UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: PROTON-PUMP INHIBITOR PRODUCTS LIABILITY LITIGATION	**2:17-MD-2789 (CCC)(MF)** **(MDL 2789)** **and all member and related cases**
This Document Relates to: **ALL ACTIONS**	**Judge Claire C. Cecchi**

CASE MANAGEMENT ORDER NO. 75
(Supplemental Briefing on Preemption Motions)

I. SCOPE AND APPLICABILITY

This Case Management Order ("CMO") is intended to conserve judicial resources, eliminate duplicative discovery, serve the convenience of the parties and witnesses, and promote the just and efficient conduct of this litigation. The following shall apply to all cases in MDL 2789. This CMO modifies certain deadlines set forth in CMO No. 69. This CMO does not modify the trial date or selection of cases set forth in CMO No. 68.

II. SUPPLEMENTAL BRIEFING ON PREEMPTION MOTIONS

A. Presently pending before the Court are motions for summary judgment on the failure to warn claims alleged by plaintiffs in the six Bellwether Trial Cases on the ground that their warnings claims are preempted by federal law. Movants rely on the Supreme Court's

decisions in *Wyeth v. Levine*, 555 U.S. 555 (2009), and *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019). In *Albrecht*, the Supreme Court held that the question of preemption is a question of law "for a judge to decide, not a jury," 139 S. Ct. at 1672, and that this includes a determination regarding "factual questions" related to "what information the FDA had before it" and "whether the drug manufacturer submitted all material information to the FDA," *id.* at 1680. On March 23, 2022, the district court to which the *Albrecht* case was remanded granted summary judgment on grounds of preemption. *In re Fosamax Alendronate Sodium Prods. Liab. Litig.*, MDL No. 2243, 2022 U.S. Dist. LEXIS 52627 (D.N.J Mar. 23, 2022) ("*Fosamax* Remand Preemption Decision").

B. Given that the *Fosamax* Remand Preemption Decision was issued after briefing on the preemption motions in these cases was complete, the Special Master, after reviewing the motion papers and exhibits and conducting oral argument on the pending motions, has determined that additional briefing would be beneficial.

C. Counsel for plaintiffs and defendants in the six Bellwether Trial Cases shall provide supplemental briefing of no more than 20 pages addressing the issue of whether, and why, these PPI cases are or are

not factually and/or legally distinguishable from the *Fosamax* Remand Preemption Decision. Such briefing should be accompanied by specific supporting record citations and relevant documents attached as exhibits.

D. Counsel for plaintiffs and defendants in the six Bellwether Trial Cases shall also submit numbered Proposed Findings of Fact and Conclusions of Law with specific supporting citations and relevant documents attached as exhibits. Such Proposed Findings of Fact and Conclusions of Law shall at a minimum address the following issues:

i. Whether the United States Food & Drug Administration (the "FDA") was fully informed at all relevant times of the justifications for an adequate warning under state law. The parties should identify with specificity what materials or information (including but not limited to adverse event reports, studies, case reports, case series and data evaluations or re-evaluations) were submitted to FDA and when those materials or information were submitted, as well as what, if any, materials or information in AstraZeneca's and Takeda's possession were not submitted to FDA. The parties should also

address the relevance of any such materials or information to the question of whether FDA was or was not fully informed.

ii. Whether AstraZeneca or Takeda at any time possessed "newly acquired evidence" that could support a Changes Being Effected label change pursuant to 21 C.F.R. §314.70(c)(6)(iii)(A). If any such "newly acquired evidence" existed, the parties should identify with specificity the newly acquired evidence, and indicate whether it was submitted to FDA and if so, when.

iii. Whether the warnings on the Nexium or Prevacid labels were at any time inadequate as a matter of law. If so, when was that and what would need to be changed in the labels in order for the warnings to be adequate as a matter of law. If not, explain the basis for the conclusion that the labels were at all times adequate as a matter of law.

E. The supplemental briefing and Proposed Findings of Fact and Conclusions of Law shall be filed on or before **May 27, 2022**.

F. If any party believes that any Proposed Findings of Fact submitted by an opposing party are materially incorrect, then on or before **June 6,**

2022, that party may submit a response of no more than 10 pages identifying any factual errors and providing supporting citations.

G. Special Master Ellen Reisman shall issue a Report and Recommendation on the parties' preemption motions in the six Bellwether Trial Cases on or before **July 8, 2022**.

H. Objections to the Report and Recommendation issued by Special Master Ellen Reisman on the parties' preemption motions in the six Bellwether Trial Cases shall be filed on or before **July 20, 2022**.

I. Responses to objections to Report and Recommendation issued by Special Master Ellen Reisman on the parties' preemption motions in the six Bellwether Trial Cases shall be filed on or before **July 29, 2022**.

J. If the Court determines that a hearing or oral argument on the parties' preemption motions, or limited/certain parts thereof, is necessary, such a hearing will be scheduled at the Court's convenience thereafter.

SO ORDERED

SIGNED on this 29th day of April, 2022.

ELLEN K. REISMAN
Special Master