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**
THIS DOCUMENT RELATES TO:	:	**MDL No. 3094**
	:	**24-md-3094**
ALL ACTIONS/ALL CASES	:	

MEMORANDUM

MARSTON, J. **October 17, 2024**

This MDL involves personal injury actions stemming from the use of glucagon-like peptide-1 (GLP-1) receptor agonists and GLP-1/glucose-dependent insulinotropic polypeptide (GIP) dual receptor agonists (collectively, "GLP-1 RAs") manufactured by Defendants and sold under the brand names Ozempic, Wegovy, Rybelsus, Trulicity, and Mounjaro.[1] (Doc. No. 1.) Each Plaintiff claims they were prescribed one or more of the five identified drugs for the treatment of type 2 diabetes and/or long-term weight management and that as a result, they suffered gastrointestinal symptoms and/or injuries, such as gastroparesis, ileus/intestinal obstruction, cholecystitis, and severe nausea and vomiting.[2]

The MDL is in the early stages of discovery. Most recently, the Court granted Defendants' motion to bifurcate discovery and allow early motion practice on two "cross

[1] Ozempic, Wegovy, and Rybelsus are manufactured by the Novo Nordisk Defendants, and Trulicity and Mounjaro are manufactured by Defendant Eli Lilly and Company. Cases involving a sixth GLP-1 RA, named Saxenda, are also being considered by the Judicial Panel on Multidistrict Litigation (JPML) for inclusion in this MDL. (*See* Doc. No. 201.)

[2] The Court has stayed two individual cases in which the plaintiffs allegedly suffered veinous thromboembolisms after using one of the identified GLP-1 RAs. (*See* Doc. No. 207.) The parties are currently seeking permission from the JPML to include these and similar cases in this MDL. At this time, however, the MDL is limited to cases alleging gastrointestinal injuries. (*See* Doc. No. 1 at 2.)

cutting" issues: (1) gastroparesis diagnostic testing and (2) preemption and adequacy of warnings. (*See* Doc. No. 235; *see also* Doc. No. 175.)[3] In deciding that motion, the Court rejected Plaintiffs' argument that to decide preemption and warning adequacy, the Court will need to consider the legal effect, if any, of Defendants' campaign to market the drugs at issue. (Doc. No. 235 at 9–10.) The Court explained that although Defendants' marketing to a specific Plaintiff or in a specific state may ultimately be relevant discovery later in this litigation, the parties should refrain from pursuing discovery into Defendants' marketing campaigns for now. (*Id.* at 10 n.9.) Plaintiffs now move for reconsideration of that ruling. (Doc. No. 245.) Defendants oppose Plaintiffs' motion. (Doc. No. 254.) The parties presented argument during status conferences on September 23, 2024 and October 15, 2024.

I. LEGAL STANDARD

Before turning to the parties' arguments, the Court must first determine what standard governs Plaintiffs' motion. Defendants argue that Plaintiffs' motion seeks reconsideration of an issue previously presented to and decided by the Court, and is, therefore, governed by the standard applicable to such motions under Federal Rule of Civil Procedure 59(e). (Doc. No. 254 at 7.) Plaintiffs disagree, arguing that the "Court should view the instant motion not as reconsideration but as the first full hearing on this matter." (Doc. No. 245-1 at 8.) Plaintiffs reason that the "preclusion of marketing discovery was not decided after a full development and submission of the arguments as to why so-called 'marketing' discovery is relevant to the preemption and adequacy of the warnings issues." (*Id.* at 5.) The record refutes Plaintiffs' argument.

[3] The Court reserved ruling on whether early discovery and motion practice should also proceed as to a third issue, general causation. (Doc. No. 235 at 11.)

A. Timeline of Marketing Arguments

Contrary to Plaintiff's assertion, the Court considered at length whether to allow early discovery into Defendants' marketing practices.

1. July 3 Briefing on Cross Cutting Issues

The issue was first mentioned in Plaintiffs' letter brief opposing bifurcated discovery. Defendants had argued that the Court should "prioritize the resolution of three pivotal questions," which they refer to as "cross cutting" issues: (1) gastroparesis diagnostic testing, (2) preemption and adequacy of warnings, and (3) general causation. (Doc. No. 174.) Plaintiffs' opposition brief, which was 15 single-spaced pages, argued that the Court should instead select six bellwether cases and allow general and case-specific discovery to proceed simultaneously as to those Plaintiffs. (Doc. No. 175.) Of note, Plaintiffs argued that the Court should not allow early motions on "whether the labels" approved for each of the subject drugs "are adequate as a matter of law" because that legal question:

> must be addressed in the context of individual plaintiff's claims, including, for example, failure-to-warn claims. Discovery on such claims will properly include discovery of plaintiffs' and their physicians' knowledge of and understanding of the contents of the label. That discovery should proceed alongside—because it may inform and be informed by—discovery of what Defendants themselves understood about the risks of these drugs, *of their relentless and multifaceted marketing of the drugs, and how such marketing may have affected a plaintiff's or physician's understanding of the labels*. Rather than artificially separate or phase those related areas of discovery, the parties should proceed with comprehensive bellwether discovery.

(*Id.* at 12 (emphasis added).) Plaintiffs did not otherwise discuss marketing in their letter brief.

Despite the limited discussion of marketing discovery, the issue became the main point of contention in each subsequent hearing when the Court discussed the parties' competing proposals.

2. July 10 Oral Argument on Cross Cutting Issues

During the July 10, 2024 status conference, the Court held oral argument on whether to allow early discovery and motion practice on the cross cutting issues identified by Defendants. Plaintiffs' counsel opened his presentation by saying: "Plaintiffs allege that the Defendants aggressively marketed a type of drug that is at issue in these cases by targeting individuals online through TV ads, through unprecedented amounts of money." (July 10, 2024 Hr'g. Tr. at 50:4–8.) He later reiterated Plaintiffs' belief that marketing permeated the legal issues at play:

> I raise this now so that Your Honor understands that *this marketing and promotion effort pervades every element of the claims involved in this case*. So when we talk about issues that the Defendants claim to be cross cutting, when they call it warnings, when they talk about FDA preemption, when they talk about causation, when they talk about the diagnosis of individual patients and specific causation, we think that there is—that they have covered so many issues, the waterfront, if you will, that there is no way for us to follow the path the defendant suggests.

(*Id.* at 52:11–21 (emphasis added).)

Defense counsel for Novo Nordisk responded to these arguments by saying, "I know there are a number of marketing allegations made at the outset of the argument, and we will certainly contest those allegations at the right time. But we don't believe that should influence the timing or the viability of the motions that we have identified in this brief . . . ." (*Id.* at 68:20–25.) To which, Plaintiffs replied on rebuttal, "[T]he discovery that [Defendants] are calling targeted and phased is really discovery on the entire case, because there is no way to look at labeling without talking about marketing. There is no way because what they say to the world is part and parcel of the marketing case . . . ." (*Id.* at 99:8–13.)

3. July 26 Status Conference

Because neither party had meaningfully discussed marketing discovery in their briefs, the Court continued to probe the issue in the next few conference calls with counsel.

During the July 26, 2024 status conference, the Court asked counsel, "If I allow the discovery in the early motion practice on [preemption and adequacy of warnings], are we going to have to address the marketing concerns raised by the plaintiffs?" (July 26, 2024 Hr'g. Tr. at 8:18–21.) Defendants claimed such discovery was not necessary and allowing it would negatively "impact the efficiency of the process." (*Id.* at 9:2–4.) Plaintiffs, however, responded, "We think that the marketing claims as well as certain third-party relationships are directly at issue . . . when we are talking about side effects. . . . We also think that this evidence obviously goes towards whether or not the claims are preempted. . . . So we think that there is a variety of reasons that these are germane to these issues that the defendants call cross cutting." (*Id.* at 9:21–10:16.)

Next, the Court asked whether summary judgment on preemption and label adequacy would "require us to consider the effects of marketing on the learned intermediary doctrine." (*Id.* at 10:20–22.)[4] Plaintiffs argued:

> Yes, Your Honor. We think that that is directly at issue for a couple of reasons. First of all, what the learned intermediary knew. So the learned intermediary is a way that the defendants discharged their obligation, but it does not relieve them of the obligation to properly warn. . . . And then finally, we believe that the defendants in these cases undertook a direct duty to warn the patients directly. And so we are not sure that the learned intermediary is going to govern *because of these direct consumer marketing attempts*.

(*Id.* at 10:23–11:17 (emphasis added).) Plaintiffs also noted, "[T]he marketing from a regulatory perspective can undermine any warnings that are provided. So . . . as an alternative argument, the marketing here, and given especially the scope of the marketing, if it does not adequately

[4] "Under the learned intermediary doctrine, drug manufacturers must direct required drug-safety warnings to physicians, and not to patients." *Zitney v. Wyeth LLC*, 243 A.3d 241, 246 (Pa. Super. Ct. 2020).

balance the benefits and the risks of the drugs from a regulatory perspective, the warning can be relatively ineffective." (*Id.* at 12:4–12.) Defendants continued to vehemently disagree with the notion that marketing discovery was needed for the Court to decide the limited issue of whether "as a matter of law, . . . the warnings in the label are adequate." (*Id.* at 12:19–21.)

4. August 2 Status Conference

One week later, on August 2, 2024, the issue was discussed again. Defense counsel for Eli Lilly asked to follow up on the Court's questions from the previous week "with regard to adequacy of labeling" and Plaintiffs' response that Defendants had an obligation to warn that ran "directly to patients," as opposed to the prescribing physician. (Aug. 2, 2024 Hr'g. Tr. at 7:2–5.) Defendants explained that they had "looked at the law" and found that "in Pennsylvania, the learned intermediary doctrine is strictly applied . . . [t]here is no direct consumer exception to a learned intermediary doctrine under Pennsylvania law. And in the last 25 years . . . since the state of New Jersey adopted a very narrow exception, no other state has adopted any sort of exception for direct consumer advertising under the learned intermediary doctrine." (*Id.* at 7:8–18.) Defense counsel then cited a few cases which decided "adequacy of warning as a matter of law" by looking to the warnings given to the medical provider through the produce label and not to "any specific warning to the patient directly." (*Id.* at 7:19–8:7.)

Plaintiffs responded that nothing in the law on learned intermediary doctrine rendered the marketing discovery irrelevant to deciding the early preemption issue:

> [N]one of this changes the fact that any warning on the label can be diluted or watered down . . . by the marketing. And we know that this is one of the most unprecedented marketing campaigns that Novo, and Lilly to a lesser extent, has engaged in per the marketing of these drugs. So regardless of the warning that was on the label, which we maintain was not adequate, the marketing can change that.

(*Id.* at 9:16–24.)

Defense counsel for Novo Nordisk disagreed with Plaintiffs' interpretation, explaining that a marketing campaign "does not create an end run around a learned intermediary doctrine" in the prescription drug context. (*Id.* at 10:11–14.) And to the extent marketing may ultimately be relevant in this action, that discovery should occur later:

> [T]o the extent to which they are arguing that non-labeling claims were either misrepresentations or that that was the source of the harm, that's going to be specific to the claim, to the consumer, and to the particular advertisement that allegedly that particular consumer or patient saw and acted upon in some way, shape or form. It's not part of the product liability claims as a failure to warn in a product liability and prescription drug context. . . . And so I wanted to note that, because I think why we are talking about this is with respect to whether it makes sense to address these issues as a cross cutting matter up front. And the answer to that is yes, because the learned intermediary doctrine, the adequacy issues will substantially narrow these cases. If there are individualized cases that fall outside of it because some consumer claims they saw a particular misrepresentation, that is a far narrower case than what they are asserting here and [in] the hundreds of cases that have been filed . . . . [T]he[ir] claim that there may be some limited relevance to marketing . . . comes down the line.

(*Id.* at 10:15–11:14.)

Plaintiffs disagreed, arguing again that although defense counsel's assertions "might be true in a case where the marketing was more limited," Plaintiffs' "marketing allegations" here "are much broader." (*Id.* at 11:20.) Specifically, Plaintiffs allege "that the marketing that was done here has changed the process of medicine, changed how users are treated and how it has a much broader influence than you might see in other cases where there is just marketing that a sales representative may do on a more limited level to a doctor that influences his understanding of the risks and benefits of the drugs." (*Id.* at 11:20–12:2.)

After this discussion, the Court requested copies of the cases discussed by counsel during the call.

5. August 23 Case Management Order No. 18

On August 23, 2024, the Court granted Defendants' request for bifurcated discovery as to cross cutting issues 1 and 2. (*See* Doc. No. 235.) Case Management Order No. 18 ("CMO 18") notes that in deciding this issue, the Court considered the arguments raised in the parties' July 3 letter briefs as well as the arguments "made by counsel during status conferences on July 10, July 26, and August 2." (*Id.* at 1.) This included Plaintiffs' argument that any early motion on preemption and warning adequacy required consideration of Defendants' extensive marketing campaign:

> During oral argument on these issues—and after the parties' submitted their letter briefs—Plaintiffs argued for the first time that early discovery and motion practice on Issue 2 is inappropriate because the adequacy of warnings is not just a question of preemption. Plaintiffs assert that, instead, the issue also necessarily involves consideration of the applicability of the learned intermediary doctrine and consideration of the legal effect, if any, of Defendants' unique and substantial campaign to market the GLP-1 RAs directly to consumers. To the extent these issues arise during motion practice on Issue 2—and the Court believes that they will—the Court still finds that the issues are cross cutting and worth deciding at an early stage. Notably, both the viability of the learned intermediary doctrine and the availability of Plaintiffs' direct-to-consumer marketing argument, are legal questions that turn on interpretations of state law and do not require significant discovery beyond what is already being provided in connection with preemption and labeling adequacy mentioned above.

(*Id.* at 9–10 (citations omitted).) The Court went on to explain, in a footnote:

> For example, if a state has adopted the learned intermediary or a similar doctrine, then the Court looks only to the label to determine whether the medical provider was adequately warned, and Defendants' marketing campaign may be irrelevant to that analysis. Although Plaintiffs argue that the Court will be able to look beyond the label to consider marketing because Defendants marketed these drugs directly to consumers, some states have explicitly rejected an advertising exception to the learned intermediary doctrine. The Court, however, defers ruling on this legal issue until we consider the parties' briefing on summary judgment as to Issue 2.

(*Id.* at 10 n.8 (citations omitted).) The Court clarified that we were not foreclosing marketing discovery for good. Instead, we delayed discovery into the Defendants' marketing campaigns until after the Court ruled on the preliminary cross cutting issues:

> As noted above, although Defendants' marketing to a specific Plaintiff or in a specific state may ultimately be relevant discovery once the Court decides these issues and reaches the bellwether stage of discovery, the parties should refrain from pursuing discovery into Defendants' marketing campaigns during early discovery on Issue 2. Such issues are best left until after the Court rules on whether, as a matter of law, any Plaintiff may assert a claim for failure to warn based in whole or in part on a manufacturer's direct-to-consumer marketing.

(*Id.* at 10 n.9.)

B. Analysis

As this summary shows, the record refutes any suggestion that marketing discovery "was not decided after a full development and submission of the arguments." The purpose of the letter briefs, oral argument, and follow-up calls was to determine whether early limited discovery should occur in this MDL. During those discussions, Plaintiffs vehemently argued that the Court should not bifurcate discovery but should allow all discovery to occur now, *including discovery on marketing*.[5] The Court rejected that proposal. We agreed with Defendants that early discovery on only a few key issues was appropriate and reasoned that Plaintiffs were not entitled to discovery on Defendants' marketing campaigns for now. Because the Court decided this issue after fulsome discussion, Plaintiffs' motion is properly characterized as a motion for reconsideration. *See Suharyono v. Att'y Gen. of U.S.*, 274 F. App'x 202, 204 (3d Cir. 2008) (finding lower tribunal did not abuse its discretion when it construed a motion challenging a

[5] Plaintiffs flag that the need for marketing discovery has not been *briefed*. But the fact that marketing was not meaningfully mentioned in Plaintiffs' lengthy letter brief does not mean that it was not fully considered by the Court after it was repeatedly raised and argued by counsel.

prior ruling as a motion for reconsideration); *H. Douglas & Assoc., LLC v. V.I. Conference*, Civil No. 2007–28, 2009 WL 564205, at *1 n.1 (D.V.I. Mar. 5, 2009) ("The instant motion touches on matters relating to the substance of the July 30, 2008, ruling. As such, the motion is more properly characterized as one for reconsideration.").

Motions for reconsideration are typically considered pursuant to Federal Rule of Civil Procedure 59(e).[6] *See* Fed. R. Civ. P. 59(e) (referring to a "motion to alter or amend judgment"). "The purpose of a motion for reconsideration is to correct manifest errors of law or to present newly discovered evidence." *Harsco Corp. v. Zlotnicki*, 779 F.2d 906, 909 (3d Cir. 1985). "Out of consideration for finality and judicial economy," courts grant motions for reconsideration "sparingly." *Hatcher v. SCM Grp. N. Am., Inc.*, 167 F. Supp. 3d 719, 728 (E.D. Pa. 2016) (citation omitted). The Third Circuit has identified three bases for altering a prior order: "(1) an intervening change in controlling law; (2) the availability of new evidence; or (3) the need to correct a clear error of law or prevent manifest injustice." *Allah v. Ricci*, 532 F. App'x 48, 51 (3d Cir. 2013) (quoting *Lazaridis v. Wehmer*, 591 F.3d 666, 669 (3d Cir. 2010)); *see also Max's*

[6] Plaintiffs suggest that Rule 54(b), not Rule 59(e), governs their motion to the extent the Court views it as seeking reconsideration. (Doc. No. 245-1 at 8.) Rule 54(b) states, "any order or other decision, however designated, that adjudicates fewer than all the claims or the rights and liabilities of fewer than all the parties does not end the action as to any of the claims or parties and may be revised at any time before the entry of a judgment adjudicating all the claims and all the parties' rights and liabilities." Some district courts in this Circuit have held that Rule 59(e) does not govern motions to reconsider interlocutory orders. *See, e.g.*, *Askew v. R.L. Reppert*, Civil Action No. 11-cv-04003, 2016 WL 749945, at *1 (E.D. Pa. Feb. 26, 2016) ("Ordinarily, a motion for reconsideration may be decided under either Federal Rule of Civil Procedure 59 or 60. However, neither Rule 59 or 60 applies here, because this court's February 5, 2016 Order and Opinion is not a final, appealable order that conclusively resolves all of the claims at issue in this case."). The distinction is largely immaterial, however, because even when a motion to reconsider is brought pursuant to a court's "power over interlocutory orders," courts apply the standard of review for a motion to reconsider under Rule 59(e). *Id.* (quoting *Bridges v. Colvin*, No. 5:12-cv-02316, 2015 WL 5737353, at *4 (E.D. Pa. Sept. 30, 2015)); *see also, e.g.*, *JHNY Corp. v. Dana Corp.*, Civil Action No. 2:05-CV-02829, 2006 WL 8459415, at *1 (E.D. Pa. May 24, 2006) ("A court may exercise its power under Rule 54(b) and revise an interlocutory order whenever 'justice requires.' In general, justice requires the re-evaluation of an interlocutory order upon satisfaction of the Rule 59(e) standard for reconsideration . . . ." (citations omitted)).

Seafood Café ex rel. Lou-Ann, Inc. v. Quinteros, 176 F.3d 669, 677 (3d Cir. 1999). Plaintiffs move under the third prong—the need to correct a clear error of law or prevent manifest injustice. (Doc. No. 256 at 12–13.)

A clear error of law exists if "after reviewing the evidence, [the court is] left with a definite and firm conviction that a mistake has been committed." *Norristown Area Sch. Dist. v. F.C.*, 636 F. App'x 857, 861 n.8 (3d Cir. 2016). This error must have been committed by the court, not counsel. *See United States v. Jasin*, 292 F. Supp. 2d 670, 676 (E.D. Pa. 2003) ("In order to show clear error or manifest injustice, the [moving party] must base its motion on arguments that were *previously raised* but were overlooked by the Court.'" (emphasis added)); *Digneo v. City of Philadelphia*, Civil No. 07-2372, 2008 WL 11515930, at *1 n.1 (E.D. Pa. June 13, 2008) ("[A] Motion for Reconsideration cannot be granted based on . . . newly raised arguments that could have previously been asserted.").

There is a "dearth of case law within the Third Circuit" on the meaning of "manifest injustice." *Conway v. A.I. Dupont Hosp. for Child.*, Civ. Action No. 04-4862, 2009 WL 1492178, at *6–7 (E.D. Pa. May 26, 2009). It is "clear," however, "that the standard is a high one." *Id.* And it is not met when the party merely asks the court "to rescue parties from their own errors." *Id.* at *7; *cf. PBI Performance Prods., Inc. v. NorFab Corp.*, 514 F. Supp. 2d 732, 744 (E.D. Pa. 2007) ("A litigant . . . may not use a motion for reconsideration either to attempt a new approach or to correct mistakes it made in its previous one. A motion for reconsideration should not be used as a means to argue new facts or issues that inexcusably were not presented to the court in the matter previously decided." (quotation marks and citation omitted)).

II. DISCUSSION

Plaintiffs recycle their prior argument that "a pharmaceutical company's marketing and promotional efforts are relevant to whether the company failed to provide an adequate warning."

(Doc. No. 245-1 at 9.) Plaintiffs have altered the argument, however, and now focus on Defendants' marketing to *physicians* as opposed to their marketing to *consumers*. (*Id.* at 6.) The Court strongly questions whether this satisfies the standard for reconsideration. *See, e.g.*, *PBI Performance Prods., Inc.*, 514 F. Supp. 2d at 744 ("A litigant . . . may not use a motion for reconsideration either to attempt a new approach or to correct mistakes it made in its previous one. A motion for reconsideration should not be used as a means to argue new facts or issues that inexcusably were not presented to the court in the matter previously decided." (quotation marks and citation omitted)); *Kennedy Indus.*, 2006 WL 1892685, at *1 (same); *see also Digneo v. City of Philadelphia*, 2008 WL 11515930, at *1 n.1 ("[A] Motion for Reconsideration cannot be granted based on . . . newly raised arguments that could have previously been asserted"); *accord United States v. Jasin*, 292 F. Supp. 2d 670, 676 (E.D. Pa. 2003) ("In order to show clear error or manifest injustice, the [moving party] must base its motion on arguments that were *previously raised* but were overlooked by the Court." (emphasis added)).

The Court will nevertheless address two of Plaintiffs' arguments to clear up any remaining confusion about CMO 18.

A. Relevance to Label Adequacy

First, the Court rejects Plaintiffs' assertion that marketing discovery of any kind (whether directed at consumers or physicians) is relevant to early discovery and motion practice on the narrow issues presented at this stage:

> (1) whether the Court can rule as a matter of law that Defendants' labels adequately warn for the gastrointestinal symptoms and events common to all Plaintiffs (i.e., label adequacy), and (2) whether Defendants should have (or could have) revised their labels to provide additional warnings which Plaintiffs argue were required as a matter of state law (i.e., preemption).

(Doc. No. 235 at 8.) As the Court has already explained, "to answer those questions the Court will need to know the drug at issue in the case, the warning label at issue, . . . the alleged deficiencies on the particular warning, what was provided to the FDA, and more importantly what was withheld from the FDA." (*Id.* (quotation marks omitted).) The Court does not need to consider Defendants' marketing campaigns.

Plaintiffs, citing *In re Avandia Marketing, Sales Practices and Products Liability Litigation*, argue that marketing directed to physicians is needed for the Court to determine whether the drug labels adequately warn for the symptoms and injuries that Plaintiffs experienced. (Doc. No. 245-1 at 11.) But a closer look at that case shows that although the court discussed the manufacturers' marketing campaigns, that discussion was separate from the court's initial ruling on the adequacy of the drug labels.

Like this action, *In re Avandia* is an MDL that involved failure to warn claims in the prescription drug context, and at summary judgment, the court considered "the adequacy of Avandia's label warnings regarding congestive heart failure ('CHF')." *See* 817 F. Supp. 2d 535, 537 (E.D. Pa. 2011). In deciding the adequacy question, the court focused on the text of the label and the manufacturer's knowledge. First, the court considered the warnings given in the label, including a discussion of clinical trials that suggested "only patients using Avandia with insulin were at risk" of suffering from CHF. *Id.* at 553. Second, the court looked to evidence which showed the manufacturer "knew that some studies indicated a signal of increased CHF" when the participants used Avandia on its own, but the manufacturer failed to include data on those studies in the Avandia label. *Id.* at 553–54. Finally, the court noted that the manufacturer "was aware" that animal studies had "demonstrated an association between Avandia and the thickening of heart muscles and fluid retention," signaling that "additional studies were needed

to explain the association." *Id.* at 554. Given this evidence, the court held that it "cannot conclude, as a matter of law," that the label's warnings were "clear, complete and unambiguous as to the risk of CHF from Avandia." *Id.* at 554–55; *see also id.* at 555 ("A reasonable jury could conclude that the inclusion of only clinical data for insulin combination therapy trials, the exclusion of clinical data showing a higher incidence of edema than that provided in the 'Precautions' section of the label, and the only indirect warning regarding CHF rendered the 2001 label inadequate.").

The court then turned to the manufacturer's "marketing communications," which showed the manufacturer had taken steps to "dissociate edema," which was associated with using Avandia, "from CHF." *Id.* at 555. The court found that "a reasonable jury in a jurisdiction recognizing an overpromotion exception" to the learned intermediary doctrine "could conclude that [the manufacturer's] efforts to dissociate edema from CHF diluted the effect of the [label's] warning about the relationship between edema and CHF." *Id.* (emphasis added).

As this discussion shows, there are two separate but related sets of issues when it comes to warning adequacy. First, does the label on its face adequately warn of an alleged injury, and if not, was the manufacturer foreclosed from adding such a warning? Second, if the state law claims are not preempted, does the learned intermediary doctrine apply, and if so, in jurisdictions recognizing an overpromotion exception, was an adequate warning in the label nevertheless diluted by the manufacturer's marketing efforts to physicians? *See id.*; *see also In re Testosterone Replacement Therapy Prods. Liab. Litig. Coordinated Pretrial Proceedings*, Case No. 14 C 1748, MDL No. 2545, 2017 WL 1836435, at *7–11, *15 (N.D. Ill. May 8, 2017) (considering preemption and whether the FDA-approved label on its face provided adequate

warning of relevant injuries before turning to the applicability of learned intermediary doctrine and potential marketing exceptions).

Here, the Court has granted early discovery and motion practice as to the first set of issues as it relates to the preemption analysis because a ruling on those two issues could greatly inform the nature and scope of all the failure to warn claims in this MDL. (*See* Doc. No. 235 at 9 ("A ruling, for example, that a given label, as a matter of law, adequately warned for gastroparesis or that federal law preempts state law claims to the extent state law would have required the addition of a gastroparesis warning, could limit many of the claims in this MDL or at minimum, *hone the parties' arguments as they relate to Defendants' alleged failure to warn*." (emphasis added)). The Court has declined, however, to allow early discovery and motion practice as to the second set of issues because they need not be decided unless the Court finds that the state law claims survive preemption and even then, those issues only affect some of the cases in this lawsuit. (*See id.* at 9–10 & n.8 (explaining that whether marketing information is relevant and to what extent is a legal question that varies by jurisdiction and deferring any ruling until after the Court rules on Issue 2)); *see also In re Avandia*, 817 F. Supp. 2d at 555 ("[A] reasonable jury *in a jurisdiction recognizing an overpromotion exception*[7] could conclude that [the manufacturer's] efforts to dissociate edema from CHF diluted the effect of the [label's] warning about the relationship between edema and CHF." (emphasis added)); *Patteson v. AstraZeneca, LP*, 876 F. Supp. 2d 27, 35 (D.D.C. 2012) ("Plaintiffs further argue that AstraZeneca should not be permitted to invoke the learned-intermediary doctrine where the drug

[7] In *In re Avandia*, the court found that although Pennsylvania has "adopted an 'overpromotion' exception to the learned intermediary doctrine, under which a drug manufacturer may be held liable for inadequate warnings where marketing representations dilute the warnings of an otherwise adequate label," it was "unclear" whether any other state at issue in the MDL had adopted a similar exception. *Id.* at 555 n.108; *see also Pierce*, 2005 WL 2561479, at *3.

manufacturer has 'overpromoted' the drug and 'eroded the effectiveness of otherwise adequate warnings,' through its 'aggressive marketing tactics.' *In jurisdictions recognizing this exception*, the 'overpromotion of a product negates any warnings,' such that a manufacturer of the product cannot avail itself of the doctrine." (emphasis added) (cleaned up)); *In re Zyprexa Prods. Liab. Litig.*, 649 F. Supp. 2d 18, 33 (E.D. N.Y. 2009) ("In *unusual cases*, courts have found that a drug manufacturer's excessive promotion of its product may negate or call into question operation of the learned intermediary doctrine." (emphasis added)). *But see In re Testosterone Replacement Therapy*, 2017 WL 1836435, at *16 ("Many states apply the overpromotion theory, under which a manufacturer can be liable for failure to warn even when the warnings were adequate if it engaged in an advertising campaign that in effect negated the warnings.").[8]

B. "Labeling" Defined

Next, Plaintiffs argue that they are entitled to this physician-centered marketing discovery because the Food, Drug, and Cosmetics Act ("FDCA") and its implementing regulations broadly define the term "labeling" to include such promotional materials. (Doc. No. 256 at 7–12; Sept. 23, 2024 Hr'g. Tr. at 13:2–22:22.) Plaintiffs are correct that the FDCA broadly defines

[8] The Court's initial research also suggests that even in those jurisdictions that recognize the learned intermediary doctrine and an overpromotion exception to that doctrine, the effect of any marketing campaign on the Court's causation analysis will be individualized, i.e., each individual plaintiff will have to show "that such overpromotion caused the physician to initiate or maintain the prescription at issue." *See In re Zyprexa*, 649 F. Supp. 2d at 33 ("A plaintiff arguing in favor of application of the overpromotion exception with respect to a prescription drug must establish with *individualized* proof that such overpromotion caused the physician to initiate or maintain the prescription at issue. General claims of overpromotion are not sufficient. Plaintiff has provided only the most general allegations of overpromotion of Zyprexa by Lilly; the argument is insufficient to prevent application of the learned intermediary doctrine in this case." (citations omitted)); *see also Dean v. Eli Lilly & Co.*, 387 F. App'x 28, 30 (2d Cir. 2010) ("[E]ven if an overpromotion exception to the learned intermediary doctrine exists under Florida law, it does not apply here because no record evidence indicates that overpromotion induced prescription of Zyprexa *to Dean*." (emphasis added)); *cf. Whitley v. Cubberly*, 210 S.E.2d 289, 292 (N.C. 1974) ("For example, even though all warnings required by Federal authorities may have been given, such warnings would be insufficient to exonerate Parke, Davis from all liability if over-promotion through a vigorous sales campaign should induce the medical profession in general, *and in this case Dr. Cubberly in particular*, to fail adequately to heed the warnings given." (emphasis added)).

"labeling." 21 U.S.C. § 321(m) ("The term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."). And the regulations expand on that definition to include a host of materials that could be considered "marketing":

> Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and references published (for example, the "Physicians Desk Reference") for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor are hereby determined to be labeling as defined in section 201(m) of the act.

21 C.F.R. § 202.1(*l*)(2); *see also Del Valle v. PLIVA, Inc.*, Civil Action No. B:11–113, 2011 WL 7168620, at *4 (S.D. Tex. Dec. 21, 2011) ("In essence, virtually all communication with medical professionals concerning a drug constitutes labeling."); *Holmes v. Hospira, Inc.*, Case No. EDCV 12–01708 VAP (DTBx), 2013 WL 12132046, at *10 (C.D. Cal. Jan. 10, 2013) (same); *Truddle v. Wyeth, LLC*, Civil Action No. 2:11–CV–00207–GHD–SAA, 2012 WL 3338715, at *2–3 (N.D. Miss. Aug. 14, 2012) ("The FDA's definition of labeling encompasses any communication with medical professionals concerning a drug."); *Fullington v. PLIVA, Inc.*, No. 4:10CV00236 JLH, 2011 WL 6153608, at *4 n.2 (E.D. Ark. Dec. 12, 2011) ("The relevant statutes and regulations also contain a remarkably broad definition of labeling.").

But that broad definition does not render those categories of materials relevant to this Court's consideration of whether the label approved by FDA adequately warns for the symptoms about which Plaintiffs complain and if not, whether Defendants were foreclosed from adding additional warnings. Instead, the Court considers only the "labeling" submitted to the FDA for

approval during the new drug application process and any change to that "labeling" for which a manufacturer would need to request FDA approval. *See* 21 U.S.C. § 355(b)(1)(A) ("Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as part of the application . . . (vi) specimens of the labeling proposed to be used for such drug."); 21 C.F.R. § 314.70(b)(2)(v) (explaining that certain "labeling changes" are "major changes" that require a "supplement submission and approval prior to distribution of the product made using the change"); *id.* § 314.70(c)(6)(iii) (explaining that certain "labeling changes," including "[c]hanges in the labeling to reflect newly acquired information . . . [t]o add or strengthen a contraindication, warning, precaution or adverse reaction," are "moderate changes" that require a "supplement submission at least 30 days prior to distribution of the drug product made using the change"); *see also Wyeth v. Levine*, 555 U.S. 555, 568 (2009) ("The FDA's premarket approval of a new drug application includes the approval of *the exact text in the proposed label*. Generally speaking, a manufacturer may only change a drug label after the FDA approves a supplemental application. There is, however, an FDA regulation," the changes being effect ("CBE") regulation, "that permits a manufacturer to make certain changes to its label before receiving the agency's approval." (quoting 21 U.S.C. § 314.70(c)(6)(iii)(A), (C)) (emphasis added)).[9]

In the context of brand name prescription drugs, the question of preemption is tied to that approval process. *See Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 302–03 (2019). In *Merck*, the Court explained that claims that a "drug manufacturer failed to warn customers of the . . . risks associated with using [a] drug" are preempted only when there is "'clear evidence'

[9] During the status conference on October 15, 2024, defense counsel explained that the FDA-approved label is the United States Prescribing Information ("USPI"). A medication guide may also be submitted to FDA for approval during this process.

that the FDA would not have approved a change to the drug's label." *Id.* "'[C]lear evidence' is evidence that shows the court that the drug manufacturer fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning." *Id.* (citations omitted); *see also Wyeth*, 555 U.S. at 571 ("[A]bsent clear evidence that the FDA would not have approved a change to Phenergan's label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements."); *Pietrantoni v. Concept Therapeutics Inc.*, 640 F. Supp. 3d 197, 213 (D. Mass. 2022) ("A drug manufacturer may prevail on a preemption defense if (1) the CBE process was not available, and therefore it could not make unilateral changes to the label, or (2) it establishes by clear evidence that the FDA would not have approved the changes to the label that the plaintiffs contend should have been made." (quoting *In re Zofran (Ondansetron) Prods. Liab. Litig.*, 541 F. Supp. 3d 164, 195 (D. Mass. 2021)) (alterations adopted)).

Plus, the governing regulations recognize a difference between labeling approved by FDA and "labeling" as the term is broadly defined in the FDCA. *See* 21 C.F.R. § 314.70(a)(4) (requiring a brand name drug manufacturer to "promptly revise all promotional labeling and advertising to make it consistent with any labeling change implemented in accordance with paragraphs (b) and (c) of this section"); *id.* § 201.100(d) (recognizing a distinction between "labeling, as defined in section 201(m) of the act," and "approved or permitted labeling"); *see also Strayhorn v. Wyeth Pharms., Inc.*, 737 F.3d 378, 394 (6th Cir. 2013) (discussing the broad definition of "labeling" in § 201(m) of the FDCA and § 202.1(*l*)(2) of the regulations and explaining that "[s]uch labeling must be consistent with the drug's approved labeling"); *Kellogg v. Wyeth*, No. 2:07–cv–82, 2012 WL 368658, at *4 (D. Vt. Feb. 3, 2012) ("Such labeling," as

defined in § 201(m), "must be 'consistent with and not contrary to . . . approved or permitted labeling.'" (quoting 21 C.F.R. § 201.100(d)(1)); *Mardegan v. Mylan, Inc.*, No. 10-14285, 2012 WL 12850781, at *8 (S.D. Fla. Jan. 31, 2012) (same).

In sum, although Defendants' communications to physicians are "labeling" as that term is defined by the FDCA, those communications are not needed for the Court to determine whether a drug's approved label already contains the warnings that Plaintiffs seek to add and if not, whether the FDA would have rejected additional warnings to the approved label, such that Plaintiffs' state law failure to warn claims are preempted. The Court thus rejects Plaintiffs' suggestion that Defendants' marketing to physicians is relevant to deciding the narrow issues raised at this juncture. Instead, to answer those questions, "the Court will need to know the drug at issue in the case, the warning label at issue" (i.e., the label approved by FDA), "the alleged deficiencies on the particular warning, what was provided to the FDA, and more importantly what was withheld from the FDA." (*Id.* (quotation marks omitted).)

* * *

Because discovery into Defendants' marketing campaigns to the medical community are irrelevant to the narrow questions raised on Issue 2, Plaintiffs' motion is denied. Although the Court forecloses full scale marketing discovery at this stage, Defendants are warned that they cannot forego searching files or producing relevant documents simply because they would categorize them as "marketing." For example, Plaintiffs may choose to seek documents that disclose third-party clinical trials and similar data known to Defendants when they submitted their initial applications to FDA for approval or after that approval was obtained. Such information is relevant to what Defendants knew when they submitted their application or chose not to amend their label via the CBE process. If that information appears in a notice to a

physician or in internal emails related to marketing, Defendants would be expected to disclose it during the early discovery phase notwithstanding its "marketing" nature.[10]

III. CONCLUSION

For the reasons above, Plaintiffs' motion is denied. An appropriate order follows.

[10] To the extent the parties have disputes about the relevance of a given document, the appropriateness of a particular request, or the scope of this Memorandum, they should meet and confer and if necessary, raise those issues with Special Master Stengel.