UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

IN RE: TEPEZZA MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY

LITIGATION

This Document Relates to All Cases

No. 1:23-cv-03568

MDL No. 3079

Judge Thomas Durkin

Magistrate Judge M. David Weisman

PLC's Memorandum on Initial Bellwether Trial Cases

Per CMO 3, ECF No. 69, the PLC submits this memorandum summarizing each of the 11 Initial Bellwether Discovery Cases and its proposal for which four should be tried first, and the basis for that contention. The PLC proposes that the Court select for trial one PLC selection (Rebecka Meyers), one defense selection (Sara Meilleur), and two random selections (Richard Stern and Joseph Ford) as the most representative and instructive cases for trial. The PLC is also providing a brief description of the remaining seven unselected cases, and the reasons they were not selected as instructive or representative and, accordingly, should not be selected for a bellwether trial.

As discussed below, the PLC respectfully submits that the facts and circumstances of the four cases proposed by the PLC for early trial will best serve the purposes of the bellwether process by informing the Court, Defendant, and Plaintiffs about both common and relevant issues in this litigation, including, among others, those relating to liability, causation, alternative causation, product usage, and damages.

Bellwether trials are crucial to obtain global resolution in mass-tort litigation. To achieve this objective, the plaintiffs selected for bellwether trial, as well as their claims, must be "representative of the larger group of cases or claims from which they are selected." *In re Chevron U.S.A.*, *Inc.*, 109 F.3d 1016, 1020 (5th Cir. 1997); *see also* Ann. Manual Complex Lit. § 22.315, 4th, (2024-2025 ed) (noting that if bellwether trials "are to produce reliable information about other mass tort cases, the specific plaintiffs and their claims should be representative of the range of cases").

Representativeness is litigation- and fact-specific. BELLWETHER TRIALS IN MDL PROCEEDINGS: A GUIDE FOR TRANSFEREE JUDGES, MULTIDISTRICT LITIGATION MANUAL, Appendix I ("MDL Bellwether Trials Guide"). In selecting cases for a bellwether trial, parties and courts generally consider "plaintiff characteristics," "injuries," and "circumstances of exposure [of the harmful substance] (e.g., length of exposure, dose, particular product at issue, particular indication for use)." *Id*; see also In re 3M Combat Arms Earplug Prod. Liab. Litig., 3:19-md-2885, Order No. 3568, at 1 (N.D. Fla. Oct. 27, 2022) (considering the plaintiffs' injury and age in selecting cases for bellwether trial).

The purpose of selecting initial trial cases from a large pool of bellwether discovery cases is to learn and test general issues for the benefit of all—the Court, Plaintiffs, and Defendant. There are several significant issues, and those cases that have the most representative facts, and that do not turn on case-specific issues, should be selected to serve as the initial trial cases, as they will prove most instructive

to the litigation as a whole. As noted below, the PSC has selected cases that meet and fit these goals.

The objective of this process is to learn universal information and test those cross-cutting issues alleged in the individual complaints, including, among others, Plaintiffs' core liability theories in negligence, strict products liability (failure to warn), and general causation for the audiologic injuries pursued in this MDL. Trial of the core liability theories in several representative bellwether trials highlights issues of notice as it relates to injury risks, and response to such notice; the sufficiency, accuracy, and adequacy of the product's efficacy claims, warnings, and instructions; company communications with and promotion to the medical community and patients concerning the same; and the product's risk and utility as promoted or used to be examined in various contexts and over time.

Similarly, with regard to general causation, presenting the issue to juries through representative trial cases allows the parties to see clear patterns in what the evidence directs with regard to the general-causation question, e.g., "Is Tepezza a substantial factor in the development of hearing loss?" Cases presenting exceptional circumstances jeopardize the ability to inform the parties on the answer to that question. Of great concern, such cases present a serious risk of shifting the focus from the cross-cutting issues referenced above to unique and specialized issues. The consequence: neither the parties nor the Court get the general information applicable to all cases that the bellwether process seeks to achieve making resolution of the litigation as a whole less likely.

As such, the PLC respectfully requests that the Court select the cases proposed herein as the bellwether trial cases.

I. Background

As the Court is aware, this MDL involves cases against Horizon relating to Plaintiffs' receipt of Tepezza infusions resulting in hearing loss and other otologic injuries. Plaintiffs, through their individual complaints, allege several state-law causes of action, including strict products liability (based on theories of design defect and failure to warn), negligence, breach of warranty, fraud, and unjust enrichment, among others.

Of the initial 12 bellwether cases identified per CMO 3, 11 cases remain following dismissal of the *Merriweather* case. ECF No. 246. The parties have been working diligently to proceed in these cases. As a result, 11 plaintiffs and 38 treaters, prescribers, and other medical professionals have been deposed. Further, medical records from dozens of providers have been obtained and reviewed. CMO 3 provides for these cases to be narrowed to four for continued preparation for trial. The Court has broad discretion in dictating the way in which a bellwether trial should operate, and the way plaintiffs should be chosen for trial. *Collazo v. WEN by Chaz Dean, Inc.*, No. 2:15-CV-01974, 2018 WL 3424957, at *2 (C.D. Cal. July 12, 2018).

II. Plaintiffs' Proposal

The PLC proposes that the following four cases be selected and tried in the following order as the first bellwether trials:

- (1) Richard Stern (1:23-cv-02659)
- (2) Rebecka Meyers (1:23-cv-03585)
- (3) Sara Meilleur (1:23-cv-15501)
- (4) Joseph Ford (1:23-cv-02703)

A. Case summaries of the PLC's Proposed Trial Picks

1. Richard Stern (1:23-cv-02659) (Random selection)

Richard Stern is a 64-year-old male from Ridge, New York. He is married and has two adult children. He has been self-employed with R&M Stern Inc. since 2003, repairing commercial kitchen equipment and appliances.

In late 2020, Mr. Stern started experiencing double vision and bulging in his eyes. In February 2021, his ophthalmologist diagnosed him with thyroid eye disease (TED) and Graves' disease and prescribed steroids. The steroids failed to alleviate Mr. Stern's double vision or eye bulging and discomfort. In May 2021, his ophthalmologist prescribed Tepezza.

When Mr. Stern reported to the infusion center on May 6, 2021, he reported no hearing difficulty or ear pain. No baseline audiogram was performed. Mr. Stern received eight infusions of Tepezza from May 26–September 26, 2021. The Tepezza infusions temporarily alleviated Mr. Stern's double vision and proptosis, but his symptoms returned within a year.

Mr. Stern started experiencing hearing loss after his Tepezza infusions and was diagnosed by his otolaryngologist with bilateral sensorineural hearing loss and tinnitus on December 9, 2021. Hearing aids were recommended, but not obtained.

In October 2022, Mr. Stern went back to his ophthalmologist, complaining again of double vision and eye discomfort. In his notes, the doctor stated that Mr. Stern developed hearing problems following the Tepezza infusions and further noted that Mr. Stern cannot tolerate Tepezza given his hearing difficulties. Mr. Stern has undergone several subsequent post-Tepezza surgeries to address his TED/Graves' disease. Although Mr. Stern is an avid hunter, he testified he always wears proper ear protection when hunting and shooting firearms.

As part of the Core Discovery workup for Mr. Stern's case, the parties deposed ophthalmologist Dr. Gideon Schenck, otolaryngologist Dr. Benjamin Acker, endocrinologist Dr. Sanjay Godhwani, and audiologist Dr. Nancy Fontana.

2. Rebecka Meyers (1:23-cv-03585) (PLC selection)

Rebecka Meyers is a 66-year-old female who resides in Patagonia, Arizona with her husband. They do not have any children. Before retirement, Dr. Meyers lived in Salt Lake City where she was a pediatric surgeon and clinical researcher at the University of Utah. Dr. Meyers was diagnosed with thyrotoxicosis on November 1, 2019, and was referred to ophthalmologist due to associated eye symptoms. Her endocrinologist recommended treatment with Tepezza in February 2020.

Dr. Meyers underwent Tepezza eight infusions from April 29–September 25, 2020. She did not undergo a baseline hearing test. She began noticing changes in her hearing over the summer of 2020, which she reported directly to her Patient Access

Liaison at Horizon. She reported hearing loss in October 2020 when she presented to neuro-otologist Dr. Neil Patel. Her audiogram on October 14, 2020 showed bilateral sensorineural hearing loss with probable ototoxicity. Dr. Meyers was prescribed the high-dose steroid prednisone to treat her auditory symptoms. An audiogram on October 30, 2020 showed no change in hearing levels, with "ongoing tinnitus."

Dr. Meyers underwent a third audiogram on February 21, 2021, which continued to show bilateral sensorineural hearing loss of mild-medium intensity. She testified she has experienced mild improvement in the intervening years, with her most recent audiogram in June 2022 showing continued high-frequency sensorineural hearing loss. Hearing aids were discussed but Dr. Meyers never obtained them.

Ms. Meyer's medical history is positive for tobacco and alcohol use. She smoked half a pack per day from 1980 to 1994, when she decreased to 1 or 2 cigarettes per day for 10–15 years and stopped in 2008. Her hobbies are gardening, camping, and riding horses. She has no significant noise exposures.

As part of the Core Discovery workup for Dr. Meyers' case, the parties deposed neuro-ophthalmologist Dr. Allison Crum, neurotologist Dr. Neil Patel, and endocrinologist Dr. Deepika Reddy.

3. Sara Meilleur (1:23-cv-15501) (Defendant selection)

Sara Meilleur is a 76-year-old female from Loudon, Tennessee. She worked as kindergarten teacher until her retirement in 2004. Ms. Meilleur began experiencing eye problems in 2022. She was referred to a neuro-ophthalmologist who diagnosed TED in July 2022 and recommended treatment with Tepezza. She underwent eight

Tepezza infusions from July 18–December 12, 2022. Ms. Meilleur's TED did not improve significantly with Tepezza.

Ms. Meilleur was not referred for a baseline hearing assessment before beginning Tepezza. She did, however, have an audiogram in 2019 unrelated to her Tepezza treatment. The results of her 2019 hearing assessment showed bilateral, mild, high frequency hearing loss that did not require amplification. A hearing assessment conducted in May 2023 (after Ms. Meilleur's Tepezza treatment) noted the presence of tinnitus and revealed mild-to-moderate hearing loss for which she was recommended hearing aids. Ms. Meilleur received her hearing aids on May 30, 2023. She has worn them daily since.

Ms. Meilleur's medical history is significant for obesity, high cholesterol, and previous tobacco use (35+ years cessation before her Tepezza use). Ms. Meilleur also had chronic renal failure, for which she was prescribed Torsemide from 2012 to 2014, and has taken ibuprofen and Tylenol PM for a number of years. Her family history includes a brother who developed hearing loss in his eighties. She has no significant noise exposure.

As part of the Core Discovery workup in Ms. Meilleur's case, the parties deposed hearing aid specialist Mr. Michael Simpson, primary care physician Dr. Ramani Reddy, and neuro-ophthalmologist Dr. Adam DeBusk.

4. Joseph Ford (1:23-cv-02703) (Random selection)

Joseph Ford is a 72-year-old male from the Philadelphia area (currently resides in Kennet Square, Pennsylvania). He has been married for more than 50 years and has two grown children. Mr. Ford was diagnosed with hypothyroidism in May 2019

and was under the case of an endocrinologist. In 2021, his weight decreased dramatically at the same time he started developing proptosis. These symptoms were indicative of a hyperthyroid state and consistent with TED. A neuro-ophthalmologist diagnosed TED on June 29, 2021, and recommended treatment with Tepezza. He underwent four Tepezza infusions from August 12–October 14, 2021.

Mr. Ford was not referred for a baseline hearing exam before beginning Tepezza treatment. The most recent prior audiogram in his medical records is from August 2014. At that time, Mr. Ford reported right-sided hearing loss associated with a chronic sinus infection. Subsequent work-up revealed a diagnosis of chronic lymphatic leukemia as the cause of his sinus infections. He had a right endonasal dacryocystorhinostomy procedure on August 17, 2015, which resolved the build-up in his sinuses and allowed his ear tubes to drain properly, resolving his hearing symptoms.

After his fourth infusion, in October 2021, Mr. Ford contacted his doctor about decreased hearing. She advised him to discontinue Tepezza and seek treatment with an ENT. On November 15, 2021, his ENT noted Mr. Ford had a "decline in hearing sensitivity" and "constant tinnitus." After an audiogram was performed, he was diagnosed with bilateral sensorineural hearing loss and bilateral tinnitus. His ENT advised Mr. Ford to return if his hearing continued to decline. Mr. Ford testified he the ENT advised that there was no treatment or hearing aids to help with his tinnitus and that his best and/or only options included strategies to manage the symptoms (e.g., meditation, cognitive behavioral therapy, etc.). Mr. Ford is an avid sports fan

and now wears headphones when he watches sports on TV to be able to hear the broadcast.

Mr. Ford worked in the Naval shipyards in Philadelphia for approximately 35 years. Therefore, some of his work environments had significant noise exposure, and he was mandated to wear ear protection including earplugs with earmuffs over the ears. The second half of his employment, however, was in a management position, which involved more travel and supervising projects, with much less associated noise exposure. After his retirement, Mr. Ford worked as a school bus driver from 2010 to 2020. As part of this employment, he was required to pass annual hearing exams with the Pennsylvania Department of Transportation.

Mr. Ford's prescription history includes levothyroxine for hypothyroidism and gabapentin for peripheral neuropathy. His social history is positive for tobacco use, which he discontinued around 2000. Mr. Ford's chronic medical history includes his leukemia, diagnosed in 2014, with four months of chemotherapy that same year.

For the Core Discovery workup in Mr. Ford's case, the parties deposed ophthalmologist Dr. Mary Stefanyszyn, ENT Dr. Adam Mariotti, primary care physician Dr. Michael Kirk, and otolaryngologist Dr. Michael Ruckenstein.

B. The PLC proposes an equitable distribution of selections: one plaintiff selection (Meyers), one defense selection (Meilleur), and two random selections (Stern and Ford).

The PLC recommends the Court select one plaintiff pick, one defense pick, and two random picks for the first bellwether trials, and begin the trials with a random selection (Stern). This achieves a fair and representative distribution of picks from the initial 11 Bellwether Discovery Cases, balancing the parties' preferences with

cases selected randomly. See Manual for Complex Litigation, § 22.315, 4th, (2024–25 ed). This is precisely the reason the Court and parties identified cases from each of these groups in the initial selections, and it is the course adopted by courts looking to achieve a fair balance in identifying bellwether cases. Polansky v. Exec. Health Res., Inc., No. CV 12-4239, 2018 WL 1964195, at *4 (E.D. Pa. Apr. 26, 2018). As past MDL courts have noted, it is essential that the bellwether trial cases include a fair sampling of cases. In re Yasmin & Yaz (Drospirenone) Mktg., Sales Pracs. & Prods. Liab. Litig., No. 3:09-MD-02100-DRH, 2010 WL 4024778, at *1 (S.D. Ill. Oct. 13, 2010); see also In re Guidant Defibrillators Prods. Liab. Litig., No. 05-1708 DWF/AJB, 2006 WL 905344, at *3 (D. Minn. Mar. 23, 2006) (noting the need for a fair and representative sample of bellwether trial cases). Plaintiffs' proposal accomplishes this goal by including cases from each of the three groups of cases.

C. The PLC's recommended cases are representative of the key Plaintiff demographics and characteristics, and are therefore appropriate initial bellwether trial selections.

The PLC's proposal not only equitably accounts for both the parties preferences but also offers the following features of representativeness consistent with the Plaintiffs in the MDL: (1) an equal gender split; (2) a ranging number of infusions (from four to eight); (3) an array of infusion dates from 2020–22; (4) age range consistent with the majority of filed cases (predominantly 60s and 70s); (5) consistent injuries with the broader case pool; (6) geographic distribution across four states; and (7) representative legal claims. Each of the PLC's proposed trial picks are direct-filed cases in this District, where Defendant's corporate headquarters are located, which will facilitate convenient progress of the trials.

1. The PLC's proposed cases are evenly split by gender.

The PLC's recommendation is roughly representative of MDL Plaintiffs' gender demographic. The filed cases are comprised of approximately 67% women and 33% men. Absent dropping the total trial picks to three or increasing it to six, there is no way to match that ratio precisely. To capture the general composition of the total cases, the PLC proposes two men (Richard Stern and Joseph Ford) and two women (Rebecka Meyers and Sarah Meilleur) as this balance is roughly similar to the population of the filed case population. Gender is a consideration for representativeness only to the extent that women are more likely to experience TED and therefore receive Tepezza infusions. There does not seem to be any indication, at least at this stage of the litigation, that women or men are disproportionately likely or unlikely to experience auditory side effects from the medication.

2. The number of infusions ranges from four (Ford) to eight (Meyer, Meilleur & Stern), which is consistent with the distribution of total infusions across the filed cases.

Tepezza is typically administered as an intravenous infusion every three weeks for a total of eight infusions. Some patients do not complete the full course of infusions due to the side effects. The medical literature reports that hearing loss is frequently reported between the third and fifth infusion. Sears CM, et al., *Hearing Dysfunction After Treatment With Teprotumumab for Thyroid Eye Disease*, AM. J. OPTHALMOL. 2022 Aug 240:1–13, see also Kay-Rivest E, et al., *Prospective Assessment of Otologic Adverse Events due to Teprotumumab: Preliminary Results*,

¹ Declaration of Timothy Becker (Jan. 17, 2025), at ¶ 3.a.

Otolaryngol. Head Neck Surg. 2023 May; 168 (5):1164–69. Because of this difference in exposures, the PLC believes the exposure to Tepezza to be an issue the Court should consider in the selection of representative cases.

Approximately one third of the Plaintiffs in the MDL did not complete a full course of treatment, receiving less than eight infusions.² Conversely, approximately two thirds of Plaintiffs underwent at least eight infusions.³ To achieve representativeness, the PLC recommends two cases brought by Plaintiffs who completed treatment with eight infusions and two cases brought by Plaintiffs who received less than eight infusions: Stern (8); Meilleur (8), Meyers (7); and Ford (4). As with gender, absent changing the number of trial cases, a precise ratio of cases in partial vs. complete treatment is not possible.

The number of infusions completed by Plaintiffs is a major variable across all cases, and these four cases are representative of that variable. *Collazo v. WEN by Chaz Dean, Inc.*, No. 2:15-CV-01974-ODW-AGR, 2018 WL 3424957, at *2 (C.D. Cal. July 12, 2018) (citing Eldon E. Fallon, *et. al.*, *Bellwether Trials in Multidistrict Litigation*, 82 Tul. L. Rev. 2323, 2362 (2008)); *see also* MDL Bellwether Trials Guide (noting that "circumstances of exposure" is a relevant factor considered when determining representativeness); *see also Adams v. Deva Concepts, LLC*, 2023 WL 6518771 (S.D. N.Y Oct. 4, 2023) (agreeing with Defendant that "dose and duration of use" among claimants is a relevant factor in bellwether determination).

² Becker Decl. at ¶ 3.b.

 $^{^3}$ Id.

3. Infusion dates of the PLC's proposed picks are distributed across the average range of the MDL pool (2020–22).

The dates of infusion are also a critical factor not only for the purposes of establishing facts relevant to liability, but also for the Court to consider in any preemption motions or punitive-damage analysis. The PLC's proposed trial picks allow those facts to be tested across the range of infusion dates. Tepezza was first approved in 2020, and the FDA required a label change in 2023 to warn of permanent and severe hearing loss (rejecting Horizon's weaker language). The first bellwether plaintiff to receive infusions was Rebecka Meyers (April—September 2020). Selecting Dr. Meyers's case as a trial pick will allow the parties to test the claims from the earliest possible date.

As MDL courts consider bellwether selections, "[b]ellwether cases are intended to be representative of their peers ... serving as the common springboard from which Court decisions on substance (like the dismissal motions and early summary judgment motions), procedure, and discovery can then apply to like cases and claims") In re Society Ins. Co. Covid-19 Business Interruption Protection Ins. Litig., No. 20 C 5965, 2021 WL 3290962, at *4 (N.D. Ill. Aug. 1, 2021); see also In re Paraquat Prods. Liab. Litig., No. 3004, 2023 WL 3948249, at *3 (S.D. Ill. June 12, 2023) (citing In re E. I. du Pont de Nemours and Co. C-8 Personal Injury Litig., 54 F.4th 912, 919 n.3 (6th Cir. 2022) (bellwether trials "serve the twin goals of being informative indicators

⁴ Becker Decl. at ¶ 3.c.

of future trends and catalysts for an ultimate resolution") (internal quotation marks and citation omitted)).

While most Plaintiffs were not infused in 2020, selecting the Meyers case allows the parties to determine common questions such as "When did newly acquired information support a CBE to strengthen the warning label?" The overwhelming majority of filed cases (80%) were brought by Plaintiffs who received their initial infusion in either 2021 or 2022. Accordingly, the PLC's other three recommendations beyond Meyers are three cases in which the Plaintiff's infusions fall within this time period: Stern (May–October 2021); Ford (August–October 2021); and Meilleur (July–December 2022). These cases are representative of the timeframe in which all MDL Plaintiffs received infusions. See Bellwether Trials in MDL Proceedings (noting that dates of filing or when claims arose can be a relevant factor to consider). Importantly, if the Court were to deny a Rule 56 preemption motion in the Meyers case, the impact would affect nearly all filed cases given the early date of use.

4. The age range of the PLC's proposed trial picks is in the sweet spot as to Plaintiffs throughout the MDL.

Age is another factor courts consider in determining the representativeness of bellwether plaintiffs. See In re Boston Scientific Corp. Pelvic Repair Sys. Prods. Liab. Litig., MDL No. 2326, Pretrial Order No. 51, at 1 (S.D. W.Va, Aug. 7, 2013) (holding that the selected plaintiffs "were not representative based on age..." and directing parties to select cases with plaintiffs within the age range of 40 to 60 years old.); In re 3M Combat Arms Earplug Prod. Liab. Litig., 3:19-md-2885, Order No. 3568, at 7,

⁵ *Id*.

n.6 (N.D. Fla. Oct. 27, 2022) (finding "plaintiffs between the ages of 30 and 49" to be representative of the case as a whole). The majority of Plaintiffs were in their 60s or 70s at the time of first infusion.⁶ The PLC's proposed cases are consistent with that predominance: Stern (60); Meyers (62); Meilleur (74); and Ford (69), and are thus representative of the cases in the MDL as a whole.

5. The vast majority of MDL Plaintiffs suffered a combination of hearing loss and tinnitus—as did Mr. Stern, Dr. Meyers, Mrs. Meilleur, and Mr. Ford.

Of the total filed cases, 95% allege hearing loss (some accompanied by tinnitus) as a result of using Tepezza.⁷ The PLC's recommended cases include Plaintiffs alleging similar injuries after Tepezza infusion:

- Richard Stern: diagnosed with bilateral sensorineural hearing loss and tinnitus.
- Rebecka Meyers: diagnosed with bilateral sensorineural hearing loss with probable ototoxicity and tinnitus.
- Sarah Meilleur: diagnosed with bilateral, mild, high frequency hearing loss and tinnitus.
- Joseph Ford: diagnosed with bilateral sensorineural hearing loss and tinnitus.

The injuries presented in the PLC's recommended cases are generally congruent with those exhibited by Plaintiffs in all cases across this MDL and thus representative. *Collazo v. WEN by Chaz Dean, Inc.*, No. 2:15-CV-01974, 2018 WL 3424957, at *2 (C.D. Cal. July 12, 2018) (plaintiffs selected for bellwether trials are

⁶ Becker Decl. at ¶ 3.d.

⁷ Becker Decl. at ¶ 3.e.

representative if they "are alleging similar injuries," albeit "vary[ing] in severity, from using the same products in the same way.").

6. The PLC's proposed trial picks are from four different states, which will allow the parties to test—from Chicago—claims arising in geographically diverse regions under each state's products-liability laws.

Another consideration in selecting trial picks is the importance of testing bellwether claims from a variety of locations. The MDL includes Plaintiffs from __ states across the country.8 The PLC's proposed trial picks are from four different states: Stern (New York); Meyers (Utah); Meilleur (Tennessee); and Ford (Pennsylvania). These four states represent the home states of 20% of the Plaintiffs in the MDL. Testing claims for Plaintiffs under these four different states' laws will inform the parties as to the claims of the other Plaintiffs from those states. It will also provide guidance as to claims arising in states with comparable products-liability laws to the four homes states of the PLC's proposed Plaintiffs. Because each of the PLC's proposed trial picks are directly filed in the Northern District of Illinois (like 99% of the filed cases), the parties can conduct these trials in Chicago. This adds the benefits of convenience for many of Defendants' employee witnesses and superior familiarity of the MDL judge rather than conducting trials outside the Northern District of Illinois.

⁸ Becker Decl. at ¶ 3.f.

7. The PLC's proposed cases have representative legal claims as to the Plaintiffs as a whole.

Consistent with the Plaintiffs across this MDL, the PLC's proposed trial cases allege claims for negligent and/or strict-liability failure to warn. This Court's recent rulings on the Rule 12 motions in the bellwether cases considered fraudulent-misrepresentation claims alleged by certain Plaintiffs. In Ford, the Court dismissed the fraudulent-misrepresentation claim. In Stern and Meyers, the Court allowed the claim to proceed. Because many of the complaints filed within the MDL include fraudulent-misrepresentation claims, the PLC selections encompass these claims and will allow the parties to test their respective theories as to that claim.

8. Other circumstances that provide value in PLC's proposal.

While the trial selections should not be comprised of cases with unique and challenging issues, there are some features that are present in the four plaintiff selections that provide additional value in selecting the cases, or provide no significant hurdle. As an example, noise exposure is a potential alternative cause of hearing loss. Across the MDL, Plaintiffs have life or work histories that include varying degrees of noise exposure. Mr. Ford has a work history that includes substantial noise exposure. Therefore, it is an alternative-cause issue common to many cases that can be informative by selecting his case as a trial case.

Similarly, Dr. Meyers was prescribed Tepezza by an endocrinologist. Most plaintiffs in this MDL (including the PLC's other three proposed trial picks) received their Tepezza prescription from an ophthalmologist or neuro-ophthalmologist. In selecting a case that includes a prescribing doctor that is an endocrinologist, the

PLC's proposed selections include cases that cover the entire array of the types of prescribing doctors in this case.

In the same vein, Dr. Meyers has made a wage-loss claim. Recognizing that many plaintiffs in the MDL are not making a claim for lost wages, that is simply a damage issue that should not preclude her case from moving forward as a bellwether given the overriding benefit to evaluating the liability of a case with early infusions.

D. Case summaries of the Initial Bellwether Discovery Cases the PLC does not recommend for the initial trial picks

The PLC respectfully submits that the Court should not select the following seven remaining cases as initial trial cases. These cases are not suited to serve as bellwether trial cases because, although they present meritorious claims, they all have one or more factors and unique circumstances or issues that render them atypical, unnecessarily complicated or not instructive for the hundreds of other cases in this MDL.

1. Peter Chryssos (1:23-cv-03033) (PLC selection)

Peter Chryssos is a 67-year-old male from Katonah, New York. He owns his own financial-services company, which he founded in 1989. He was also a local/municipal politician in Katonah for approximately 15 years. He was married in 1988 and divorced in 2013. He has two adult sons. He has no significant history for noise exposure.

Mr. Chryssos was first diagnosed with TED in May 2022. He originally sought treatment for proptosis on December 27, 2021. By January 26, 2022, Mr. Chryssos was also experiencing dry eyes and double vision, which prompted an orbital CT and

a referral for thyroid testing. An endocrinologist diagnosed Mr. Chryssos with Graves' disease. Due to the Graves' diagnosis and eye symptoms, his ophthalmologist suspected TED and referred him to a neuro-ophthalmologist. On May 18, 2022, the neuro-ophthalmologist diagnosed Mr. Chryssos with active phase TED and recommended treatment with Tepezza.

Mr. Chryssos had a baseline hearing test before initiating Tepezza treatment. That audiogram showed hearing within normal limits to mild sensorineural hearing loss with low-grade asymmetry. He was referred to an ENT who assessed low-grade asymmetric hearing loss and tinnitus. The ENT testified that this was a normal finding for someone of Mr. Chryssos's age; he did not recommend any treatment.

Mr. Chryssos underwent five Tepezza infusions form June 24–September 16, 2022. Within a month of his first infusion, he began experiencing side effects associated with Tepezza, with his doctor noting Mr. Chryssos was experiencing hair loss, increased blood sugar, muscle cramps, shortness of breath, and hyperglycemia. Mr. Chryssos reported a decrease in hearing to his endocrinologist in September 2022 and was referred for another hearing test. On September 14, 2022, his hearing test showed a significant change with moderately severe sensorineural hearing loss. His audiologist noted his hearing declined bilaterally from 3-8kHz compared to his baseline test on May 25, 2022.

After five infusions, Mr. Chryssos discontinued his Tepezza treatment due to the magnitude of side effects he was experiencing. Mr. Chryssos continues to experience consistent hearing loss and tinnitus. On December 12, 2022, three months after stopping Tepezza infusions, his hearing test showed moderately severe high-frequency sensorineural hearing loss. His audiologist noted his hearing "remains unchanged bilaterally" compared to his September 2022 hearing exam. Mr. Chryssos testified his diminished hearing inhibits his ability to network professionally, which negatively impacts his business. He currently wears non-prescription hearing aids for crowded social situations.

For Core Discovery workup in Mr. Chryssos's case, the parties deposed neuroophthalmologist Dr. Evan Schloss, audiologist Dr. Jaclyn Alpert, and otolaryngologist Dr. John Scott.

The PLC does not believe this matter should be selected as a bellwether case due to the number and severity of side effects experienced by Mr. Chryssos while receiving Tepezza. He was hospitalized for shortness of breath and required monitoring of his blood sugar. These factors unnecessarily complicate the case making it more difficult for a jury to evaluate the hearing loss injury claim.

2. Consuelo Egger (1:23-cv-15306) (PLC selection)

Consuelo Egger is a 75-year-old female resident of Imperial, California. She moved from Mexico to California in 2006. Ms. Egger is married with no children. She retired in the early 2000s after working as a teacher, childcare worker, and administrative assistant. None of her jobs involved significant noise exposure.

Ms. Egger speaks limited English and requires a Spanish translator for formal communications. This makes communication with English speakers difficult for her. This language barrier can be mitigated, but not eliminated, through the use of a translator. As evidenced in her deposition, some words and phrases do not translate

well, which, on occasion, creates a disconnect between the question asked and her testimony.

Ms. Egger has a history of hypothyroidism, which she has treated with levothyroxine. In 2021, Ms. Egger was diagnosed with TED after she reported double vision and proptosis. In early 2022, Ms. Egger was assessed by her ophthalmologist and determined to be a reasonable candidate for Tepezza. She was referred to another ophthalmologist (Dr. Don Kikkawa) who prescribed Tepezza on February 8, 2022.

Before initiating Tepezza infusions, Ms. Egger completed an audiogram, which revealed mild-to-moderate hearing loss. Ms. Egger began taking Tepezza in March 2022. After several infusions of the drug, she began experiencing noticeable hearing loss and tinnitus, which she reported to her physicians and to Horizon representatives. She was advised that this problem would be temporary and would subside once she stopped the drug. Based on this advice, she continued with her eight-dose course of Tepezza, which concluded in August 2022.

Ms. Egger's hearing loss did not subside. In October 2022, she received an additional audiogram, which demonstrated substantial additional hearing loss in both ears beyond what was seen in her February 2022 audiogram. At that time, it was also recommended that Ms. Egger try hearing aids to address her diminished hearing. She did so, but ultimately decided against wearing hearing aids long-term. A third audiogram was conducted of Ms. Egger in January 2024, which showed some improvement of her hearing as compared to her prior audiogram, but still

demonstrated diminished hearing when compared to her initial pre-Tepezza audiogram.

Ms. Egger continues to struggle with tinnitus and persistent hearing loss in both ears. These injuries have made it more difficult for her to communicate, especially in larger group settings and have generally made her life more challenging to navigate in nearly all respects.

For Core Discovery workup in Ms. Egger's case, the parties deposed ophthalmologist Dr. Don Kikkawa, ophthalmologist Dr. Shira Robins, and hearing instrument specialist Susan Mendoza.

The PLC submits this case has unique challenges given Ms. Eggers is a native Spanish speaker who speaks limited English as a second language. The deposition made clear that, even with an interpreter, communication was a barrier, which also existed in communication with her physicians. The fact that her prescribing physician has accepted substantial payments from Horizon in honoraria, consulting fees, and travel is another unique feature of her case that makes it non-representative of the broader pool and presents the risk of non-common issues predominating aspects of her trial.

3. Brooke Bounds (1:23-cv-06423) (Defendant selection)

Brooke Bounds is a 35-year-old female who resides in Orlando, Florida. She is married with two children. She currently works in sales but was previously employed as a car wash supervisor. She was diagnosed with Grave's Orbitopathy and hyperthyroidism in 2011. She suffered from blurry vision, dry eyes, eye pain/pressure,

eyelid retraction, proptosis, eye redness, and light sensitivity. Following her diagnoses, she was prescribed eye drops, radioactive iodine treatment, and steroids.

On June 13, 2022, her ophthalmologist diagnosed Ms. Bounds with TED and prescribed Tepezza. She underwent eight Tepezza infusions from December 19, 2022—May 22, 2023.

After completion of Tepezza infusions, Ms. Bounds began treatment for her hearing loss with an otolaryngologist. She ordered two audiograms: one on June 19, 2023, and a follow-up test on November 9, 2023. He diagnosed Ms. Bounds with mild low-frequency hearing loss and subjective tinnitus, with the second audiogram showing unchanged hearing levels. He does not consider Ms. Bounds as a candidate for hearing aids.

Comparing the audiogram from September 14, 2015 (before her Tepezza infusions) to the June 19, 2023 audiogram (after her infusions) shows a worsening of 20 decibels at 1000Hz in the both ears.

For Ms. Bounds' Core Discovery workup, the parties deposed otolaryngologist Dr. Thuong Trinh, oncologist Dr. Geetha Akula, and ophthalmologist Dr. Michael Warner.

The PLC does not believe this to be an appropriate candidate for selection as a bellwether trial given Ms. Bounds's substantial youth in comparison with her fellow Plaintiffs. Ms. Bounds is 35-years old.; less than 5% of filed cases involve plaintiffs under 40,9 so the case is not representative.

 $^{^9}$ Becker Decl. at ¶ 3.d.

4. Geri Kanesta-Rychner (1:23-cv-05221) (PLC selection)

Geri Kanesta-Rychner is a 74-year-old female from Tacoma, Washington. She is widowed with no children. Ms. Kanesta-Rychner worked as an executive assistant before retiring in 2004 and has no history of occupational noise exposure. Her medical history does not indicate the use of any ototoxic medications besides Tepezza.

Ms. Kanesta-Rychner was diagnosed with hyperthyroidism in 1990 and treated until 1994, when her condition stabilized. Her thyroid condition reemerged in late 2018, and she was diagnosed with Graves' disease and moderate TED in February 2020 by an oculoplastic physician, who prescribed Tepezza. She underwent eight Tepezza infusions from April 27–September 28, 2022.

Ms. Kanesta-Rychner had a baseline hearing assessment on April 19, 2022, that showed mild-to-moderate sensorineural hearing loss bilaterally. She had no subjective symptoms and declined hearing aids. Following her third Tepezza infusion, Ms. Kanesta-Rychner began to experience tinnitus and hearing loss, which she reported to her endocrinologist in June 2022. She also reported tinnitus and hearing loss to her prescribing physician at visits in August and October 2022. Her prescriber advised Ms. Kanesta-Rychner that hearing loss from Tepezza is temporary.

A second hearing assessment, conducted in August 2022, showed deterioration in Ms. Kanesta-Rychner's hearing bilaterally from her baseline exam. She initially declined hearing aids due to the cost, but later acquired hearing aids in August 2024. Despite some partial recovery, Ms. Kanesta-Rychner continues to report hearing loss and tinnitus and currently uses her hearing aids.

As part of Ms. Kanesta-Rychner's Core Discovery workup, the parties deposed ophthalmologist Dr. David Pratt, hearing instrument specialist Jelan O'Neal, and endocrinologist Dr. Dali Chen.

The PLC does not consider this to be an ideal candidate for bellwether selection because Ms. Kanesta-Rychner's case was filed in the Western District of Washington and transferred to this District per the JPML's Transfer Order creating this MDL. Defendant has not waived it *Lexecon* rights. *See*, *e.g.*, CMO 3, ECF No. 69, PageID #956. The parties therefore would have to conduct this trial in Seattle, which is not convenient and would restrict the PLC's ability to call Horizon's employees in the Chicagoland area.

5. Gloria Pledger (1:23-cv-06562) (Random selection)

Gloria Pledger is a 59-year-old female from Bushwood, Maryland. She has been employed by the United States Department of Education since 1984, where she currently works as a Program Analyst. She was diagnosed with Graves' disease in February 2019. She underwent a total thyroidectomy in April 2019 and has been taking Synthroid, a synthetic thyroid hormone, to manage her thyroid levels post-surgery. In January 2021, her ophthalmologist recommended Tepezza to treat her TED symptoms. Due to the COVID-19 pandemic, Ms. Pledger did not begin treatment with Tepezza until July 2021. She underwent eight Tepezza infusions from July 15—December 22, 2021. She did not receive a baseline audiological evaluation before beginning Tepezza.

Ms. Pledger reported tinnitus to her Tepezza prescriber at a visit in July 2022, and to her primary care physician at a visit in October 2022. She was diagnosed with

mild sensorineural hearing loss in her left ear from 6000 to 8000 Hertz, with normal hearing in her right ear from 250 to 8000 Hertz, during an audiology visit on December 29, 2022. At this time, she was not a candidate for hearing aids. Following an audiogram conducted April 16, 2024, she was diagnosed with asymmetric sensorineural hearing loss, with mild hearing loss in both ears, including the right ear from 6000 to 8000 Hertz. The audiologist recommended hearing aids at this appointment, but Ms. Pledger declined out of fear of social stigmatization for wearing hearing aids at such a young age. She continues to experience hearing loss, which she manages by limiting social interaction with large groups and using headphones during work meetings, and tinnitus, which she manages using meditation.

Ms. Pledger's medical history is positive for high blood pressure and other medications, including Losartan, potassium, Nexium, and anti-anxiety medications.

As part of the Core Discovery workup in Ms. Pledger's case, the parties deposed otolaryngologist Dr. Bryan Ego-Osuala, primary care physician Dr. Maunank Patel, and ophthalmologist Dr. Paul Cunningham.

The PLC does not consider this case to be a good candidate for an initial bellwether trial because Ms. Pledger's injuries (specifically asymmetrical hearing loss and tinnitus) are not congruent with the predominant injuries experienced by the MDL Plaintiffs (bilateral hearing loss and tinnitus). Trying a case with asymmetrical loss will not provide the parties with information that will help resolve a meaningful number of cases in the MDL.

6. Amarilis Polanco (1:23-cv-02503) (Defendant selection)

Amarilis Polanco is a 53-year-old female who lives in Perth Amboy, New Jersey. Ms. Polanco is divorced and has two children. She works as a hair stylist and occasionally drives for Uber. Ms. Polanco is originally from the Dominican Republic, but is a United States resident, and has plans to obtain her U.S. citizenship. Ms. Polanco was diagnosed with TED on November 13, 2019, and was referred to an ophthalmologist due to associated eye symptoms. He recommended treatment with Tepezza. Ms. Polanco did not receive a baseline audiogram.

Ms. Polanco underwent eight Tepezza infusions from May 11–October 5, 2021. On August 24, 2024, her prescriber noted in his medical records that Ms. Polanco showed signs of bilateral, low-volume tinnitus that had grossly resolved. Ms. Polanco testified that shortly after receiving Tepezza infusions, she began to notice problems with her hearing. Specifically, she noticed a high ringing sound that distracts her frequently, and occasionally suffers from hearing loss. Ms. Polanco speaks English as a second language. She testified at her deposition with the assistance of a translator. Ms. Polanco testified that she tried to explain her hearing problems to both her primary care physician and her prescribing physician. But neither doctor speaks nor understands Spanish, so despite telling them over the course of several appointments, they likely did not understand her, as there was never a translator in attendance of her appointments.

As part of the Core Discovery workup in Ms. Polanco's case, the parties deposed ophthalmologist Dr. Paul Langer, primary care physician Dr. Anil Singh, and internist and primary care physician Dr. Alok Goyal.

The PLC submits this case, like Ms. Egger's, has unique challenges given Ms. Polanco is a native Spanish speaker with English as a second language. The communication barrier was evident during her deposition, which also existed in communication with her physicians. Particularly in relation to interactions with physicians, questions regarding the adequacy of any warnings provided are more complex and not representative of the broader pool. Also, the intermittent nature of Ms. Polanco's continuing hearing loss distinguishes her injuries from the injuries most commonly experienced by her fellow Plaintiffs (both the Initial Bellwether Discovery Cases and the Plaintiffs throughout the MDL).

7. Sara Perkett (1:23-cv-15994) (Defense selection)

Sara Perkett is a 53-year-old resident of Windermere, Florida. She is married with four children and currently works at a hotel at Walt Disney World and a substitute teacher at a local school district.

Ms. Perkett was diagnosed with TED and Grave's Orbitopathy in August 2013. She suffered from double vision, eye redness, dry eyes, and proptosis. After her diagnosis, Ms. Perkett was prescribed eye drops, steroid treatments, and radioactive iodine treatments to alleviate her TED symptoms. Ms. Perkett was also prescribed laser treatments. In August 2017, Ms. Perkett completed an audiogram that indicated tinnitus and slight sensorineural hearing loss in her left ear.

On November 8, 2021, her ophthalmologist prescribed Tepezza. Ms. Perkett underwent eight Tepezza infusions from April 11–September 19, 2022. Following her complaints of tinnitus at her fourth infusion, her doctor advised her to consult with

an ENT and follow up with her ophthalmologist. In August 2022, after her sixth Tepezza infusion, Ms. Perkett consulted with an otolaryngologist.

Audiometric testing performed while Ms. Perkett was under her otolaryngologist's care confirmed that she suffered from bilateral sensorineural hearing loss. She also suffered from tinnitus in both ears and eustachian tube dysfunction. When comparing Ms. Perkett's August 2017 and March 2024 audiograms, she had a shift of 20 dB at 4000 Hz in both the left and right ears. She also has persistent tinnitus.

As part of the Core Discovery workup in Ms. Perkett's case, the parties deposed oncologist Dr. Geetha Akula, otolaryngologist Dr. Michael Stuart, and ophthalmologist Dr. Keshini Parbhu.

The PLC does not find this case warrants consideration as a bellwether trial case given the length and severity of the underlying conditions and the multiple treatment interventions prior to Tepezza infusions. Further, Ms. Perkett is more than a decade younger than the average Plaintiff in the MDL. Finally, she remains employed which would present a comparative hardship to her (where it does not for the PLC's proposed trial picks, all of whom are retired).

III. Conclusion

After a thorough review of discovery records for each of the 11 Initial Bellwether Discovery Cases and data compiled from all MDL cases, the PLC believes that Richard Stern (1:23-cv-02659), Rebecka Meyers (1:23-cv-03585), Sara Meilleur (1:23-cv-15501), and Joseph Ford (1:23-cv-02703) are representative of the entire pool of litigants and present no unique difficulties. This approach will best inform the

parties of the information they need to progress this MDL toward resolution, including testing Defendant's preemption defense at Rule 56 at the earliest possible time. Accordingly, the PLC recommends those cases be tried, in that order, to serve as the initial four bellwether trial cases.

Dated: January 17, 2025

/s/ Timothy J. Becker
Timothy J. Becker
JOHNSON // BECKER, PLLC
444 Cedar Street, Suite 1800
St. Paul, Minnesota 55101
(612) 436-1800
tbecker@johnsonbecker.com

Plaintiffs' Co-Lead Counsel

/s/ Trent B. Miracle

Trent B. Miracle
FLINT COOPER COHN
THOMPSON & MIRACLE
222 East Park Street, #500
Edwardsville, Illinois 62025
(618) 620-1207
tmiracle@flintcooper.com

Plaintiffs' Co-Lead Counsel

Respectfully submitted,

/s/ Ashlie Case Sletvold
Ashlie Case Sletvold
PEIFFER WOLF CARR KANE
CONWAY & WISE, LLP
6370 SOM Center Road, Suite 108
Cleveland, Ohio 44139
(216) 589-9280

 $\underline{asletvold@peifferwolf.com}$

Plaintiffs' Co-Lead Counsel

/s/ Molly Condon Wells

Molly Condon Wells
WALLACE MILLER
150 North Wacker Drive, Suite 1100
Chicago, Illinois 60606
(312) 261-6193
mcw@wallacemiller.com

Plaintiffs' Liaison Counsel

UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

IN RE: TEPEZZA MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY

No. 1:23-cv-03568 MDL No. 3079

LITIGATION

Judge Thomas M. Durkin

This Document Relates to All Cases

Magistrate Judge M. David Weisman

Declaration of Timothy J. Becker

I, Timothy J. Becker, state and declare as follows:

- 1. I am a partner in the law firm of Johnson Becker, PLLC, duly authorized to practice law in the State of Minnesota and before this Court. I am in good standing before both Courts. I have personal knowledge of the facts and assertions set forth below. I gained that information in connection with my role as Co-Lead Counsel and as a member of the Plaintiffs' Leadership Committee. If called to testify I could report on the veracity of the facts and documents set forth below.
- 2. I supply this Declaration in support of the PLC's Memorandum on Initial Bellwether Trial Cases.
- 3. The PLC engaged a database vendor to host the data provided by Plaintiffs in their Plaintiff Profile Forms served on Defendant per CMO 3, ECF No. 69, PageID #953–54 (ECF No. 69-1). In my capacity as Co-Lead Counsel, I reviewed the cumulative data served through December 30, 2024. Of the 190 cases identified in the production data, data was available for 186 cases. (Plaintiffs who have filed their cases within the past 30 days may not yet have submitted their PPFs.) Based on my

review of those data, I report the following regarding the characteristics of the Plaintiffs:

- a. There is no field for gender in the PPF. Based on the names of the Plaintiffs, the gender split of the Plaintiff with cases filed in this MDL are approximately 64% female (119 cases) and 36% male (67 cases).
- b. Of the 186 filed cases with data available, 60 Plaintiffs, or approximately one third, completed less than eight infusions of Tepezza and two thirds (126 Plaintiffs) reported completing eight or more.
- c. Of the Initial Bellwether Discovery Plaintiffs, Rebecka Meyers was the first to receive a Tepezza infusions (2020). Most Plaintiffs (146/186 or nearly 80%) began their infusions in either 2021 or 2022.
- d. The age of first infusion for Plaintiffs in this MDL ranges from 30–87. The majority of Plaintiffs (107/186) received their first infusion in their 60s or 70s. Less than 5% of Plaintiffs are under the age of 40.
- e. Only 10 Plaintiffs (5%) do not allege hearing loss as their primary injury in their PPF. Instead, they identify another audiological injury such as tinnitus.
- f. Plaintiffs from 36 different states are represented in the filed cases in this MDL. Of the 185 Plaintiffs who to date have indicated their home state in their served PPF, 38—or 20%—come from New York, Utah, Tennessee, or Pennsylvania (the home states of the PLC's proposed trial picks).

I declare under penalty of perjury that the foregoing is true and correct.

Executed on January 17, 2025

/s/ $Timothy\ J.\ Becker$

Timothy J. Becker