IN RE REGLAN LITIGATION	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY CASE NO. 289 CIVIL ACTION **REPORT AND RECOMMENDATION TO TERMINATE CENTRALIZED MANAGEMENT PURSUANT TO DIRECTIVE #02-19 AND R. 4:38A.**

TO: The Honorable Glenn A. Grant, J.A.D., Acting Administrative Director,

The purpose of this Report is to request that the centralized management of the In Re Reglan litigation be terminated from the Middlesex County Vicinage. There are no active cases remaining in this litigation.

Following a period of comments on an application requesting centralized management without mass tort designation of the state court litigation relating to the drug Reglan, in both its branded and generic forms, (hereinafter referred to as "Reglan") the New Jersey Supreme Court entered an Order on July 8, 2010 assigning all pending and future New Jersey state court actions seeking damages or other relief arising out of the use of the drug Reglan for centralized case management purposes, without mass tort designation, to Superior Court, Law Division, Atlantic County for handling by Superior Court Judge Carol E. Higbee. On October 31, 2014, the Supreme Court entered an Order, effective November 3, 2014, transferring all pending Reglan litigation in the Order's attached exhibit to Middlesex County and assigning management to the Honorable Jessica R. Mayer.

Upon Judge Mayer's appointment to the Appellate Division in June 2017, the New Jersey Supreme Court temporarily reassigned all non-asbestos multicounty litigation matters to the Honorable James F. Hyland, J.S.C., including the centralized management of In Re Reglan. On June 18, 2017, the New Jersey Supreme Court made the temporary reassignments to Judge Hyland permanent. Upon Judge Hyland's retirement, in January 2021, all mass tort/multi-county litigation ("MCL") matters in Middlesex County were reassigned to the Honorable Bruce J. Kaplan, J.S.C.

Via email dated, May 6, 2021, the Court informed counsel of its intent to terminate the centralized management of the In Re Reglan litigation, given that no active cases remained, to which the Court received no objection. As such, this Report has been written to request that the In Re Reglan litigation now be decentralized.

A. Background

Reglan is a prescription drug indicated for short-term therapy for adults with symptomatic, documented gastroesophageal reflux (GERD) who fail conventional therapy and for relief of symptoms associated with acute and recurrent diabetic gastric stasis. Generally speaking, the drug's method of action is to speed the movement of food through the digestive system. The Federal Food and Drug Administration ("FDA") first approved a new drug application ("NDA") for Reglan in 1980. The Reglan NDA has transferred to different manufacturers, and the plaintiffs in these actions sued the following defendants in their capacity as Reglan NDA holders or companies related to the Reglan NDA holders: Wyeth LLC; Wyeth Pharmaceuticals, Inc.; ESI Lederle, Inc.; Wyeth Holdings Corporation; Pfizer, Inc. (collectively "Wyeth"); Schwarz Pharma, Inc. ("Schwarz"); and Alaven Pharmaceuticals LLC ("Alaven") (collectively, the "Brand Defendants").

Five years after the approval of Reglan, FDA began approving abbreviated new drug applications ("ANDA") for generic metoclopramide products. The plaintiffs in these actions, either individually or pursuant to master long form complaints, sued approximately forty (40) different companies alleged to be holders of various metoclopramide ANDAs or associated with the manufacture, sale or distribution of generic metoclopramide products. The plaintiffs alleged they developed tardive dyskinesia or other movement disorders as a result of their long-term use of Reglan. The FDA-approved labeling for Reglan contained warnings relating to tardive dyskinesia and other movement disorders (as well as other potential side effects), but plaintiffs maintained the warnings were inadequate.

The original Master Long Form Complaint ("MLFC") filed by plaintiffs in October 2010 after the creation of the MCL contained the following causes of actions against all or only certain defendants: Conscious misrepresentation involving risk of physical harm (Wyeth only); negligent misrepresentation (Wyeth only); design defect (N.J.S.A. 2A:58C-2.c); failure to warn (N.J.S.A. 2A:58C-2.b); breach of express warranties (N.J.S.A. 12A:2-313, N.J.S.A. 2A:58C-2.b(3)); wrongful death (N.J.S.A. 2A:31-1); survival action (N.J.S.A. 2A:15-3); punitive damages

(N.J.S.A. 2A:58C-1); strict liability under other states' law; negligence; negligence per se; common law fraud; fraudulent concealment under other states' law; constructive fraud; negligent misrepresentation; negligent infliction of emotional distress; breach of express warranty under other states' law; breach of implied warranties under other states' law; violation of consumer protection laws of other states; wrongful death under other states' law; survival action under other states' law; gross negligence; unjust enrichment; civil conspiracy; and punitive damages.

The litigation was impacted by the decision of the Supreme Court of the United States in PLIVA, Inc. v. Mensing, 564 U.S. 604 (2011), issued on June 23, 2011. Mensing involved state-law claims asserted against generic metoclopramide manufacturers that were similar to certain of the claims asserted against the Generic Defendants in the MLFC. In a nutshell, the United States Supreme Court held that state-law failure-to-warn claims against generic drug manufacturers are preempted by federal law (the FDCA and federal regulations promulgated thereunder) because federal law requires generic metoclopramide's labeling be the same as the Reglan labeling, and it is unlawful for generic metoclopramide manufacturers to change that labeling without FDA approval.

Following issuance of the Mensing decision, the plaintiffs were permitted to amend their MLFC to attempt to assert claims against the Generic Defendants that plaintiffs believed were not preempted under Mensing. The Generic Defendants moved to dismiss all claims against them as preempted by federal law. On May 4, 2012, Judge Higbee determined that all plaintiffs' claims were failure-to-warn claims, and she granted the motion on all claims in plaintiffs' complaints, with one exception: "[T]o the extent that generic manufacturers of metoclopramide tablets failed to update the labels to be the same as the brand-name label, they are excluded from preemption." Following that discovery, various generic defendants filed motions to dismiss or for summary judgment on the remaining "failure to update" claim on federal preemption grounds, but Judge Higbee denied those motions on July 13, 2013. On interlocutory appeal, the Supreme Court of New Jersey affirmed. See In re Reglan Litigation, 226 N.J. 315 (2016).

On September 26, 2013, the Court entered a discovery and case schedule for thirteen (13) designated cases. Discovery commenced, and the discovery schedules later were modified, but in the end no case proceeded to trial. Instead, beginning in late 2014, first the Brand Defendants and then eventually all Generic Defendants entered into global settlements with the plaintiffs who filed actions in this MCL and in similar coordinated proceedings in Pennsylvania and California. Those

global settlement agreements were reached between 2014 and early 2017. As each global settlement was reached, the parties and the courts in each of the three jurisdictions devoted their attention to finalizing the settlements and dismissing the thousands of cases in the three jurisdictions. Dismissals were filed in all settling plaintiffs' actions.

However, four plaintiffs in this MCL opted out of participation in the negotiated global settlements with Teva and PLIVA: Melanie Villa (MID-L-010053-14), Michelle Schwartz (MID-L-010457), Donald Benton (MID-L-10173-14), and Marie Goodson (MID-L-10337-14). These cases proceeded to discovery. The Schwartz action was dismissed on summary judgment on November 2, 2020. The other three plaintiffs reached settlements and their actions were dismissed on February 7, 2020 (Villa) and March 26, 2021 (Benton and Goodson).

B. Current Status of the Litigation

Following the aforementioned settlements and subsequent dismissals of the Benton and Goodson Cases on March 26, 2021, no active cases remain in this MCL.

C. Summary of Significant Events

- **July 8, 2010**: Supreme Court entered an Order assigning cases to Judge Higbee for centralized case management purposes in Atlantic County;
- **July 15, 2010**: Case Management Order ("CMO") 1 was entered by Judge Higbee;
- **October 14, 2010**: CMO 3 was entered, establishing procedures for the filing of master long form complaint and short form complaints by each plaintiff;
- **October 15, 2010**: Plaintiff's Master Long Form Complaint ("MLFC") was filed;
- **November 15, 2010**: Plaintiff's Amended MLFC was filed;
- **May 16, 2011**: CMO 11 was entered, establishing the procedure for product identification by plaintiffs;
- **July 14, 2011**: A Case Management Conference was held at which the Mensing decision was discussed. Plaintiffs were ordered to file Second Amended MLFC to include post-Mensing theories. Briefing schedules were established for Generic Defendants' motion to dismiss Second Amended MLFC and Brand Defendants' dispositive motion based on lack of use of brand Reglan products. Those Orders were placed in CMO 13, which was entered on 8/19/11;
- **8/1/2011**: Plaintiffs' Second Amended MLFC was filed;

- **May 4, 2012**: A Memorandum of Decision (MOD) was entered on Generic Defendants' motion to dismiss claims against them in Second Amended MLFC. All claims were dismissed except claims alleging Generic Defendant(s) did not change their labeling to match Reglan labeling;
- **May 12, 2013**: CMO 21 was entered; a discovery schedule was entered for 17 cases from which 4 bellwether cases were to eventually be chosen;
- **September 26, 2013**: CMO 23 was entered, establishing revised case management schedules for remaining 13 of 17 cases originally listed in CMO 21;
- **July 16, 2014**: CMO 24 was entered, vacating CMO 23 and establishing a discovery schedule for 7 cases designated by parties as bellwethers;
- **October 31, 2014**: New Jersey Supreme Court entered an Order, effective November 3, 2014, transferring all pending Reglan litigation in the Order's attached exhibit to Middlesex County and assigning management to the Honorable Jessica R. Mayer;
- **June 18, 2017**: Judge Hyland's temporary mass tort/MCL assignments were made permanent;
- **January 25, 2021**: New Jersey Supreme Court enters an Order reassigning the Reglan MCL to Judge Kaplan, effective February 1, 2021;
- **March 26, 2021**: Stipulations of dismissal of Benton and Goodson cases, the last cases in the Reglan MCL, were entered.

D. <u>Conclusion</u>

In light of the fact that there are no active cases remaining in the centralized management of Reglan, it is respectfully recommended that the centralized management of the In Re Reglan Litigation be terminated.