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June 12, 2025

VIA FEDERAL EXPRESS
Hon. Michael J. Blee, J.A.D.
Acting Administrative Director
Administrative Office of the Courts
of the State of New Jersey
Richard J. Hughes Justice Complex
25 Market Street
Trenton, NJ 08625

Re: Request for Multicounty Designation of* NAION Ozempic/Wegovy *Litigation

Dear Judge Blee:

This letter is submitted on behalf of twenty-one (21) plaintiffs[1] who have cases filed in Middlesex County, New Jersey and who have developed Nonarteritic Anterior Ischemic Optic

[1] See **Exhibit A**. Plaintiffs are represented by five different law firms: Weitz & Luxenberg, P.C., Motley Rice LLC, Parker Waichman, Anapol Weiss and Sullivan Papain Block McManus & Cannavo P.C.

Neuropathy (NAION) resulting from use of Ozempic and/or Wegovy. Ozempic and Wegovy are glucagon-like peptide-1 receptor agonists ("GLP-1Ras") manufactured and sold by Novo Nordisk, Inc. ("Novo Nordisk") and prescribed for treatment of type 2 diabetes and weight loss, respectively. Both medications contain the same active ingredient, semaglutide. These medications have resulted in extreme weight loss and not surprisingly, are immensely popular. But the scientific literature has identified a very concerning heightened risk of developing NAION amongst users of these drugs. NAION results in permanent vision loss with the typical scenario of a patient waking up in the morning unable to see out of one eye. Sadly, there is no treatment whatsoever for NAION.

The FDA is currently reviewing whether regulatory action is required,[2] while the European Medicines Agency (EMA) has already determined the product information should be updated to include the risk of NAION with a warning to patients that upon sudden vision loss or worsening vision, a physician should be contacted right away and the medication should be stopped if NAION is confirmed.[3]

Plaintiffs seek a Multicounty Litigation (MCL) designation in accordance with Rule 4:38A. It is our impression based on conversations with counsel for Defendant, Novo Nordisk, that they agree a coordination is warranted. In that we anticipate this application will be unopposed by Novo Nordisk, if that is correct, it is respectfully requested that the AOC timeline for creating an MCL be expedited. Presently the twenty-one cases in suit in New Jersey State Court are before at least eight (8) different judges. Extensions for responses to the complaints have been afforded in the earlier filed cases in light of an anticipated coordination to avoid multiple serial motions before different judges on the pleadings. However, many weeks have already elapsed, and Plaintiffs are eager to see their cases advance in accordance with Best Practices.[4]

Background

Novo Nordisk branded semaglutide as Ozempic, and on December 5, 2016 announced submission of Ozempic's New Drug Application (NDA) to the FDA for regulatory approval of once-weekly injectable in 0.5 mg or 1 mg for treatment of type 2 diabetes. On December 5, 2017, the FDA approved the application and granted premarket approval to Novo Nordisk. Wegovy was later approved for obese and overweight adults with at least one chronic health condition on June

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[2] U.S. Food & Drug Administration, October - December 2024 | Potential Signals of Serious Risks/New Safety Information Identified by the FDA Adverse Event Reporting System (FAERS) (Mar. 31, 2025), https://www.fda.gov/drugs/fdas-adverse-event-reporting-system-faers/october-december-2024-potential-signals-serious-risksnew-safety-information-identified-fda-adverse

[3] European Medicines Agency, PRAC concludes eye condition NAION is a very rare side effect of semaglutide medicines Ozempic, Rybelsus and Wegovy (June 6, 2025), https://www.ema.europa.eu/en/news/prac-concludes-eye-condition-naion-very-rare-side-effect-semaglutide-medicines-ozempic-rybelsus-wegovy

[4] Plaintiffs waited until now to file this application since we wanted to have sufficient numerosity to show the AOC that an MCL was warranted.

4, 2021. This was the first FDA approved drug for weight loss since 2014. Wegovy and Ozempic are chemically identical and primarily differ based upon dosage.

While the precise cause of NAION is unknown, the general belief amongst the neuro-ophthalmologic community is that the condition is caused by insufficient blood supply or ischemia to the optic nerve head (ONH) resulting in swelling and compression of ONH microcirculation.[5] There is no treatment for NAION and is the second most common cause of blindness due to optic nerve damage.[6] Reduced or loss of vision has a detrimental impact on a person's day-to-day life. Many NAION patients cannot drive or have driving restrictions, cannot read or have trouble reading, and may be unable to continue in their line of employment. Many patients are forced to rely on family and friends and lose their independence.

Multiple recent peer-reviewed published studies and articles have revealed an increased risk of developing NAION with use of semaglutide. Clinical observations by astute neuro-ophthalmologists at the Harvard affiliated Massachusetts Eye and Ear ("Mass Eye and Ear") who noted a surge of NAION cases amongst patients on Ozempic led them to conduct a retrospective, matched cohort study of neuro-ophthalmic patients at Mass Eye and Ear, Boston. "The relatively high Hazard Ratios (4.28 and 7.64 for our T2D and overweight or obese cohorts, respectively) identified by our Cox regression analyses reveal a substantially increased risk of NAION among individuals prescribed semaglutide relative to those prescribed other medications to treat T2D and obesity or overweight."[7] Numerous studies and articles have since been published documenting similar findings and concluding use of Ozempic and Wegovy can result in NAION. Furthermore, on the basis of the results from several large epidemiological studies, the EMA determined "exposure to semaglutide in adults with type 2 diabetes is associated with an approximately two-fold increase in the risk of developing NAION compared with people not taking the medicine" and again has recommended a label change.[8]

Plaintiffs allege Novo Nordisk, Inc. knew or should have known of the risk of NAION and failed to adequately warn of the risks, failed to design a safe product and failed to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of Ozempic and Wegovy. Each Plaintiff has also alleged violation of the New Jersey Consumer Fraud Act.

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[5] Wu, Kevin Yang and Evoy, François "NAION: Diagnosis and Management," EyeNet Magazine, August 1, 2022. available at https://www.aao.org/eyenet/article/naion-diagnosis-and-management

[6] Id.

[7] Hathaway JT, Shah MP, Hathaway DB, et al. "Risk of Nonarteritic Anterior Ischemic Optic Neuropathy in Patients Prescribed Semaglutide," *JAMA Ophthalmol.*, Vol. 142, No. 8 (July 3, 2024) at 732-739, available at https://jamanetwork.com/journals/jamaophthalmology/fullarticle/2820255

[8] European Medicines Agency, supra note 3.

Ozempic/Wegovy Litigation in New Jersey

Presently there are twenty-one (21) cases pending in New Jersey state court, all involving allegations of the development of NAION and resulting vision loss. Novo Nordisk has its principal place of business in Plainsboro, New Jersey and it is thus anticipated that many more cases will be filed in Middlesex County. Indeed, the undersigned have numerous additional cases they will be filing, as will other counsel who have already filed cases, and presumably additional lawyers as new cases of NAION are diagnosed among Ozempic and Wegovy users. The cases filed presently involve two New Jersey plaintiffs as well as Plaintiffs from twelve other states represented by five firms based in New Jersey, New York, Pennsylvania and Rhode Island.

Of note, there are also at least twenty-five (25) cases filed against Novo Nordisk and related entities alleging various gastrointestinal injuries (GI) including gastroparesis and ileus. **Our MCL Petition is solely requesting coordination of cases alleging a NAION injury.** While we understand the gastrointestinal injury cases involve a common defendant, the cases filed by the above-mentioned firms involve the distinct injury of NAION which is due to a different mechanism of action. Additionally, while there may be some overlap in discovery in terms of regulatory documents, document production in the NAION cases will be premised on distinct search terms and will likely involve mostly different custodians. The parties will also rely on opinions from different specialists, such as neuro-ophthalmologists, which would not be utilized in gastrointestinal injury cases. Presently, there is also no overlap in counsel for Plaintiffs with NAION injuries and Plaintiffs with gastrointestinal injuries that have been filed in state court New Jersey.

There is a Multi-District Litigation (MDL) pending in the Eastern District of Pennsylvania which is limited to gastrointestinal injuries and the Judicial Panel on Multi-District Litigation (JPML) has previously denied transfer of cases alleging DVT injuries because there is a different "mechanism of harm" and "new types of injuries would significantly complicate the management of this litigation."[9] Accordingly, we believe limiting the scope of the MCL to cases alleging a NAION injury would allow for the most effective management of these cases. Alternatively, if the Court is inclined to grant this petition for an MCL and include the GI cases, we believe there should be separate tracks with different case management orders. In addition to the above stated differences, phased discovery has been ongoing in the MDL since last year and presumably there will be some coordination of the GI cases in that regard whereas there is no federal counterpart or MDL for NAION cases. Some of the firms who have New Jersey state court NAION cases also have gastrointestinal case filed in the MDL, however, the undersigned counsel has no cases in the MDL as we are not pursuing the gastrointestinal cases. Another reason why separate MCLs or else separate tracks are warranted is because of the issue of notice and the inevitable defense of federal

[9] See U.S. Judicial Panel on Multidistrict Litigation Order Denying Transfer, Case MDL No. 3094 (Doc. 273) (Dec. 12, 2024)

preemption. The facts for the NAION cases in that regard are entirely different than the facts involving the GI cases so any and all briefing would be distinct.

Why Coordination is Appropriate

As set forth in the guidelines, Multicounty designation is warranted when a litigation involves a large number of parties; many claims with common, recurrent issues of law and fact that are associated with a single product; there is geographical dispersement of parties; there is a high degree of commonality of injury; there is a value interdependence between different claims; there is a degree of remoteness between court and actual decision makers in the litigation; among other considerations. This litigation meets the above enunciated criteria. There are already at least twenty-one (21) filed cases before eight (8) different judges. All cases will involve the recurrent legal issues of failure to warn, design defect, breach of warranty, violation of the New Jersey Consumer Fraud Act and other common product liability claims. If an MCL is formed, pursuant to In Re: Accutane Litigation, 235 N.J. 229 (2018) the MCL Judge will apply the New Jersey Products Liability Act to all cases which simplifies matters instead of having eight different judges perform complex choice of law analysis for the cases involving plaintiffs presently from thirteen (13) different states. Moreover, there are significant overlapping factual liability issues relating to Defendant's notice and knowledge of the risk of NAION; Novo Nordisk's failure to warn of the risks of injury; Novo Nordisk's failure to adequately test and design the product; Novo Nordisk's failure to assess safety signals; and Novo Nordisk's failure to conduct post-marketing surveillance.

Proper Venue for Consolidation

All NAION cases filed against Novo Nordisk to date have been filed in Middlesex County due to the Defendant's principal place of business in Plainsboro. The only MCLs currently pending in Middlesex County are Fosamax, Taxotere/Docetaxel and Zostavax. Pursuant to a November 27, 2023 Case Management Order, all discovery in the Taxotere litigation has been stayed. Similarly, all discovery in the Zostavax litigation has been stayed through June 30, 2025 and a Master Settlement Agreement has been agreed upon. While counsel for the Plaintiffs agree Middlesex County before the Honorable Bruce Kaplan would be an appropriate venue for this MCL, the Plaintiffs believe consolidation in Atlantic or Bergen County would also be appropriate should the Supreme Court determine one of the other counties is better suited for case management.

In light all the factors and information discussed above, plaintiffs respectfully request the Supreme Court designate the NAION Ozempic/Wegovy cases for Multicounty Management.

Respectfully submitted,

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Daniel Lapinski, Esq., Motley Rice (Counsel for Plaintiffs) (Via Email)

Exhibit A

1. *Acord v. Novo Nordisk, Inc.* – MID-L-003439-25
2. *Bovee v. Novo Nordisk Inc.* – MID-L-001080-25
3. *Boyd v. Novo Nordisk Inc.* – MID -L-002280-25
4. *Decker v. Novo Nordisk Inc.* – MID -L-003553-25
5. *Elder v. Novo Nordisk Inc.* – MID -L- 003185-25
6. *Engel v. Novo Nordisk Inc.* – MID -L-002471-25
7. *Everhart v. Novo Nordisk Inc.* – MID -L-002670-25
8. *Fanelli v. Novo Nordisk Inc.* – MID -L-002176-25
9. *Farmer v. Novo Nordisk Inc.* – MID -L-002565-25
10. *Guastella v. Novo Nordisk Inc.* – MID -L-002521-25
11. *McFadden v. Novo Nordisk Inc.* – MID -L-002654-25
12. *Mitchell v. Novo Nordisk Inc.* – MID -L-002445-25
13. *Monastiero v. Novo Nordisk Inc.* – MID -L-003493-25
14. *Penrod v. Novo Nordisk Inc.* – MID -L- 003045-25
15. *Pinco v. Novo Nordisk Inc.* – MID -L- 003572-25
16. *Pitsicalis v. Novo Nordisk Inc.* – MID L-002923-25
17. *Poppiti v. Novo Nordisk Inc.* – MID -L-002401-25
18. *Rogers v. Novo Nordisk Inc.* – MID – L- 003583-25
19. *Schrager v. Novo Nordisk Inc.* – MID -L-002568-25
20. *Siurek v. Novo Nordisk Inc.* – MID – L – 003492-25
21. *Wagers v. Novo Nordisk Inc.* – MID -L-003377-25