com
aburton@welshrecker.com

James F. Hurst, P.C.
Mark Premo-Hopkins, P.C.
Renee D. Smith
Diana M. Watral, P.C.
KIRKLAND & ELLIS LLP
300 North LaSalle
Chicago, IL 60654
Telephone: (312) 862-2000
Facsimile: (312) 862-2200
james.hurst@kirkland.com
mark.premohopkins@kirkland.com
renee.smith@kirkland.com
diana.watral@kirkland.com

Attorneys for Eli Lilly and Company

/s/ Loren H. Brown

Loren H. Brown
Lucas P. Przymusinski
DLA PIPER LLP (US)
1251 Avenue of the Americas
27th Floor
New York, NY 10020-1104
Telephone: (212) 335-4846
Facsimile: (212) 335-4501
loren.brown@us.dlapiper.com
lucas.przymusinski@us.dlapiper.com

Ilana H. Eisenstein (PA Bar No. 94907)
Raymond M. Williams (PA Bar No. 90771)
Rachel A.H. Horton (PA Bar No. 316482)
DLA PIPER LLP (US)
1650 Market Street, Suite 5000
Philadelphia, PA 19103
Telephone: (215) 656-3300
Facsimile: (215) 606-3301
ilana.eisenstein@us.dlapiper.com
raymond.williams@us.dlapiper.com
rachel.horton@us.dlapiper.com

Matthew A. Holian
Katherine W. Insogna
DLA PIPER LLP (US)
33 Arch Street, 26th Floor
Boston, MA 02110
Telephone: (617) 406-6000
Facsimile: (617) 406-6100
matt.holian@us.dlapiper.com
katie.insogna@us.dlapiper.com

*Attorneys for Novo Nordisk A/S, Novo Nordisk
North America Operations A/S, Novo Nordisk
US Holdings, Inc., Novo Nordisk US
Commercial Holdings, Inc., Novo Nordisk, Inc.,
Novo Nordisk Research Center Seattle, Inc., and
Novo Nordisk Pharmaceutical Industries, LP*

cc: MDL Counsel of Record