# BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: GLP-1 RECEPTOR AGONIST CASES MDL DOCKET NO.\_\_\_\_

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION FOR TRANSFER OF ACTIONS TO THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF LOUISIANA PURSUANT TO 28 U.S.C. § 1407 FOR COORDINATED OR CONSOLIDATED PRETRIAL PROCEEDINGS

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# **INTRODUCTION**

Pursuant to 28 U.S.C. § 1407 and JPML Rule 6.2, Plaintiffs et al. ("Plaintiffs") respectfully submit this Memorandum in Support of their Motion for Transfer and request that the Panel centralize all currently filed cases ("Subject Actions"), as well as any subsequently filed cases involving common factual issues, in the Western District of Louisiana before Judge James D. Cain, Jr.

Movants are Plaintiffs in nine cases pending in seven different federal courts across the United States, alleging that they suffered gastrointestinal and associated injuries after receiving glucagon-like peptide-1 receptor agonists ("GLP-1RAs"), such as Ozempic, Wegovy, and Mounjaro. Plaintiffs seek to recover under theories of negligence, strict liability, breach of warranty, fraudulent misrepresentation, negligent misrepresentation, and violation of state statutes. The undersigned firm is currently investigating over 10,000 additional cases of clients who have advised us that they suffered stomach and intestinal paralysis for which they were hospitalized. Almost all continue to suffer from the effects of this severe injury.

In addition to the nine cases described above, other firms across the country have filed nine cases in six federal district courts and are investigating many more GLP-1RA cases, which will result in further litigation. Coordination of pretrial proceedings is necessary to avoid duplicative discovery, unduly burdensome discovery obligations, and inconsistent rulings on pretrial motions. Indeed, centralization is consistent with the Panel's repeated decisions to consolidate personal injury and product liability claims arising from the same drug class.<sup>1</sup>

<sup>&</sup>lt;sup>1</sup> See In re Proton Pump Inhibitor, 261 F. Supp. 3d 1351, 1354 (J.P.M.L. 2017); In re: AndroGel Prods. Liab. Litig., 24 F. Supp. 3d 1378, 1378 (J.P.M.L. 2014); In re: Incretin Mimetics Prods. Liab. Litig., 968 F. Supp. 2d 1345, 1346 (J.P.M.L. 2013); In re Prempro Prods. Liab. Litig., 254 F. Supp. 2d 1366, 1366-67 (J.P.M.L. 2003); In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig., 990 F. Supp. 834, 836 (J.P.M.L. 1998).

# **FACTUAL BACKGROUND**

Semaglutide (marketed by Novo Nordisk as Ozempic, Wegovy, and Rybelsus), liraglutide (marketed by Novo Nordisk as Saxenda, inter alia), tirzepatide (marketed by Eli Lilly as Mounjaro, inter alia), and dulaglutide (marketed by Eli Lilly as Trulicity) belong to a class of drugs known as glucagon-like peptide-1 receptor agonists ("GLP-1RAs"). GLP-1RAs mimic the hormone glucagon-like peptide 1 ("GLP-1")—a gut hormone that activates the GLP-1 receptor in the pancreas—in order to stimulate the release of insulin and suppress glucagon, thereby reducing blood glucose levels.

Manufacturers acknowledge the existence of gastrointestinal side effects of GLP-1RAs. However, the subject suits allege that manufacturers have misrepresented these drugs as safe while downplaying the severity of the gastrointestinal events—such as gastroparesis (stomach paralysis), ileus (lack of movement through intestines), and intestinal pseudo obstruction—caused by their GLP-1RAs and have failed to adequately warn prescribing physicians and patients about the extent and the severity of the risks posed by GLP-1RAs. All of the claimed injuries involve the patients' inability to pass food through their digestive tracts resulting in severe and almost unremittent vomiting requiring hospitalization. These effects are shared by the entire class of drugs.<sup>2</sup>

Manufacturers have engaged in extensive direct-to-consumer marketing campaigns.<sup>3</sup> The

of drugs can exacerbate the symptoms of diabetic gastroparesis." *Id.* 

<sup>&</sup>lt;sup>2</sup> See Clipper F. Young et al., Diabetic Gastroparesis: A Review, 33 DIABETES SPECTR. 290, 291 (Aug. 2020), available at <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7428659/pdf/diaspectds190062.pdf">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7428659/pdf/diaspectds190062.pdf</a> (last visited Nov. 10, 2023). For example, the need to warn the diabetic or pre-diabetic patient population target market for these drugs about the risk of gastroparesis is especially important because "[t]his class"

<sup>&</sup>lt;sup>3</sup> See Ozempic TV advertisement, available at <a href="https://www.youtube.com/watch?v=3ac8OgBJJ">https://www.youtube.com/watch?v=3ac8OgBJJ</a> U (last visited Nov. 7, 2023) (touting the glycemic, cardiac, and weight loss benefits of Ozempic, without mentioning gastroparesis or ileus); Rybelsus TV advertisement, available at <a href="https://www.youtube.com/watch?v=xE96HdgcKew">https://www.youtube.com/watch?v=xE96HdgcKew</a> (last visited Nov. 7, 2023) (touting the glycemic and weight loss benefits of Rybelsus, without mentioning gastroparesis or ileus);

marketing campaigns have been incredibly successful for manufacturers, with the media declaring GLP-1RAs "[b]lockbuster weight loss drugs." Wegovy and Ozempic, for example, experienced a "surge" in prescriptions between December 2022 and June 2023, with a "six-fold increase" and 65% increase in prescriptions for the drugs, respectively. Demand for GLP-1RAs has been so high that manufacturers cannot meet demand. Due to the surge in use of these drugs, courts are experiencing an upsurge in gastroparesis and ileus claims related to GLP-1RAs.

# A. Saxenda (liraglutide)

In the winter of 2014, Novo Nordisk launched Saxenda (liraglutide) (daily injections) as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management

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Wegovy TV advertisement, available at https://vimeo.com/812688423 (last visited Nov. 7, 2023) (advertising Wegovy's weight loss benefits, without mentioning gastroparesis or ileus); Ben Adams, The top 10 pharma drug ad spenders for 2022, FIERCE PHARMA (May 1, 2023), available https://www.fiercepharma.com/special-reports/top-10-pharma-drug-brand-ad-spenders-2022 (last visited Nov. 7, 2023) (indicating that, in 2022, Novo spent an estimated \$180.2 million on Ozempic advertisements, \$167.2 million on Rybelsus advertisements); Mounjaro 2023 Super Bowl TV advertisement, available at https://www.youtube.com/watch?v=dsHDY-pZjxA (last visited Nov. 7, 2023) (touting Mounjaro's ability to regulate blood sugar and aid weight reduction, without mentioning gastroparesis or ileus); Saxenda TV advertisement, available at https://www.ispot.tv/ad/q p4/saxenda-science-to-obesity (last visited Nov. 8, 2023) (touting Saxenda's weight loss benefits, while failing to mention the risks of gastroparesis or ileus); Victoza TV advertisement, available at https://www.youtube.com/watch?v=WiW8EUIPnl8 (last visited Nov. 8, 2023) (describing Victoza's benefits for people with type 2 diabetes, without mentioning gastroparesis ileus); **Trulicity** advertisement, available or TV at https://www.youtube.com/watch?v=xipiotOLGDY (last visited Nov. 8, 2023) (same).

<sup>&</sup>lt;sup>4</sup> Samantha Delouya, *Blockbuster weight-loss drugs boost pharmaceutical companies Novo Nordisk and Eli Lilly*, CNN (Nov. 2, 2023), *available at* <a href="https://www.cnn.com/2023/11/02/business/novo-nordisk-eli-lilly-earnings-boost-weight-loss-ozempic/index.html">https://www.cnn.com/2023/11/02/business/novo-nordisk-eli-lilly-earnings-boost-weight-loss-ozempic/index.html</a> (last visited Nov. 8, 2023).

<sup>&</sup>lt;sup>5</sup> Fred Pennic, *Prescribing Trends Surge: Wegovy & Ozempic Gain Popularity, Survey Shows*, HIT CONSULTANT (Nov. 6, 2023), *available at* <a href="https://hitconsultant.net/2023/11/06/prescribing-trends-surge-wegovy-ozempic-gain-popularity/">https://hitconsultant.net/2023/11/06/prescribing-trends-surge-wegovy-ozempic-gain-popularity/</a> (last visited Nov. 10, 2023).

<sup>&</sup>lt;sup>6</sup> Brian Bushard, Shortage of Weight-Loss Drugs like Wegovy and Ozempic Persist—And Could for 'Some Years,' FORBES (Sept. 16, 2023), available at <a href="https://www.forbes.com/sites/brianbushard/2023/09/16/shortage-of-weight-loss-drugs-like-wegovy-and-ozempic-persist-and-could-for-some-years/?sh=7f876352631e">https://www.forbes.com/sites/brianbushard/2023/09/16/shortage-of-weight-loss-drugs-like-wegovy-and-ozempic-persist-and-could-for-some-years/?sh=7f876352631e</a> (last visited Nov. 7, 2023).

in adult patients with an initial body mass index (BMI) of 30 kg/m2 or greater (obese), or 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition. On April 20, 2023, Novo Nordisk added ileus to the Post-Marketing Experience section of Saxenda's label.<sup>7</sup> The label for Saxenda does not mention and has never mentioned gastroparesis as a potential consequence of use.

# **B.** Trulicity (dulaglutide)

In the fall of 2014, Eli Lilly launched dulaglutide as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus to be marketed as Trulicity in single dose pre-filled syringes and pre-filled pens. On February 21, 2020, Eli Lilly added an indication for Trulicity for "reduction of major adverse cardiovascular events in adults with type 2 diabetes mellitus." Trulicity's label has never warned of the risk of gastroparesis, and mention of ileus was only added to the Postmarketing Experience sections of the label in November 2022.

# C. Ozempic, Rybelsus, and Wegovy (semaglutide)

In December 2017, Novo Nordisk launched Ozempic (semaglutide) as an injectable 0.5 mg or 1 mg (once weekly) for use as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Novo Nordisk has represented that, in clinical trials, "onceweekly semaglutide had a safe and well tolerated profile with the most common adverse event

<sup>&</sup>lt;sup>7</sup> FDA Approval Letter for NDA 206321/S-016 (Apr. 20, 2023), available at <a href="https://www.accessdata.fda.gov/drugsatfda\_docs/appletter/2023/206321Orig1s016ltr.pdf">https://www.accessdata.fda.gov/drugsatfda\_docs/appletter/2023/206321Orig1s016ltr.pdf</a> (last visited Nov. 30, 2023).

<sup>&</sup>lt;sup>8</sup> FDA Approval Letter for BLA 125469/S-033 (Feb. 21, 2020), *available at* <a href="https://www.accessdata.fda.gov/drugsatfda\_docs/appletter/2020/125469Orig1s033ltr.pdf">https://www.accessdata.fda.gov/drugsatfda\_docs/appletter/2020/125469Orig1s033ltr.pdf</a> (last visited Nov. 30, 2023).

<sup>&</sup>lt;sup>9</sup> FDA Approval Letter for BLA 125469/S-051 (Nov.17, 2022), available at <a href="https://www.accessdata.fda.gov/drugsatfda\_docs/appletter/2022/125469Orig1s051ltr.pdf">https://www.accessdata.fda.gov/drugsatfda\_docs/appletter/2022/125469Orig1s051ltr.pdf</a> (last visited Nov. 30, 2023).

being nausea."<sup>10</sup> On September 22, 2023, Novo Nordisk added "Gastrointestinal: ileus" to the Postmarketing Experience section of Ozempic's label. <sup>11</sup> However, despite the diagnosis of at least two patients in semaglutide cardiovascular clinical trials with gastroparesis and numerous postmarketing reports of gastroparesis, the label still does not warn of the risk of gastroparesis associated with Ozempic use and does not include ileus in the or Warnings and Precautions section of the label. Nor did Novo Nordisk act proactively to inform doctors of safety developments through sending a "Dear Doctor" letter.

In the fall of 2019, Novo Nordisk launched 7 mg and 14 mg oral Rybelsus (semaglutide) as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.<sup>12</sup> On January 12, 2023, Novo Nordisk added "Gastrointestinal: ileus" to the label's Postmarketing Experience section.<sup>13</sup> In the press release regarding the label change, Novo Nordisk bragged that "Rybelsus has been prescribed to hundreds of thousands of patients to help improve glycemic control," but did not mention the risks of ileus or gastroparesis.<sup>14</sup> Further, the label for

<sup>&</sup>lt;sup>10</sup> Company Announcement: Novo Nordisk files for regulatory approval of once-weekly semaglutide in the US and EU for the treatment of type 2 diabetes (Dec. 5, 2016), available at <a href="https://hugin.info/2013/R/2061793/774071.pdf">https://hugin.info/2013/R/2061793/774071.pdf</a> (last visited Nov. 30, 2023).

<sup>11</sup> FDA Approval Letter for NDA 209637/S-020 and NDA 209637/S-021 (Sept. 22, 2023), available at <a href="https://www.accessdata.fda.gov/drugsatfda\_docs/appletter/2023/209637Orig1s020,s021ltr.pdf">https://www.accessdata.fda.gov/drugsatfda\_docs/appletter/2023/209637Orig1s020,s021ltr.pdf</a> (last visited Nov. 30, 2023); Ozempic Label (revised Sept. 2023), available at <a href="https://www.accessdata.fda.gov/drugsatfda\_docs/label/2023/209637s020s021lbl.pdf">https://www.accessdata.fda.gov/drugsatfda\_docs/label/2023/209637s020s021lbl.pdf</a> (last visited Nov. 30, 2023).

<sup>&</sup>lt;sup>12</sup> FDA Approval Letter for NDA 213051 (Rybelsus) (Sept. 20, 2019), available at <a href="https://www.accessdata.fda.gov/drugsatfda">https://www.accessdata.fda.gov/drugsatfda</a> docs/appletter/2019/213051Orig1s000ltr.pdf (last visited Nov. 30, 2023).

<sup>&</sup>lt;sup>13</sup> FDA Approval Letter for NDA 213051/S-012 (Jan. 12, 2023), available at <a href="https://www.accessdata.fda.gov/drugsatfda\_docs/appletter/2023/213051Orig1s012ltr.pdf">https://www.accessdata.fda.gov/drugsatfda\_docs/appletter/2023/213051Orig1s012ltr.pdf</a> (last visited Nov. 30, 2023).

<sup>&</sup>lt;sup>14</sup> Novo Nordisk, *Novo Nordisk announces FDA approval of label update for Rybelsus (semaglutide) allowing use as a first-line option for adults with type 2 diabetes* (Jan. 12, 2023), available at <a href="https://www.novonordisk-us.com/media/news-archive/news-details.html?id=154651">https://www.novonordisk-us.com/media/news-archive/news-details.html?id=154651</a> (last visited Nov. 30, 2023).

Rybelsus has never mentioned gastroparesis.

In June of 2021, Novo Nordisk launched 2.4 mg Wegovy (semaglutide) injections as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in obese adults and in overweight adults with at least one weight-related comorbid condition. In order to bring Wegovy to market on a "condensed timeline," Novo Nordisk fast tracked the launch in every aspect, "[f]rom development through regulatory to sales and marketing." In December 2022, ileus was added to the Postmarketing Experience section of Wegovy's label. However, Wegovy's label has never mentioned the risk of gastroparesis.

# D. Mounjaro (tirzepatide)

In May of 2022, Eli Lilly launched Mounjaro (tirzepatide)—once weekly injectable tirzepatide—as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. On July 28, 2023, Eli Lilly updated Mounjaro's label to include mention of ileus in the Postmarketing Experience section of the label. Mounjaro's label has never mentioned gastroparesis as a potential consequence of use.

# **LITIGATION BACKGROUND AND STATUS**

Currently, eighteen GLP-1RA civil actions are pending in eleven federal district courts: the Western District of Louisiana, the District of Idaho, the Northern District of Mississippi, the District of South Dakota, the Southern District of Iowa, the District of Utah, the District of

<sup>&</sup>lt;sup>15</sup> Julian Upton, *Rethinking Obesity: Wegovy*, 41(9) PHARM. EXECUTIVE (Sept. 14, 2021), *available at* <a href="https://www.pharmexec.com/view/wegovy">https://www.pharmexec.com/view/wegovy</a> (last visited Nov. 30, 2023) (quoting Novo Nordisk US executive vice president, head of North America operations, and President Doug Langa).

Wegovy Label (revised Dec. 2022), *available at* https://www.accessdata.fda.gov/drugsatfda\_docs/label/2022/215256s005lbl.pdf (last visited Nov. 30, 2023).

Mounjaro Label (revised July 2023), available at <a href="https://www.accessdata.fda.gov/drugsatfda\_docs/label/2023/215866Orig1s002s006lbl.pdf">https://www.accessdata.fda.gov/drugsatfda\_docs/label/2023/215866Orig1s002s006lbl.pdf</a> (last visited Nov. 30, 2023).

Nebraska, the Western District of Wisconsin, the Eastern D	District of New York, the Western	
District of New York, and the Eastern District of Pennsylvania.	. The following firms filed on behalf	
of the Plaintiffs in these cases:		
Pla	intiffs expect that many additional	
cases will be filed by other firms in the coming days and several weeks.		

# **ARGUMENT**

#### A. Centralization Is Warranted For These Cases.

# 1. Consolidation Is Appropriate Under Section 1407.

Under 28 U.S.C. § 1407, the Panel may consolidate multiple cases if the moving parties sufficiently demonstrate that:

- 1. the lawsuits involve one or more common questions of fact;
- 2. consolidation will best serve the convenience of the parties and witnesses; and
- 3. consolidation will promote the just and efficient conduct of such lawsuits.

28 U.S.C. § 1407(a). As shown below, the GLP-1RA cases meet the statutory requirements for centralization. And on this record, centralization in one district court for pretrial proceedings is the best course of action. *See In re: Taxotere*, 584 F. Supp. 3d 1378, 1379-80 (J.P.M.L. 2022); *see also In re Zyprexa*, 314 F. Supp. 2d 1380, 1381 (J.P.M.L. 2004).

# a. Class-Wide Consolidation Is Appropriate.

The Panel has long recognized that consolidation is warranted for multiple cases involving multiple defendants and concerning prescription drugs in the same class. Indeed, the Panel has chosen to centralize cases in very similar situations:

• In re Proton Pump Inhibitor, 261 F. Supp. 3d 1351, 1354 (J.P.M.L. 2017) (centralizing 24

cases involving kidney injuries related to an entire class of drugs with at least 17 branded versions plus their generic counterparts);

- In re: AndroGel, 24 F. Supp. 3d 1378, 1378 (J.P.M.L. 2014) (centralizing 45 cases regarding a class of "testosterone replacement therapies" that were brought against nine defendants);
- *In re: Incretin Mimetics*, 968 F. Supp. 2d 1345, 1346 (J.P.M.L. 2013) (centralizing 53 cases regarding "four anti-diabetic medications" that were brought against four defendants);
- *In re Prempro*, 254 F. Supp. 2d 1366, 1366-67 (J.P.M.L. 2003) (centralizing 6 cases involving hormone replacement therapies that were brought against two defendants); and
- *In re Diet Drugs*, 990 F. Supp. 834, 836 (J.P.M.L. 1998) (centralizing 9 cases involving "three diet drugs" that were brought against more than ten defendants).

By contrast—and as further shown below—declining to centralize cases "likely would delay the resolution of the common core issues in this litigation." *In re: AndroGel*, 24 F. Supp. 3d at 1379. For this and several other reasons, centralization is warranted. *E.g.*, *id*.

# b. <u>Centralization Is Proper Because These Cases All Have Similar Facts And Allegations.</u>

First, each GLP-1RA case alleges similar facts against one or more manufacturer and concerns a class of drugs used to treat type 2 diabetes, to manage weight, and to reduce cardiovascular risks in patients with type 2 diabetes. Each lawsuit contains almost identical allegations about these drugs and their propensity to cause gastrointestinal injuries and their sequelae. Put more plainly, each lawsuit is based on the same or substantially similar facts:

- (1) Plaintiff was prescribed a GLP-1RA;
- (2) Plaintiff's prescribing physician(s) relied on Defendants' numerous representations regarding the safety and efficacy of their drugs;
- (3) Defendants knew or should have known of the serious, debilitating risk of gastrointestinal injuries and sequelae therefrom;
- (4) Defendants failed to adequately warn prescribing physicians about the severity and the extent of the risks posed by their drugs;

- (5) Had Defendants adequately warned Plaintiffs' prescribing physicians, these doctors either would have altered their prescribing practices, declined to prescribe the drugs in question, or more closely monitored patients taking these drugs and then discontinued the drugs;
- (6) Plaintiff took a GLP-1RA drug as prescribed; and
- (7) Plaintiff suffered gastrointestinal paralysis and sequelae therefrom as a direct and proximate result of taking a GLP-1RA.

Responding to these common allegations, Defendants will likely deny that their drugs can cause certain gastrointestinal injuries and sequelae therefrom. Defendants, in turn, will attempt to offer alternative explanations regarding Plaintiffs' injuries, Defendants' defective and inadequate warnings, the adequacy of the labeling for Defendants' drugs, and Defendants' conduct. These defenses also involve common questions of fact on both liability and causation. Therefore, centralization is appropriate. *E.g.*, *In re: Androgel*, 24 F. Supp. 3d at 1379.

Moreover, Plaintiffs submit that these related lawsuits will collectively involve common questions against Defendants, including, but not limited to:

- Whether Defendants' GLP-1RAs were defective as designed, manufactured, and marketed, whether Defendants knew about said defects, and when Defendants knew about said defects;
- Whether Defendants knew that their GLP-1RAs were unsafe and/or dangerous in that they could cause serious gastrointestinal injuries, including, but not limited to, gastroparesis and ileus;
- Whether Defendants adequately warned prescribing physicians about the extent of the risk of harm and the dangers posed by Defendants' GLP-1RAs;
- Whether Defendants knowingly marketed and sold defective and unreasonably dangerous GLP-1RAs to prescribing physicians, thereby causing patients to suffer gastrointestinal injuries and consequences therefrom;
- Whether Defendants knew that their representations regarding their GLP-1RAs were false, misleading, or incomplete; and
- Whether Defendants' misrepresentations and omissions about their GLP-1RAs to prescribing physicians caused Plaintiffs—and others—to suffer crippling injuries.

# c. Centralization Will Benefit The Courts And The Parties.

Centralization will prevent inconsistent rulings, eliminate duplicative discovery, benefit the parties, witnesses, and their counsel, and conserve the resources of the judiciary, the parties, and their counsel. *See, e.g., In re Zostavax*, 330 F. Supp. 3d 1378, 1379 (J.P.M.L. 2016); *In re MLR*, *LLC*, *Patent Litig.*, 269 F. Supp. 2d 1380, 1381 (J.P.M.L. 2003). A transferee judge can "employ any number of techniques . . . to manage pretrial proceedings efficiently." *In re Proton Pump Inhibitor*, 261 F. Supp. 3d 1351, 1354 (J.P.M.L. 2017) (citation & footnote omitted). Consequently, "formal centralization under section 1407 is the best course." *Id*.

# d. The Need For Centralization Will Only Increase.

As noted above, the need for centralization is warranted because there are already eighteen GLP-1RA cases on file in eleven different federal district courts across the country. These lawsuits span seven federal circuits. Considering the surge in prescriptions written for GLP-1RAs in the last year and the number of cases the undersigned's firm has under investigation, more cases are imminent. As in *In re Diet Drugs*, 990 F. Supp. at 836, "the sheer size of the litigation, coupled with its rapid growth rate at the present time, serve to underscore the economies of scale that centralized pretrial management of the federal court actions will provide." *Id*.

# e. The Lack Of Centralization Will Become Problematic.

The alternative to centralization is not a viable one. Allowing more than several cases to continue separately will ultimately result in separate scheduling orders, duplicative discovery, and could lead to inconsistent rulings on the admissibility of evidence, liability, causation, and the reliability of liability and causation experts. The Panel should thus authorize an MDL so that pretrial proceedings "will be conducted in a manner leading to the just and expeditious resolution

<sup>&</sup>lt;sup>18</sup> See also In re: Farxiga, 273 F. Supp. 3d 1380, 1380-83 (J.P.M.L. 2017) (same); In re: Biomet M2A Magnum Hip Implant, 896 F. Supp. 2d at 1340 (same); In re: Androgel, 24 F. Supp. 3d at 1378-79 (same); In re: Incretin Mimetics, 968 F. Supp. 2d at 1346 (same).

of all actions to the overall benefit of the parties." *In re: Prempro*, 254 F. Supp. 2d at 1368.

# 2. Informal Coordination Will Be Impractical.

The Panel must decide whether the common questions "are incapable of resolution through other available means such as informal coordination." MANUAL FOR COMPLEX LITIGATION (FOURTH) § 22.33 (2004). On this record, informal coordination is not a practical alternative to centralization. 19 "[T]he number of actions, districts, and involved counsel, and the complexity of the litigation, make effective coordination on an informal basis impracticable." In re Uber Tech., Inc., Data Breach Litig., 304 F. Supp. 3d 1351, 1354 (J.P.M.L. 2018). It would be inefficient and uneconomical to engage in informal coordination among eleven different courts, in seven different circuits, with numerous law firms involved. See In re: Roundup, 214 F. Supp. 3d 1346, 1348 (J.P.M.L 2016). Here, "[t]he number of involved districts . . . pose[s] [a] significant obstacle[] to informal coordination" especially for discovery. In re Viagra, 224 F. Supp. 3d at 1331. As is common in an MDL proceeding, Plaintiffs anticipate taking the depositions of prescribing physicians, treating physicians, third-party witnesses, and current and former employees of Defendants who worked on these GLP-1RAs, many of whom will be deposed in multiple cases or will discuss overlapping issues. It would be exceedingly difficult to informally coordinate the timing and scope of this discovery across numerous cases in different stages of litigation. *Id*.

In addition, "a single court can more effectively manage the discovery disputes . . . likely to arise, including those relating to discovery from third party witnesses, depositions of apex

<sup>&</sup>lt;sup>19</sup> In re Bard Implanted Port Catheter Prods. Liab. Litig., 2023 WL 5065100, at \*1-\*2 (J.P.M.L. Aug. 8, 2023); In re Generac Solar Power Sys. Mtkg., Sales Practices & Prods. Liab. Litig., 2023 WL 3829305, at \*1-\*2 (J.P.M.L. June 2, 2023); In re Onglyza (Saxagliptin) & Kombiglyze XR, 289 F. Supp. 3d 1357, 1358 (J.P.M.L. 2018); In re Sorin 3T Heater-Cooler Sys., 289 F. Supp. 3d 1335, 1337 (J.P.M.L. 2018); In re Eliquis, 282 F. Supp. 3d 1354, 1355 (J.P.M.L. 2017); In re: Viagra, 224 F. Supp. 3d 1330, 1331 (J.P.M.L. 2016).

witnesses, and the scope of relevant discovery, generally." *In re Ahern Rentals, Inc.*, 481 F. Supp. 3d 1355, 1356 (J.P.M.L. 2020). Centralization of these proceedings, rather than informal coordination, would thus be more convenient for the parties and witnesses and would "promote the just and efficient conduct of such actions." 28 U.S.C. § 1407 (a); *see also* MANUAL FOR COMPLEX LITIGATION (FOURTH) § 10.22 (2004).

So far, the Defendants in GLP-1RA cases have filed Rule 12(b)(6) motions, and Plaintiffs anticipate that Defendants will seek Rule 12(b)(6) dismissal in recently-filed cases. Without a centralized process, staggered motions will result in inconsistent rulings on nearly identical motions and underlying facts. The same is also likely for *Daubert* and summary judgment motions, given the complex medical, scientific, and legal concepts at issue in these cases. Indeed, given that multiple cases are on file in some courts, it is possible that two courts could issue conflicting rulings on the laws of one state. Having one judge evaluate these issues will achieve far greater consistency than the efforts of multiple judges and parties across the country.

"Were this litigation smaller, such duplicative discovery and motion practice might be effectively coordinated on an informal basis by the parties and involved courts." *In re Dollar Gen. Corp. Motor Oil Mktg. & Sales Pracs. Litig.*, 190 F. Supp. 3d 1361, 1362 (J.P.M.L. 2016). The number of cases and courts, however, renders this option impractical. And "[c]entralization of these . . . actions before a single judge will yield greater efficiency and cost benefits for both the parties and the courts than informal cooperation and coordination can achieve." *Id.* at 1363. Additionally, duplicative motion practice encourages forum shopping and strains judicial resources. Because cases are guided by different scheduling orders, parties file and courts decide motions at different times, which means that an issue unsuccessfully litigated in one district could be re-litigated elsewhere by the losing party. This situation strains judicial resources. *See id.* 

In sum, informal coordination cannot practically eliminate these risks within so many cases and courts. Centralization, however, will "eliminate duplicative discovery, prevent inconsistent pretrial rulings on *Daubert* and other issues, and conserve the resources of the parties, their counsel, and the judiciary." *In re Mirena*, 249 F. Supp. 3d 1357, 1361 (J.P.M.L. 2017); . Accordingly, "on this record, informal coordination is not an efficient alternative to centralization." *In re Eliquis*, 282 F. Supp. 3d 1354, 1355 (J.P.M.L 2017).

The Panel has routinely found informal coordination to be unworkable where, as here, multiple cases are on file in more than several federal courts.<sup>20</sup> Moreover, the inevitable filing of additional cases will further render informal coordination even less practical. *See In re: Xarelto*, 65 F. Supp. 3d 1402, 1404 (J.P.M.L. 2014).<sup>21</sup>

# B. The Western District of Louisiana Is A Suitable Transfer Forum.

The Western District of Louisiana has the resources to oversee these cases ably and efficiently. The median time interval from filing to resolution is a mere 9.4 months.<sup>22</sup> Further, no MDLs are pending in the Western District of Louisiana. Overall, the court is an appropriate

<sup>&</sup>lt;sup>20</sup> See In re: Onglyza (Saxagliptin) & Kombiglyze XR, 289 F. Supp. 3d 1357, 1358 (J.P.M.L. 2018); In re: Sorin 3T Heater-Cooler Sys., 289 F. Supp. 3d 1335, 1337 (J.P.M.L. 2018); In re: Eliquis, 282 F. Supp. 3d 1354, 1355 (J.P.M.L. 2017); In re: Viagra, 224 F. Supp. 3d 1330, 1331 (J.P.M.L. 2016); see also In re Fluoroquinolone, 122 F. Supp. 3d 1378, 1379-1380 (J.P.M.L. 2015).

The Panel has denied motions to transfer if a "reasonable prospect" exists that section 1404 motions will eliminate the multidistrict nature of a litigation. See, e.g., In re Gerber Probiotic, 899 F. Supp. 2d 1378, 1379-80 (J.P.M.L. 2012). But on this record, there is no "reasonable prospect" that section 1404 motions would work better than consolidation. See In re Chantix, 648 F. Supp. 3d 1381, 1382 (J.P.M.L. 2022). The record supports just the opposite conclusion. See id. No such motions have been filed or adjudicated. Not one plaintiff has said that he or she "would agree to transfer to a different district . . . ." In re Digital Adver. Antitrust Litig., 555 F. Supp. 3d 1372, 1377 (J.P.M.L. 2021). Section 1404 motions thus "do not offer a 'reasonable prospect' of eliminating the multidistrict character of this litigation." In re Fisher-Price Rock 'N Play Sleeper, 412 F. Supp. 3d 1357, 1359 (J.P.M.L. 2019) (citation & footnote omitted).

<sup>&</sup>lt;sup>22</sup> See <a href="https://www.uscourts.gov/statistics/table/c-5/statistical-tables-federal-judiciary/2023/06/30">https://www.uscourts.gov/statistics/table/c-5/statistical-tables-federal-judiciary/2023/06/30</a> (last visited Nov. 30, 2023).

transferee district for these cases. E.g., In re: Actos, 840 F. Supp. 2d at 1356.

Within the Western District of Louisiana, Plaintiffs request that the Panel appoint Judge James D. Cain, Jr. to oversee these cases. Judge Cain has decades of experience in private practice and several years of judicial service. Since receiving his commission on in the summer of 2019, Judge Cain has issued 1,289 orders or opinions that are available on Westlaw. In 2021, Judge Cain sat by designation in the Ninth Circuit Court of Appeals. See e.g., Lemmon v. Snap, 995 F.3d 1085, \* (9th Cir. 2021) ("The Honorable James David Cain, Jr., United States District Judge for the Western District of Louisiana, sitting by designation."). In addition, Judge Cain has substantial experience in multi-plaintiff litigation. Since the local devastation in the Lake Charles area including the courthouse itself—from Hurricane Delta in October 2020 and Hurricane Laura in August 2020, <sup>23</sup> Judge Cain has presided over 6,877 hurricane cases. <sup>24</sup> See In re McClenny Moseley & Assocs., 2023 WL 2954435, at \*1 (W.D. La. Mar. 4, 2023) (noting that "thousands of other hurricane cases have proceeded through this court since December 2020"). In fact, Judge Cain handled 22% of all insurance lawsuits filed in the nation in 2022,<sup>25</sup> and 40% of all insurance lawsuits filed during the month of August 2022—a month that saw a record-breaking 4,042 insurance cases filed nationwide.<sup>26</sup> In these cases, Judge Cain has issued numerous orders and

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<sup>&</sup>lt;sup>23</sup> In re: Hurricane Laura and Hurricane Delta Claims, CMO 1 (W.D. La. May 30, 2023) (https://www.lawd.uscourts.gov/sites/lawd/files/UPLOADS/Laura%20Delta%20-%20CMO 0.pdf) (accessed 12/1/23).

<sup>&</sup>lt;sup>24</sup> Federal insurance litigation in Louisiana tops in U.S., new report finds, Louisiana Record (June 15, 2023) (<a href="https://louisianarecord.com/stories/644285105-federal-insurance-litigation-in-louisiana-tops-in-u-s-new-report-finds">https://louisianarecord.com/stories/644285105-federal-insurance-litigation-in-louisiana-tops-in-u-s-new-report-finds</a>) (accessed 12/1/23).

<sup>&</sup>lt;sup>25</sup> Insurance Lawsuits Skyrocket in Communities Hit Hard by Extreme Weather Events, Syracuse University Transactional Records Access Clearinghouse (<a href="https://trac.syr.edu/reports/700/">https://trac.syr.edu/reports/700/</a>) (accessed 12/1/23).

<sup>&</sup>lt;sup>26</sup> Ground Zero: One in Five Federal Insurance Lawsuits Nationwide Filed in Lake Charles, The Advocate (Oct. 21, 2022) (<a href="https://www.theadvocate.com/lake\_charles/ground-zero-one-in-five-federal-insurance-lawsuits-nationwide-filed-in-lake-charles/article\_1201142e-5160-11ed-bf00-579c5dc1e8f9.html">https://www.theadvocate.com/lake\_charles/ground-zero-one-in-five-federal-insurance-lawsuits-nationwide-filed-in-lake-charles/article\_1201142e-5160-11ed-bf00-579c5dc1e8f9.html</a>) (accessed 12/1/23)

dispositive rulings and held trials.

Judge Cain anticipated the volume of cases that would follow the 2020 Hurricanes that hit his community and developed an innovative Case Management Order to provide for uniform and streamlined discovery, court organized mediation, and prompt attention by the Court to any cases that did not resolve through the CMO process. <sup>27</sup> That model proved so successful that with support of the plaintiff and defense bar it was copied nearly exactly by the Eastern District of Louisiana the next year. <sup>28</sup> At a recent CLE it was reported that out of the 7,468 cases filed a total of 5,920 have resolved through the CMO process (1036 are stayed due to the court's suspension of an allegedly unethical plaintiff's firm<sup>29</sup>). <sup>30</sup> Judge Cain is thus familiar with the challenges that complex litigation poses, and he has the "expertise to efficiently manage this litigation." *In re Roundup*, 214 F. Supp. 3d at 1348. <sup>31</sup>

Also significant here, the hurricane litigation before Judge Cain is coming to a close. By March of 2023, "over half" of the Hurricane Laura and Delta cases had "already been resolved." *In re McClenny Moseley & Assocs.*, 2023 WL 2954435, at \*1. As noted in a recent report regarding judicial statistics, the Western District of Louisiana "terminated 4,242 cases of various types." It is believed that thousands of other hurricane cases have resolve or will soon resolve. Accordingly,

https://www.laed.uscourts.gov/sites/default/files/generalorders/Hurricane%20Ida%20Case%20Management%20Order%2001.pdf

https://www.laed.uscourts.gov/sites/default/files/generalorders/Hurricane%20Ida%20Case%20Management%20Order%2001.pdf

 $<sup>^{27}</sup>$  https://www.lawd.uscourts.gov/sites/lawd/files/UPLOADS/Laura%20Delta%20%20CMO\_0.pdf (accessed 12/1/23).

<sup>&</sup>lt;sup>30</sup> 90% settled in the early mediations and well over 99% settled before trial.

<sup>&</sup>lt;sup>31</sup> Notably, hundreds of the hurricane cases were complex commercial cases involving seven and eight figure disputes and resolutions.

https://www.uscourts.gov/statistics-reports/federal-judicial-caseload-statistics-2023 (last visited Nov. 30, 2023).

Judge Cain has the resources to oversee these cases.<sup>33</sup>

Indeed, Judge Cain is rapidly handling the GLP-1RA cases before him and is showing his immediate attention to these matters.<sup>34</sup> Notably, Judge Cain presides over the first GLP-1RA case that was filed in the country (a case that involves both of the two GLP-1RA manufacturers (Novo Nordisk and Eli Lilly), and Judge Cain has diligently advanced that case.<sup>35</sup> Judge Cain has held a Rule 16 conference, ordered the parties to submit a proposed scheduling order and a proposed preservation order by December 19, 2023, and set trial for February 2026. Ex. 1, DE #56, 58, 59. For their part, the parties have filed a Rule 26(f) report (DE #52). Undersigned counsel has served Rule 26(a)(1) disclosures, exchanged a proposed protective order, exchanged a proposed preservation order, exchanged a proposed scheduling order, and is scheduling a meet and confer with both Defendants for the week of December 3, 2023. By the time this matter is before this Panel, these orders are expected to be in place.

Furthermore, both Defendants have filed motions to dismiss in and Plaintiff has filed her opposition. Novo Nordisk's reply brief is due today (December 1<sup>st</sup>), and Eli Lilly's reply brief is due in a week (December 8<sup>th</sup>). Accordingly, briefing will have been completed on two dispositive motions in by the time this matter is before the Panel.

In contrast, the cases in other districts remain in their infancy. In the only case outside the

<sup>&</sup>lt;sup>33</sup> Also, assigning GLP-1RA cases to Judge Cain would continue the Panel's recent trend of giving judges their first opportunity to manage an MDL. *In re Profemur Hip Implant Prods. Liab. Litig.*, 481 F. Supp. 3d 1350, 1353 (J.P.M.L. 2020); *In re Stryker Orthopaedics LFIT V40 Femoral Head Prods. Liab. Litig.*, 249 F. Supp. 3d 1353, 1356 (J.P.M.L. 2017); *In re Roundup*, 214 F. Supp. 3d at 1348.

<sup>&</sup>lt;sup>34</sup> For example, while undersigned counsel consented to lengthy extensions for Defendants to file their Rule 12(b)(6) motions, undersigned counsel opposed Eli Lilly's second request for more time. *See* Ex. 1, DE #31. Judge Cain showed prompt attention to the dispute and quickly granted Eli Lilly's second extension request. *Id.* DE #37.

v. Novo Nordisk A/S et al., Case No. 2:23-cv-01020 (pending in the United States District Court for the Western District of Louisiana, Lake Charles Division (Cain, J.)).

Western District of Louisiana with any activity (*Miller*), the only thing that has happened thus far is removal from state court to federal court. Ex. 16. It does not appear that a Rule 16 conference has been held or that the parties have filed a Rule 26(f) report. The litigation before Judge Cain is thus far advanced in comparison with the litigation in other districts.

The Western District of Louisiana is appropriate under the factors for determining an appropriate forum, which are: (1) the location of the parties, witnesses, and documents; (2) the accessibility of the proposed transferee district to parties and witnesses; and (3) the respective caseloads of the proposed transferee district courts. *In re Corn Derivatives Antitrust Litig.*, 486 F. Supp. 929, 931-32 (J.P.M.L. 1980). Here, five GLP-1RA cases are already on file in the Western District of Louisiana, so a substantial group of plaintiffs, fact witnesses, and treating physicians are in Louisiana. *See In re DePuy Orthopaedics, Inc.*, 753 F. Supp. 2d 1378, 1380 (J.P.M.L. 2010). Louisiana is expected to be a hotbed of GLP1-RA litigation, as reports have shown that people in Louisiana have performed internet searches for "Ozempic" more than any other state, and Louisiana is among the top five states for "Mounjaro" searches.<sup>36</sup>

The Western District of Louisiana is also convenient and accessible. Lake Charles is a reasonable driving distance from Houston and New Orleans and is a "geographically central forum for this nationwide litigation." *In re Xarelto*, 65 F. Supp. 3d at 1405. Houston has the largest airport in Texas.<sup>37</sup> DFW and IAH (Houston) together provide five nonstop flights a day to Lake Charles, which is a mere 30 to 45 minute flight, and DFW/IAH can be reached nonstop from every significant airport in the country.<sup>38</sup> Lake Charles is additionally a reasonable distance from either

<sup>&</sup>lt;sup>36</sup> Andrea Curry, *Ozempic in America: What's the real impact? A survey reveals details*, THE INTAKE (March 28, 2023), *available at* <a href="https://www.tebra.com/theintake/medical-deep-dives/tips-and-trends/research-searching-for-ozempic">https://www.tebra.com/theintake/medical-deep-dives/tips-and-trends/research-searching-for-ozempic</a> (last visited Dec. 1, 2023).

<sup>&</sup>lt;sup>37</sup> https://en.wikipedia.org/wiki/George\_Bush\_Intercontinental\_Airport (accessed 12/1/23)

<sup>38</sup> https://flylakecharles.com/flights/ (accessed 12/1/23).

coast.

Lastly, as explained above, the Western District of Louisiana has the capacity to handle these cases as the hurricane cases have largely come to a close. This is highlighted by the speed to which the Western District of Louisiana resolves cases (9.4 months on average), and the diligence and immediate attention that Judge Cain has shown in

# **CONCLUSION**

For all the reasons herein, Plaintiffs et al. respectfully request that the Panel order coordinated or consolidated pretrial proceedings for the Subject Actions and transfer all pending and future related actions to the Western District of Louisiana.

Respectfully submitted,

Dated: December 1, 2023



