IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: TEPEZZA MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION	No. 1:23−cv−03568 MDL No. 3079
This Document Relates to All Cases	Judge Thomas M. Durkin Magistrate Judge M. David Weisman

MEMORANDUM IN SUPPORT OF MOTION TO AMEND CASE MANAGEMENT ORDER NO. 3 WITH RESPECT TO DEFENDANT'S SELECTION OF INITIAL BELLWETHER DISCOVERY CASES

Horizon Therapeutics USA, Inc. ("Horizon") respectfully moves the Court, for good cause shown, for an extension of the current April 1, 2024 deadline for the defendant's selection of bellwether cases set forth in CMO No. 3, as amended (ECF Nos. 69, 91). Horizon requires an additional 60 days (until May 30, 2024) to complete the process of medical records collection from almost 700 identified providers for the 69 bellwether-eligible plaintiffs in order to select truly representative cases for bellwether treatment, a subset of which will become the bellwether trial cases. Despite its diligent efforts over the past three months since this process commenced, Horizon still lacks sufficient data to fairly determine a) what constitutes a representative case; and b) whether a particular case is, in fact, representative – information that is readily available to plaintiffs. At the current pace of collection, Horizon still will not have sufficient data to make informed selections by the current deadline of April 1, 2024. Forcing it to do so in the absence of these data would violate principles of due process and the goals of the bellwether process.

Plaintiffs had a significant advantage in making their bellwether selections. Plaintiffs' counsel could interview their clients to understand their relevant health histories and experience with Tepezza® and had access to their clients' medical records and healthcare providers. Horizon, on the other hand, must rely solely upon the materials required by CMO No. 3 to evaluate the cases

in the bellwether pool. That includes the limited information provided in the complaints and Plaintiff Profile Forms ("PPFs") and, most importantly, the medical records either produced by plaintiffs or collected pursuant to the Authorizations for Release of Records ("authorizations") required by CMO No. 3.

In contrast to the progress the parties generally have made in discovery since the beginning of the year, the collection of medical records from third-party providers has been a slow, cumbersome process.[1] Not only does the process rely on the providers' timely compliance – a challenge in itself – but also on plaintiffs providing adequate authorizations, which has been another source of delay. Despite its diligence, Horizon has been able to collect records for barely more than half the hundreds of providers identified in the PPFs for the 69 potential bellwether plaintiffs. This is not a new development. Horizon consistently has advised plaintiffs it was unrealistic to believe records collection of this scale could be completed in the short time frame plaintiffs insisted upon in CMO No. 3.[2] Consistent with that understanding, the parties agreed to the one previous 60-day extension of both plaintiffs' and Horizon's bellwether selection deadlines. (ECF No. 91). The schedule to which the parties agreed, both in CMO No. 3 and the prior stipulated extension, was ambitious and based on the hope that records collection would proceed more

[1] Since the beginning of 2024, the parties reached agreement on an ESI Protocol (ECF No. 99), custodial search terms (ECF No. 100-1), and production protocols for custodial and non-custodial document productions (ECF Nos. 106, 110). Horizon thereafter began producing documents from 12 non-custodial sources, as well as documents from as many as 65 custodians. Horizon commenced rolling custodial productions on February 22, 2024, and already has produced 145,841 pages of documents to plaintiffs, including the Biologic License Application ("BLA") for Tepezza®, documents from Horizon's adverse event reporting system, and custodial e-mails and documents, with millions of additional pages of documents currently under review for continued rolling productions – due to be completed by the end of 2024. The parties additionally agreed to a template Plaintiff Fact Sheet (ECF No. 69-1), and plaintiffs elected not to seek a Defendant Fact Sheet.

[2] *See, e.g.,* Email from K. Jensen to PLC (Dec. 31, 2023) (Ex. A) (stating that "as you know, medical records collection is an ongoing process largely within the control of third-party medical providers, thus we reserve the right to seek additional extensions for good cause shown in the event we are not able to obtain a critical mass of medical records within the time period established by the current extension").

quickly. Unfortunately, the anticipated hurdles in the collection process and resulting delays evident at the time the parties agreed to the first extension have continued. The result is that Horizon still lacks the data necessary to make its bellwether selections.

BACKGROUND

I. Plaintiffs Allege Tepezza® – the First Treatment to Be Specifically Indicated for Debilitating TED – Caused Varying Degrees of Hearing Impairment, a Condition for Which Numerous Risk Factors Exist.

Plaintiffs allege that Horizon failed to properly warn about the risk of hearing loss associated with its biologic medication, Tepezza® (teprotumumab-trbw). Tepezza® has been categorized by the FDA as a "Breakthrough Therapy" to treat a rare disease: Thyroid Eye Disease ("TED").[3] It is a revolutionary advancement in the treatment of TED, which is an incapacitating and disfiguring autoimmune disorder that significantly impacts patients' overall health and quality of life.[4] TED is typically characterized by inflammation of fat, muscles, and tissues surrounding the eye, leading to diverse presentations, including proptosis (bulging eyes), diplopia (double vision), eyelid retraction prohibiting eye closure, and optic nerve compression leading to vision loss. Prior to Tepezza®, there were limited treatments available for TED; doctors could attempt to alleviate the symptoms of those suffering from TED primarily with high-dose steroids to calm inflammation around the eye or with multiple invasive eye surgeries to make room for the eye.[5]

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[3] TED is classified as a rare disease, with an approximate prevalence of 0.25% of the population. Colm McAlinden, An Overview of Thyroid Eye Disease, Eye and Vision (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4655452/pdf/40662_2014_Article_9.pdf

[4] *See* Press Release, U.S. Food & Drug Admin., *FDA Approves First Treatment for Thyroid Eye Disease* (Jan. 21, 2020), https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-thyroid-eye-disease.

[5] *See* Raymond S. Douglas, et al. *Efficacy and Safety of Teprotumumab in Patients with Thyroid Eye Disease of Long Duration and Low Disease Activity*. J. of Clinical Endocrinology & Metabolism. 2003; 109(1):25-35 (Ex. B).

Approved by the FDA in January 2020, Tepezza® became the first and only medication specifically indicated for TED, and the change in treatment paradigm that Tepezza® represented led to multiple publications in the New England Journal of Medicine reporting its clinically meaningful and statistically significant efficacy as compared to placebo.[6] Within two years of FDA approval,[7] leading national and international thyroid associations recognized Tepezza® as the new first-line standard of care treatment in the management of TED.[8]

Review of the limited medical records Horizon has received to date in the 69 potential bellwether discovery cases reveals that plaintiffs are not dissimilar from patients experiencing hearing loss who have underlying thyroid disease and other risk factors for hearing loss. There is a long-recognized association between thyroid disorders and hearing abnormalities.[9] Randomized controlled trials on Tepezza® report a prevalence of hearing impairment that is in line with the age-adjusted background rate in patients with thyroid disease. There are numerous other strong risk

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[6] *See* Terry J Smith, et al. *Teprotumumab for Thyroid-Associated Ophthalmopathy*. New Eng. J. of Med. 2017; 376(18):1748-1761 (Ex. C); Raymond S. Douglas, et al. *Teprotumumab for the Treatment of Active Thyroid Eye Disease*. New Eng. J. of Med. 2020; 382(4):341-352 (Ex. D).

[7] These clinical trials reported on not only efficacy, but also safety, including approximately 10% prevalence of hearing loss in patients taking Tepezza®. The FDA-approved Tepezza® label has at all times included reports of hearing impairment (including deafness) in patients treated with Tepezza® in the "Clinical Trials Experience" section. *See* 2020 Tepezza® label, https://www.accessdata.fda.gov/spl/data/8d1559f0-64a5-4c69-8818-c31f248c9b5f/8d1559f0-64a5-4c69-8818-c31f248c9b5f.xml.

[8] *See also* Douglas, *supra* n.5 (Ex. B); Burch HB, et al. *Management of thyroid eye disease: a consensus statement by the American Thyroid Association and the European Thyroid Association*. Eur Thyroid J. 2022; 11(6): e220189 (Ex. E).

[9] *See* Letter from Terry J. Smith, re *Shah et al.: Teprotumumab Related Adverse Events in Thyroid Eye Disease: A Multicenter Study*. Am. Acad. of Ophthalmology. 2023; S0161-6420(23)00760-1 (Ex. F); Berker D, et al. *Evaluation of hearing loss in patients with Graves' disease*. Endocrine. 2012; 41:116-121 (Ex. G).

factors for hearing loss,[10] including advanced age,[11] prior hearing loss, family history of hearing loss, chronic infection, cardiovascular disease, anxiety, pain medications, among others, many of which are documented in the subset of plaintiff medical records available to Horizon.

II. Plaintiffs' Cases Vary Widely on Numerous Factors Critical to Selecting Representative Bellwether Cases That Cannot Be Determined Based Solely Upon PPFs or Complaints.

The PPFs were intended to guide the broad categories of initial discovery required for bellwether selection but, much like plaintiffs' complaints, do not fully capture the variety amongst plaintiffs' disease length or severity, past and current treatment options, or alleged treatment-related injuries. Rather, the PPFs identify perfunctory signals in plaintiffs' medical histories and identify only a subset of plaintiffs' healthcare providers whose records may reveal factors that greatly differentiate each plaintiff from the next. *See* ECF No. 69-1. PPFs and medical records collected to date, while incomplete, suggest a broad spectrum of alleged hearing impairments in plaintiffs taking Tepezza®. The wide-ranging symptoms reported by plaintiffs range from short-term tinnitus (ringing in the ears) that resolves relatively quickly, to measurable hearing loss maintained over a period of months or years.[12]

The type, severity, duration, and timeline of plaintiffs' purported injuries generally cannot be determined from PPFs or complaints – this information can be gleaned only through

[10] Plaintiffs' complaints contain very little detail as to the type and severity of hearing impairments alleged by individual plaintiffs, nor do they discuss the timeline of the injury(ies), the treatments required for the injury, or any other risk factors present in their medical history. *See, e.g.*, Compl., at 2, *Baldwin v. Horizon*, No. 2:23-cv-00605 (ECF No. 7). As such, medical records review for these facts is critical since, contrary to the impression left by plaintiffs' collective complaints, plaintiffs' hearing impairments vary widely from one plaintiff to the next.

[11] Quick Statistics About Hearing | NIDCD. https://www.nidcd.nih.gov/health/statistics/quick-statistics-hearing#4. (In the US, the prevalence of hearing related issues in patients aged 45-74 ranges form 5-22% and increases to 55% and above for patients 75 and older.)

[12] Smith, *supra* n.6 (Ex. C); Douglas, *supra* n.6 (Ex. D).

examination of key medical records.[13] Plaintiffs' Tepezza® treatment timelines and options vary: some plaintiffs took Tepezza® shortly after FDA's initial approval in 2020, and others' treatment extends well into 2023.[14] Some plaintiffs took multiple cycles of Tepezza® (each cycle is 8 infusions over approximately 5 months), and some stopped Tepezza® after just a few infusions.[15] The available options to treat plaintiffs' TED are similarly varied – some had experienced thyroid disorder and TED symptoms for decades and exhausted all available treatment options prior to their physicians prescribing Tepezza®, and others received a more recent diagnosis when their physicians decided to prescribe the first-ever approved treatment for TED. Plaintiffs' health histories are often rife with risk factors for hearing loss not always apparent from PPFs.[16] These are only examples of the significant differences among plaintiffs that cannot be assessed without access to medical records, but which necessarily must be evaluated in order to select representative cases for bellwether treatment.

LEGAL STANDARD

District courts enjoy substantial discretion in case management, including in managing the case schedule and discovery. *Rizza v. Wausau Underwriters*, No. 09 CV 687, 2011 WL 867492, at *2 (N.D. Ill. Mar. 11, 2011). Federal Rule of Civil Procedure 16(b)(4) permits courts to modify

[13] *See, e.g.,* Compl., *Merriweather v. Horizon,* No. 1:23-cv-02714 (ECF No. 1) (alleging injury of "permanent hearing loss and/or tinnitus"); PPF of Norma Perez-Diaz (Ex. H) (providing bare minimum detail regarding alleged hearing injury, only marking "Yes" next to "Hearing Loss" on chart, while failing to provide remaining requested information).

[14] *See, e.g.*, PPF of Rebecka Meyers (Ex. I) (date of first infusion listed as 4/29/2020); PPF of Sharon Jeffries (Ex. J) (date of last infusion listed as 06/05/2023).

[15] *See, e.g.*, PPF of Donna Baldwin (Ex. K) (completed two full cycles of 16 infusions total); PPF of Joseph Ford (Ex. L) (reported treatment termination after 4 infusions).

[16] Information pertaining to a plaintiff's auditory health is not always fully captured by the PPF since, as with any questionnaire, PPF responses fall victim to the inherent inaccuracies of reporting bias in a way that contemporaneously created medical records do not. *See, e.g.*, PPF of Richard Stern (Ex. M) (although medical records indicate a history of prior hearing loss and exposure to loud noises, in his PPF, plaintiff did not report hearing loss prior to Tepezza® treatment and indicated no prior exposure to loud noises).

a scheduling order for good cause. In determining whether a party has shown good cause for a modification, courts in this circuit focus primarily, if not exclusively, on the diligence of the moving party. *See Peters v. Wal-Mart Stores E., LP*, 512 Fed. Appx. 622, 627-28 (7th Cir. 2013) ("[T]he good-cause standard focuses on the diligence of the party seeking amendment, not the prejudice to the nonmoving party."); *Alioto v. Town of Lisbon*, 651 F.3d 715 (7th Cir. 2011) ("In making a Rule 16(b) good-cause determination, the primary consideration for district courts is the diligence of the party seeking amendment."); *see also Lukis v. Whitepages Inc.*, 535 F. Supp. 3d 775, 802 (N.D. Ill. 2021) (extending fact discovery deadline where moving party repeatedly attempted to collect information about opposing party's data providers, which opposing party continuously resisted); *Traffix USA, Inc. v. Bay*, No. 21-cv-02093, 2022 WL 2046282, at *2 (N.D. Ill. June 7, 2022) (extending discovery deadline).

ARGUMENT

I. The Fundamental Fairness of the Bellwether Process Requires That Horizon Have Access to Sufficient Facts Upon Which to Base its Selection of Representative Cases – and Sufficient Time to Collect Those Facts.

The goal of the bellwether process is to provide the Court and the parties an insight into the merits of the inventory of plaintiffs' claims pending in the MDL. Therefore, plaintiffs chosen as bellwether cases "should be representative of the range of cases." Manual for Complex Litigation § 22.315 (4th ed. 2004); *see In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, MDL No. 2100, 2010 WL 4024778, at *1-2 (S.D. Ill. Oct. 8, 2010) (finding it "critical to a successful bellwether plan that an honest representative sampling of cases be achieved" because "[l]ittle credibility will be attached to this process, and it will be a waste of everyone's time and resources, if cases are selected which do not accurately reflect the run-of-the-mill case"). Here, the parties' selection of Initial Bellwether Discovery Cases is not simply an exercise in choosing what cases deserve further discovery; a subset of those cases will be

Bellwether *Trial* Cases. Horizon therefore requires adequate information to inform its bellwether selections now.

To ensure those selections are representative, Horizon needs to understand the contours of every bellwether-eligible case. This is necessarily a comparative process that requires sufficient data for all cases. Specifically, Horizon requires access to sufficient medical records for at least all of plaintiffs' identified providers in order to assess the range of and variation in plaintiffs' TED diagnoses, Tepezza® use, alleged injuries and severity thereof, and potential alternate causes for hearing loss.[17]

If Horizon cannot identify a truly representative sample of plaintiffs, it will result in unfair and inappropriate conclusions being drawn about the remainder of cases. *See In re Chevron USA., Inc.*, 109 F.3d 1016 (5th Cir.) (recognizing due process concerns where the bellwether cases are not a representative sample and unreliable results impose liability more broadly); *Morgan v. Ford Motor Co.*, No. 06-1080, 2007 WL 1456154, at *34 (D.N.J. May 17, 2007) ("[T]o ensure the usefulness of bellwether plaintiffs to the process and the parties' due process rights, representative plaintiffs must be chosen."). Where one party lacks adequate information upon which to identify that representative sample, it effectively tilts the process toward the other's preferences – contrary to the principles underlying the bellwether process to allocate case selections among the parties and the court. That is precisely the problem here, where Horizon lacks access to information regarding the bellwether pool.

[17] *See* Bolch Judicial Inst., Duke L. Sch., Guidelines and Best Practices for Large and Mass-Tort MDLs 26 (2d ed. 2018) https://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1004&context=bolch. (acknowledging the importance of having fact sheets and medical records for individual plaintiffs to aid in the determination of a representative plaintiff).

Given the immense weight afforded bellwether trial conclusions, courts are rightly sensitive to ensuring the fairness of the process. *See generally* U.S. Chamber Institute for Legal Reform, MDL Proceedings: Eliminating the Chaff (Oct. 2015) (Ex. N) (noting pressure to settle cases based on outcomes of bellwether trials). For example, in *Adams v. Deva Concepts, LLC*, the district court denied plaintiffs' request to proceed with a bellwether process over defendant's objection where the defendant was missing key information for plaintiffs, including which product was used, the dose and duration of use, other risk factors that could impact causation, and the relevant medical history for each plaintiff. *Adams v. Deva Concepts, LLC*, No. 20-cv-9717, 2023 WL 6518771, at *6-7 (S.D.N.Y. Oct. 4, 2023) ("Defendant must be allowed an opportunity to collect nuanced information to support its credible arguments. . . . Defendant must be given the opportunity to collect further details regarding Plaintiffs' product use, to better inform the potential categorization of bellwether claimants and to effectively test this argument. . . . Defendant is likewise entitled to [a full picture of] Plaintiffs' individual medical histories."). The Court should not rush the selection process, lest the outcome result in a nonrepresentative bellwether case group.

Importantly, while efficient resolution of mass litigation is one goal of the bellwether process, efficiency should not be confused with speed. "[T]he parties should have a reasonable amount of and time for discovery in the [bellwether-eligible cases] to ensure that no party is subjected to unfair surprise or otherwise disadvantaged." Bolch Judicial Inst., Duke L. Sch., Guidelines and Best Practices for Large and Mass-Tort MDLs 11 (2d ed. 2018)). Here, Horizon has been diligently working with its medical records vendor to navigate the process of records collection, as discussed in Section III below, with efficiency in mind, but should not, as a matter of fundamental fairness, be rushed to make critical bellwether decisions on less than all the data to

which it is entitled. The dearth of medical records for bellwether-eligible plaintiffs alone amounts to good cause for granting Horizon's requested extension of time to make its selections.[18]

II. The Current Status of Records Collection Will Not Allow Informed Selection of Bellwether Discovery Cases.

Horizon does not seek every medical record for every doctor ever seen by each of the 69 bellwether-eligible plaintiffs. But for Horizon to fairly determine representative cases, it must at least have access to the information contemplated by CMO No. 3: (1) completed PPFs; (2) executed authorizations; and – most importantly – (3) medical records from at least those treating providers identified in the PPFs. Only once such records are collected and reviewed for each of the bellwether-eligible plaintiffs can Horizon fairly identify representative cases.

As discussed in more detail below, the records collection process has been hampered by deficient PPFs, incorrectly executed or otherwise inadequate authorizations, inconsistencies in various providers' requirements for release of records, and unavoidably lengthy custodian response times. As a result, Horizon has been able to collect barely over 50% of the PPF-identified provider records across all bellwether-eligible plaintiffs to date. That number drops well below 50% when considering the dozens of additional relevant providers *not* disclosed in PPFs that Horizon has thus far identified.[19] Of the nearly 700 providers that are identified in plaintiffs' PPFs, more than 300 records requests remain outstanding at this time.

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[18] Although any prejudice to plaintiffs is not the focus of the Rule 16 analysis, *Peters*, 512 Fed. Appx. at 627-28, Horizon's request to extend its bellwether selections to May 30 would result in none. Discovery of the Defendant is proceeding without delay while bellwether selections are made. *See supra* n.1. Horizon's production of documents – due to be complete before the end of this year – will still be underway on May 30, and Plaintiffs have indicated they intend to request depositions of Horizon employees after they review those productions. All of this must be completed before the close of bellwether discovery. Horizon's request for a modest extension of its bellwether selection deadline will therefore not result in any delay. Regardless, any modest impact on the schedule pales in comparison to the prejudice to Horizon, and to the bellwether process itself, that would result from forced, premature bellwether selections.

[19] Horizon's review of the medical records obtained to date already has identified numerous relevant providers that Plaintiffs failed to identify in their PPFs. As Horizon's review continues, it anticipates this

That is not all. Horizon has been able to collect only 50% or fewer of identified provider records for *more than one third* of bellwether-eligible plaintiffs (24 of the 69) to date, and only 25% or fewer for 10 of those. For example, records collection for plaintiffs Victoria McKuhen, Karen Scott, and Norma Perez-Diaz remains severely low, at 21%, 20%, and 14%, respectively. Horizon has not even been able to commence collection for plaintiffs who have never provided the required authorizations (*e.g.*, Angela Simpson) or have only done so in the past few days (*e.g.*, Bonnie Sherer, Zdena McMullen[20]). Even in cases where 50% or more of identified provider records have been collected, records that are critical for assessment of these cases for bellwether discovery selection are still missing (*e.g.*, records of the diagnosing provider or prescriber recorders for Richard Stern; missing infusion records from Marshfield Medical Center for Plaintiff Shawna Rene). While CMO No. 3 allows Horizon to exclude these cases from bellwether consideration for lack of data, that would be an unjust result, both for Horizon and the bellwether process, because plaintiffs could effectively shape the bellwether pool by failing to facilitate access to certain plaintiffs' records.

Plaintiff-produced records do not resolve this problem. In at least 10 cases, plaintiffs have produced surprisingly few records, or none at all, and where plaintiffs have produced records, they are often incomplete.[21] Significant gaps are apparent when compared to records collected by

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trend will continue. This motion, however, is focused on the unacceptable percentage of records from PPF-identified providers that remains to be collected.

[20] Plaintiffs provided a large number of authorizations on February 29, two days after Horizon wrote to the PLC notifying it of its intent to bring this motion. In that letter, Ms. McMullen was specifically identified as one of the bellwether-eligible plaintiffs still missing authorizations (Ex. X), despite that Horizon had previously alerted plaintiffs to this problem at least 7 times. *See, e.g.*, Email from L. Hammond to PLC (Dec. 6, 2023) (Ex. O); Email from L. Hammond to PLC (Dec. 8, 2023) (Ex. P); Email from L. Hammond to PLC (Dec. 12, 2023) (Ex. Q); Email from L. Hammond to PLC (Dec. 18, 2023) (Ex. R); Email from L. Hammond to PLC (Dec. 21, 2023) (Ex. S); Letter from G. Hollingsworth to A. Beridon, *et al.* (Jan. 12, 2024) (Ex. T); Letter from G. Hollingsworth to A. Beridon, *et al.* (Jan. 29, 2024) (Ex. U).

[21] For example, plaintiffs have produced only 8 pages of records for Fredrick Tyler.

Horizon for the same providers. For example, records obtained for Shawna Rene from the Cancer Center at Marshfield Medical Center-Eau Claire totaled over 750 pages, whereas plaintiffs produced only 92 pages from the same provider. The same is true for Plaintiff Denise Sadonis, where Horizon has collected 886 pages of records from Dr. Jeffrey Ratliff of Jefferson Health, whereas plaintiffs produced only 118 pages of records from Dr. Ratliff.

To force Horizon to select representative cases based on the currently available subset of all essential data risks disproportionately favoring cases in which records collection is more complete, ignoring perhaps more representative cases obscured by the penumbra of still uncollected records.[22]

III. Horizon has Been Diligent in its Efforts to Proceed Efficiently Throughout the Records Collection Process.

The current status of records collection is not of Horizon's making. Horizon has devoted substantial effort to facilitating this process, working tirelessly with its records collection vendor and plaintiffs to move the process along since the first PPFs and authorizations were received from plaintiffs around midnight on December 1, 2023 (*i.e.*, Saturday, December 2).[23] Within two days of receipt, on Tuesday, December 5, Horizon had reviewed and submitted all of these authorizations to its vendor and initiated orders for every authorized provider so the vendor could serve records requests. By December 6, Horizon had already sent plaintiffs the first of many letters identifying deficiencies in their authorizations that would delay records retrieval.

[22] The problem of insufficient medical records is not limited to the bellwether-eligible plaintiffs remaining for Horizon to choose from. Even as to plaintiffs' selections, Horizon lacks access to critical information needed to prepare for core discovery in those cases and to assess them as potential bellwether trial cases. For example, for Peter Chryssos, infusion records (which often contain information about warnings to the patient, such as explicit warnings about hearing loss) are missing, and for Consuelo Egger, numerous records from her ophthalmologist and Tepezza® prescriber are missing.

[23] Notably, plaintiffs failed to submit PPFs and authorizations for 14 plaintiffs by the December 1 deadline in CMO No. 3.

Horizon continues to review authorizations as they are received from plaintiffs and either (a) promptly submits properly executed authorizations to its vendor to commence (or resume stalled) records collection, or (b) reverts to plaintiffs regarding any apparent deficiencies in those authorizations.[24] Given the tremendous number of individual authorizations submitted by or for the 69 bellwether-eligible plaintiffs (667 at last count), this process has been time-consuming and cumbersome.

Horizon also has offered solutions to plaintiffs in an effort to accelerate the records collection process. On January 10, 2024, Horizon notified plaintiffs of overarching issues identified in the PPFs and authorizations across the pool of bellwether-eligible cases, reminding plaintiffs that such broadly observed deficiencies increase the mutually burdensome communications required to resolve them and delay the records collection process.[25] Horizon suggested that plaintiffs submit signed "blank" authorizations, with no provider details, in an effort to eliminate at least one of the many factors delaying the collection process by allowing Horizon or its vendor to complete the provider details on behalf of plaintiffs based on the PPF data and submit or resubmit authorizations as deficiencies arose.[26] While the PLC acknowledged the problem and agreed to the proposed solution, only 35 of the 69 bellwether-eligible plaintiffs have provided such blank authorizations to date.[27] Plaintiffs who have not done so have been requested

[24] *See infra* Section IV regarding those deficiencies.

[25] Letter from G. Hollingsworth to PLC (Jan. 10, 2024) (Ex. V).

[26] *Id.*

[27] Tim Becker, plaintiffs' co-lead counsel, represented at a January 22 meet and confer with Horizon that the PLC recognized the delays in records collection that can arise when plaintiffs exclusively submit provider-specific authorizations. He agreed that the plaintiffs represented by PLC's firms would provide blank authorization forms, and that the PLC would inform counsel for other plaintiffs that the PLC was so proceeding. Email from G. Hollingsworth to PLC (Jan. 24, 2024) (Ex. W) (confirming discussion details from M&C held on Jan. 22, 2024). Despite this representation, to date, no plaintiffs represented by co-lead counsel Ashlie Sletvold's firm (Peiffer Wolf Carr Kane Conway & Wise), and only one plaintiff represented by co-lead counsel Trent Miracle's firm (Flint Cooper), have submitted blank authorization forms.

by custodians to readdress and resubmit authorizations (*e.g.*, Anthony Armenti), which adds unnecessary delay to the process.

IV. The Speed of Records Collection Depends Upon Third Parties and Plaintiffs and is Largely Outside of Horizon's Control.

Despite Horizon's efforts to follow up on records requests, response time is dictated by the regulatory framework and can be further delayed by third-party medical provider-custodians. Pursuant to the HIPAA Privacy Rule, medical providers have – and often do take – a full 30 calendar days from receipt of a records request in which to "act" on it. 45 C.F.R. § 164.524(b)(2) (also providing for a potential extension of this period for an *additional* 30 days). Adding to that already challenging timeline, the responsive action is not always production of responsive records. It may simply be acknowledging receipt of the request, advising that the authorization is inadequate in some regard or that payment of a fee is required for records release, or arranging for production on some future date. Indeed, custodians frequently take longer than the allotted 30 days to provide even a confirmation of whether records exist, and even longer to actually produce the records. Even rejected authorizations often are returned only after 30 days have elapsed, requiring resubmission of the request with a corrected authorization (once obtained from plaintiff) that restarts the 30-day response period.[28]

Deficiencies in the PPFs and authorizations submitted by plaintiffs also create delay beyond Horizon's control. At least 30 of the 69 bellwether-eligible plaintiffs initially failed to properly execute authorizations for their identified providers and, as a result, not a single record

[28] As an example, after more than 30 days, Publix pharmacy, similar to many other major pharmacies, rejected authorizations from Plaintiffs Cheryl Schmidt and Mark Wilson for failure to mark and/or initial boxes authorizing release of *all* records (including those pertaining to mental health or HIV/AIDS), and requested revised authorization forms, the receipt of which would then restart the request process. *See* Horizon's Letter to Plaintiffs Regarding Extension to Select Bellwether Cases (Ex. X). Worse, plaintiffs have generally refused Horizon's requests to resubmit authorizations prior to receiving a copy of the objection from the pharmacy. *See, e.g.*, Email from D. Kuttles to D. Das, *et al.* (Feb. 6, 2024) (Ex. Y).

had been collected in 28 cases as of January 1, 2024. Authorization issues included (and have continued to include) such deficiencies as incorrectly spelled plaintiff names, missing social security numbers, incorrect or missing provider details (*e.g.*, address, facility name/location, provider name), vague or incorrect date ranges of treatment, and/or missing signatures.[29] Resolving these deficiencies takes time because of the iterative process involved and, as noted above, Horizon's proposed solution of "blank" authorizations has not been fully embraced by plaintiffs. In addition, the initial PPFs submitted by approximately half of bellwether-eligible plaintiffs were significantly deficient, missing such critical information as relevant providers, diagnosis and treatment dates, and medical history.[30]

Given all the foregoing hurdles, and despite Horizon's diligence, the fact that it will take more than 3 months to collect medical records from more than 300 remaining providers is hardly surprising. Nor are the reasons for the length of this process relevant to the requested relief. The fact remains that, at the current pace of collection, Horizon will not have the information necessary to make its bellwether selections by April 1. Fundamental unfairness and prejudice would result from a forced determination of "representative" cases based on Horizon's access to only about half the data the parties agreed in CMO No. 3 were the prerequisite to bellwether selections.

CONCLUSION

For the foregoing reasons, the Court should grant Horizon's request to amend its deadline for selection of Initial Bellwether Discovery Cases to May 30, 2024.

[29] Horizon sent emails to the PLC dated December 6, 7, 8, 11, 12, 18, and 21 regarding initial authorization deficiencies, and sent further communications to individual Plaintiffs on January 12, 24, 26, and 29, highlighting specific authorization deficiencies.

[30] *See, e.g.*, Email from L. Hammond to PLC (Dec. 6, 2023) (Ex. O) (indicating deficiencies in almost half of plaintiffs' PPF submissions – *e.g.*, missing providers in the Carol Sanchez PPF, missing treatment data in the Amarilis Polanco PPF, and missing medical history data in the Bonnie Sherer PPF).

Dated: March 5, 2024

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I certify that on March 5, 2024, copies of the foregoing Memorandum in Support of Motion to Amend Case Management Order No. 3 With Respect to Defendant's Selection of Initial Bellwether Discovery Cases was filed using the CM/ECF filing system, which will send notice of electronic filing to all parties appearing on the Court's ECF service list.

/s/ *Robert E. Johnston*
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